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## II

(Non-legislative acts)

## INTERNATIONAL AGREEMENTS

## COUNCIL DECISION

of 13 November 2012

**on the conclusion of the Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand**

(2012/828/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with Article 218(6)(a)(v) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

- (1) The Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand <sup>(1)</sup> entered into force on 1 January 1999 <sup>(2)</sup>.
- (2) In accordance with Council Decision 2011/464/EU <sup>(3)</sup>, the Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand ('the Agreement') was signed by the Commission on 23 February 2012, subject to its conclusion.
- (3) As a consequence of the entry into force of the Treaty of Lisbon on 1 December 2009, the European Union has replaced and succeeded the European Community.
- (4) The Agreement should be concluded,

HAS ADOPTED THIS DECISION:

*Article 1*

The Agreement between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand ('the Agreement') is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

*Article 2*

The President of the Council shall designate the person empowered to proceed, on behalf of the Union, to transmitting the diplomatic notes provided for in Article 2 of the Agreement, in order to express the consent of the Union to be bound by the Agreement <sup>(4)</sup>.

*Article 3*

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

Done at Brussels, 13 November 2012.

*For the Council*

*The President*

V. SHIARLY

<sup>(1)</sup> OJ L 229, 17.8.1998, p. 62.

<sup>(2)</sup> OJ L 5, 9.1.1999, p. 74.

<sup>(3)</sup> OJ L 195, 27.7.2011, p. 1.

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

**AGREEMENT****between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand**

THE EUROPEAN UNION

and

NEW ZEALAND,

hereinafter 'the Parties',

HAVING concluded the Agreement on mutual recognition in relation to conformity assessment <sup>(1)</sup>, done at Wellington on 25 June 1998 (hereinafter 'the Agreement on Mutual Recognition');

NOTING the need to simplify the operation of the Agreement on Mutual Recognition;

WHEREAS Article 3 of the Agreement on Mutual Recognition sets out the form of the Sectoral Annexes in detail, and, specifically, provides that Section II of each Sectoral Annex to the Agreement shall contain a list of the designated conformity assessment bodies;

WHEREAS Article 4 of the Agreement on Mutual Recognition restricts the application of the Agreement to products that originate in the Parties according to non-preferential rules of origin;

WHEREAS Article 12 of the Agreement on Mutual Recognition establishes a Joint Committee that, inter alia, gives effect to decisions on the inclusion of conformity assessment bodies in, and their removal from, the Sectoral Annexes and sets out a procedure for such inclusion and removal;

WHEREAS Articles 8 and 12 of the Agreement on Mutual Recognition refer to the Chair of the Joint Committee;

WHEREAS Article 12 of the Agreement on Mutual Recognition does not explicitly empower the Joint Committee to amend the Sectoral Annexes, except to give effect to the decision by a designating authority to designate or to withdraw designation of a particular conformity assessment body;

CONSIDERING that Article 3 of the Agreement on Mutual Recognition should be amended, both to reflect the changes proposed to Article 12 thereof to limit the requirement for the Joint Committee to take action on the recognition or withdrawal of recognition of conformity assessment bodies to cases that have been contested by the other Party under Article 8 of the Agreement on Mutual Recognition, and to allow greater flexibility in the structure of Sectoral Annexes to the Agreement;

CONSIDERING that in order that trade between the Parties is not unnecessarily restricted, the origin restriction in Article 4 of the Agreement on Mutual Recognition should be deleted;

CONSIDERING that in order to reflect the fact that the Joint Committee is co-chaired by the Parties, the references to the Chair of the Joint Committee should be deleted from Articles 8 and 12 of the Agreement on Mutual Recognition;

CONSIDERING that enhanced exchange of information between the Parties regarding the operation of the Agreement on Mutual Recognition will facilitate its operation;

CONSIDERING that in order to make timely adaptations to the Sectoral Annexes so as to take account of technical progress, and other factors such as enlargement of the European Union, the Joint Committee should be explicitly empowered in Article 12 of the Agreement on Mutual Recognition to amend the Sectoral Annexes in areas other than to give effect to the decision by a designating authority to designate or to withdraw designation of a particular conformity assessment body, and also to adopt new Sectoral Annexes;

<sup>(1)</sup> OJ L 229, 17.8.1998, p. 62.

CONSIDERING that in order to simplify the operation of the Agreement on Mutual Recognition, the need for the Joint Committee to take decisions on the recognition or withdrawal of recognition of conformity assessment bodies should be limited to cases that have been contested by the other Party under Article 8 of the Agreement on Mutual Recognition;

CONSIDERING that in order to simplify the operation of the Agreement on Mutual Recognition, a simpler procedure for the recognition, withdrawal of recognition, and suspension of conformity assessment bodies should be set up in Article 12 thereof, and the position regarding conformity assessment carried out by bodies before their designation is suspended or withdrawn should be clarified;

CONSIDERING that the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia is identical in form to the Agreement on Mutual Recognition, and is therefore being amended in parallel in order to retain coherence between the Agreements;

CONSIDERING that the legal references and mode of operation of the Sectoral Annexes on medicinal products GMP inspection and batch certification and on medical devices are outdated, and the opportunity has been taken to amend them to reflect the current position,

HAVE AGREED AS FOLLOWS:

#### Article 1

### Amendments to the Agreement on Mutual Recognition

The Agreement on Mutual Recognition is hereby amended as follows:

1. Article 3(2) is replaced by the following:

'2. Each Sectoral Annex shall, in general, contain the following information:

- (a) a statement of its scope and coverage;
- (b) the legislative, regulatory and administrative requirements pertaining to the conformity assessment procedures;
- (c) the designating authorities;
- (d) a set of procedures for the designation of conformity assessment bodies, and
- (e) additional provisions as required.'

2. Article 4 is replaced by the following:

'Article 4

#### Scope and coverage

This Agreement shall apply to products specified in the statement of scope and coverage in each Sectoral Annex.'

3. Article 6 is replaced by the following:

'Article 6

#### Designating authorities

1. The Parties shall ensure that the designating authorities responsible for designating conformity assessment

bodies have the necessary power and competence to designate, suspend, remove suspension and withdraw the designation of such bodies.

2. In making such designations, suspensions, removals of suspension and withdrawals, designating authorities shall, unless specified otherwise in the Sectoral Annexes, observe the procedures for designation set out in Article 12 and the Annex.'

4. Article 7(1) is replaced by the following:

'1. The Parties shall exchange information concerning the procedures used to ensure that the designated conformity assessment bodies under their responsibility comply with the legislative, regulatory and administrative requirements outlined in the Sectoral Annexes and the competence requirements specified in the Annex.'

5. Article 8 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. Such contestation has to be justified in an objective and argued manner and in writing to the other Party and to the Joint Committee.'

(b) paragraph 6 is replaced by the following:

'6. Except when decided otherwise by the Joint Committee, the contested conformity assessment body shall be suspended by the competent designating authority from the time its technical competence and compliance is contested in accordance with this Article until either agreement is reached in the Joint Committee on the status of that body or the challenging Party notifies the other Party and the Joint Committee that it is satisfied as to the technical competence and compliance of that body.'

6. Article 9 is replaced by the following:

'Article 9

### Exchange of information

1. The Parties shall exchange information concerning the implementation of the legislative, regulatory and administrative provisions identified in the Sectoral Annexes and shall maintain an accurate list of conformity assessment bodies designated in accordance with this Agreement.

2. Consistent with their obligations under the World Trade Organization Agreement on Technical Barriers to Trade, each Party shall inform the other Party of the changes it intends to make to the legislative, regulatory and administrative provisions relating to the subject matter of this Agreement and shall, except as provided for in paragraph 3 of this Article, notify the other Party of the new provisions at least 60 calendar days before their entry into force.

3. Where a Party takes urgent measures that it considers warranted by considerations of safety, health or protection of the environment in order to manage a risk posed by a product covered by a Sectoral Annex, it shall notify immediately the other Party of the measures, with a brief indication of their objective and rationale, or as otherwise specified in the Sectoral Annex.'

7. Paragraphs 3 to 7 of Article 12 are replaced by the following:

'3. The Joint Committee shall meet at least once a year unless the Joint Committee or the Parties decide otherwise. If required for the effective functioning of this Agreement, or at the request of either Party, an additional meeting or meetings shall be held.

4. The Joint Committee may consider any matter related to the functioning of this Agreement. In particular, it shall be responsible for:

- (a) amending the Sectoral Annexes in accordance with this Agreement;
- (b) exchanging information concerning the procedures used by either Party to ensure that the conformity assessment bodies maintain the necessary level of competence;
- (c) in accordance with Article 8, appointing a joint team or teams of experts to verify the technical competence of a conformity assessment body and its compliance with other relevant requirements;
- (d) exchanging information and notifying the Parties of modifications of legislative, regulatory and administrative provisions referred to in the Sectoral Annexes including those which require modification of the Sectoral Annexes;

(e) resolving any questions relating to the application of this Agreement and its Sectoral Annexes, and

(f) adopting new Sectoral Annexes in accordance with this Agreement.

5. Any amendments to the Sectoral Annexes made in accordance with this Agreement and any new Sectoral Annexes adopted in accordance with this Agreement shall be notified promptly in writing by the Joint Committee to each Party, and shall come into effect as determined by the Joint Committee.

6. The following procedure shall apply in relation to the designation of a conformity assessment body:

- (a) a Party wishing to designate a conformity assessment body shall forward its proposal to that effect to the other Party in writing, adding supporting documentation, as may be defined by the Joint Committee;
- (b) in the event that the other Party consents to the proposal or upon the expiry of 60 calendar days without an objection having been lodged, in accordance with any applicable procedures established by the Joint Committee, the conformity assessment body shall be considered to be a designated conformity assessment body under the terms of Article 5;
- (c) in the event that, under Article 8, the other Party contests the technical competence or compliance of the proposed conformity assessment body within the aforementioned 60-day period, the Joint Committee may decide to carry out a verification of the body concerned, in accordance with Article 8;
- (d) in the case of the designation of a new conformity assessment body, conformity assessment carried out by such a body shall be valid from the date on which it becomes a designated conformity assessment body in accordance with this Agreement;
- (e) either Party may suspend, remove the suspension of, or withdraw the designation of a conformity assessment body under its jurisdiction. The Party concerned shall immediately notify the other Party and the Joint Committee of its decision in writing, together with the date of such decision. The suspension, removal of suspension or withdrawal of the designation shall take effect from the date of the Party's decision;
- (f) in accordance with Article 8, either Party may, in exceptional circumstances, contest the technical competence of a designated conformity assessment body under the jurisdiction of the other Party. In this case the Joint Committee may decide to carry out a verification of the body concerned, in accordance with Article 8.

7. In the event that the designation of a conformity assessment body is suspended or withdrawn, conformity assessment carried out by that body before the date of effect of the suspension or withdrawal shall remain valid unless either the responsible Party has limited or cancelled that validity, or the Joint Committee determines otherwise. The Party under whose jurisdiction the suspended or withdrawn conformity assessment body was operating shall notify the other Party in writing of any such changes relating to a limitation or cancellation of validity.’
8. Article 15 is amended as follows:
- (a) paragraph 3 is replaced by the following:
- ‘3. The Joint Committee may adopt Sectoral Annexes to which Article 2 applies and which will provide the implementing arrangements for this Agreement.’;
- (b) paragraph 4 is replaced by the following:
- ‘4. Amendments to the Sectoral Annexes, and the adoption of new Sectoral Annexes, shall be determined by the Joint Committee.’.
9. The Annex is hereby amended as follows:
- (a) paragraph 9 is replaced by the following:
- ‘9. Designating authorities shall inform their Party’s representatives on the Joint Committee, established under Article 12 of this Agreement, of the conformity assessment bodies to be designated, suspended or withdrawn. The designation, suspension or withdrawal of designation of conformity assessment bodies shall take place in accordance with this Agreement and the rules of procedure of the Joint Committee.’;
- (b) paragraph 10 is replaced by the following:
- ‘10. When advising their Party’s representative on the Joint Committee established under this Agreement, of the conformity assessment bodies to be designated, the designating authority shall provide the following details in respect of each conformity assessment body:
- (a) the name;
- (b) the postal address;
- (c) the facsimile (fax) number and e-mail address;
- (d) the range of products, processes, standards or services it is authorised to assess;
- (e) the conformity assessment procedures it is authorised to carry out; and
- (f) the designation procedure used to determine competence.’.

10. The Sectoral Annex on medicinal products GMP inspection and batch certification, including Appendix 1 and Appendix 2, is replaced by the following:

**'SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION TO THE EUROPEAN COMMUNITY – NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT**

SCOPE AND COVERAGE

1. The provisions of this Sectoral Annex cover all medicinal products which are industrially manufactured in New Zealand and in the European Union, and to which Good Manufacturing Practice (GMP) requirements apply.

For medicinal products covered by this Sectoral Annex, each Party will recognise the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other Party and the relevant manufacturing authorisations granted by the competent authorities of the other Party.

In addition, the manufacturer's certification of the conformity of each batch to its specifications will be recognised by the other Party without re-control at import.

'Medicinal products' means all products regulated by the pharmaceutical legislation in the European Union and New Zealand referred to in Section I. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radiopharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feedingsuffs, and, where appropriate, vitamins, minerals, herbal remedies and homoeopathic medicinal products.

'GMP' is that part of quality assurance which ensures that products are consistently produced and controlled during manufacture to the quality standards appropriate to their intended use and as required by the marketing authorisation granted by the importing Party. For the purpose of this Sectoral Annex it includes the system whereby the manufacturer receives the specification of the product and/or process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification (equivalent to Qualified Person certification in the European Union).

2. With respect to medicinal products covered by the legislation of one Party ('regulating Party') but not the other, the manufacturing company may request the authority nominated by the relevant contact point of the regulating Party listed in point 12 of Section III, for the purpose of this Agreement, that an inspection be made by the locally competent inspection service. This provision will apply, inter alia, to the manufacture of active pharmaceutical ingredients and intermediate products and products intended for use in clinical trials, as well as jointly determined pre-marketing inspections. Operational arrangements are detailed under point 3(b) of Section III.

**Certification of manufacturers**

3. At the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture of medicinal products will certify that the manufacturer:
- is appropriately authorised to manufacture the relevant medicinal product or to carry out the relevant specified manufacturing operation;
  - is regularly inspected by the authorities, and
  - complies with the national GMP requirements recognised as equivalent by the two Parties, referred to in Section I. Where different GMP requirements are used as a reference (in line with the provisions in point 3(b) of Section III), this is to be mentioned in the certificate.

The certificates will also identify the site(s) of manufacture (and contract testing laboratories, if any). The format of the certificate will be decided by the Joint Sectoral Group.

Certificates will be issued expeditiously, and the time taken should not exceed 30 calendar days. In exceptional cases, such as when a new inspection has to be carried out, this period may be extended to 60 calendar days.



**Batch certification**

4. Each batch exported will be accompanied by a batch certificate prepared by the manufacturer (self-certification) after a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate will attest that the batch meets its specifications and will be kept by the importer of the batch. It will be made available upon request of the competent authority.

When issuing a certificate, the manufacturer will take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate will detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It will contain a statement that the batch processing and packaging records were reviewed and found to be in conformity with GMP. The batch certificate will be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Union the 'qualified person' as referred to in relevant European Union legislation. In New Zealand, the responsible person is named on the licence to manufacture issued under the relevant New Zealand legislation.

*SECTION I***LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS**

Subject to Section III, general GMP inspections will be carried out against the GMP requirements of the exporting Party. The applicable legislative, regulatory and administrative provisions related to this Sectoral Annex are set out in the Table.

However, the reference quality requirements of products to be exported, including their manufacturing method and product specifications, will be those of the relevant product marketing authorisation granted by the importing Party.

Applicable legislative, regulatory and administrative provisions for the European Union	Applicable legislative, regulatory and administrative provisions for New Zealand
— Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products, as amended	— Medicines Act, 1981 — Medicines Regulations, 1984
— Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended	— New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Parts 1, 2, 4 and 5
— Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended	— Agricultural Compounds and Veterinary Medicines Act, 1997 — Agricultural Compounds and Veterinary Medicines Regulations, 2001
— Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, as amended	— Agricultural Compounds and Veterinary Medicines (ACVM) Standard for Good Manufacturing Practice — Agricultural Compounds and Veterinary Medicines (ACVM) Guideline for Good Manufacturing Practice
— Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended	— and any legislation adopted on the basis of, or that amends, the above legislation
— Guide to Good Distribution Practice (94/C 63/03)	
— Volume 4 — Guidelines for good manufacturing practices for medicinal products for human and veterinary use	

## SECTION II

**OFFICIAL INSPECTION SERVICES**

The lists of official inspection services related to this Sectoral Annex have been jointly determined by the Parties and will be maintained by them. If a Party requests from the other Party a copy of its latest lists of official inspection services, the requested Party will provide the requesting Party with a copy of those lists within 30 calendar days of the date of receipt of the request.

## SECTION III

**OPERATIONAL PROVISIONS****1. Transmission of inspection reports**

Upon reasoned request, the relevant inspection services will forward a copy of the last inspection report of the manufacturing or control site, in the case where analytical operations are contracted out. The request may concern a 'full inspection report' or a 'detailed report' (see point (2)). Each Party will deal with these inspection reports with the degree of confidentiality requested by the Party of origin.

If the manufacturing operations of the medicinal product in question have not been inspected recently, i.e. when the last inspection dates back to more than two years or a particular need to inspect has been identified, a specific and detailed inspection may be requested. Parties will ensure that inspection reports are forwarded in no more than 30 calendar days, this period being extended to 60 calendar days should a new inspection be carried out.

**2. Inspection reports**

A 'full inspection report' comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A 'detailed report' responds to specific queries about a firm by the other Party.

**3. Reference GMP**

- (a) Manufacturers will be inspected against the applicable GMP of the exporting Party (see Section I).
- (b) With respect to medicinal products covered by the pharmaceutical legislation of the importing Party but not the exporting one, the locally competent inspection service willing to carry out an inspection of the relevant manufacturing operations will inspect against its own GMP or, in the absence of specific GMP requirements, against the applicable GMP of the importing Party. This will also be the case when the locally applicable GMP are not considered equivalent, in terms of quality assurance of the finished product, to the GMP of the importing Party.

Equivalence of GMP requirements for specific products or classes of products (e.g. investigational medicinal products, starting materials) will be determined according to a procedure established by the Joint Sectoral Group.

**4. Nature of inspections**

- (a) Inspections will routinely assess the compliance of the manufacturer with GMP. These are called general GMP inspections (also regular, periodic, or routine inspections).
- (b) 'Product- or process-oriented' inspections (which may be 'pre-marketing' inspections as relevant) focus on the manufacture of one or one series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) will be provided in confidence to the inspectorate.

**5. Inspection/establishment fees**

The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees will not be charged to manufacturers located on the territory of the other Party for products covered by this Sectoral Annex.

**6. Safeguard clause for inspections**

Each Party reserves the right to conduct its own inspection for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party, which has the option of joining the inspection. Recourse to this safeguard clause should be an exception. Should such an inspection take place, inspection costs may be recovered.

## 7. Exchange of information between authorities and approximation of quality requirements

In accordance with the general provisions of this Agreement, the Parties will exchange any relevant information necessary for the ongoing mutual recognition of inspections. For the purposes of demonstration of capability in cases of significant changes to regulatory systems in either of the Parties, additional specific information may be requested by either Party in relation to an official inspection service. Such specific requests may cover information on training, inspection procedures, general information and document exchange, and transparency of agency audits of official inspection services relevant to the operation of this Sectoral Annex. Such requests should be made through and managed by the Joint Sectoral Group as part of an ongoing maintenance programme.

In addition, the relevant authorities in New Zealand and in the European Union will keep each other informed of any new technical guidance or changes to inspection procedures. Each Party will consult the other before their adoption.

## 8. Official batch release

The official batch release procedure is an additional verification of safety and efficacy of immunological medicinal products (vaccines) and blood derivatives, carried out by the competent authorities before the distribution of each batch of product. This Agreement does not encompass this mutual recognition of official batch releases. However, when an official batch release procedure applies, the manufacturer will provide, at the request of the importing Party, the official batch release certificate if the batch in question has been tested by the control authorities of the exporting Party.

For the European Union, the official batch release procedure for medicinal products for human use is published by the European Directorate for the Quality of Medicines & HealthCare. For New Zealand, the official batch release procedure is specified in document 'WHO Technical Report Series, No 822, 1992'.

## 9. Inspectors' training

In accordance with the general provisions of this Agreement, training sessions for inspectors, organised by the authorities, will be accessible to inspectors of the other Party. The Parties will keep each other informed of these sessions.

## 10. Joint inspections

In accordance with the general provisions of this Agreement, and by mutual arrangement between the Parties, joint inspections may be authorised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form will be established through procedures approved by the Joint Sectoral Group.

## 11. Alert system

Contact points will be designated by the Parties to permit competent authorities and manufacturers to inform the authorities of the other Party with the appropriate speed in case of quality defects, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure will be jointly established.

The Parties will ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with GMP and which could affect the protection of public health, is communicated to the other Party with the appropriate degree of urgency.

## 12. Contact points

For the purpose of this Sectoral Annex, the contact points for any technical question, such as exchange of inspection reports, inspector training sessions, technical requirements, will be:

FOR NEW ZEALAND:

*For medicinal products for human use:*

Group Manager  
Medicines and Medical Devices Safety Authority (Medsafe)  
PO Box 5013  
Wellington  
New Zealand  
Tel. 64-4-819 6874  
Fax 64-4-819 6806

*For medicinal products for use in animals:*

Director, Approvals and ACVM Standards  
Ministry of Agriculture and Forestry  
(MAF) PO Box 2526  
Wellington 6140  
New Zealand  
Tel. 64-4-894 2541  
Fax 64-4-894 2501

FOR THE EUROPEAN UNION: The Director of the European Medicines Agency  
7 Westferry Circus  
Canary Wharf  
London E14 4HB  
United Kingdom  
Tel. 44-171-418 8400  
Fax 44-171-418 8416

### 13. Joint Sectoral Group

A Joint Sectoral Group made up of representatives of the Parties will be established under this Sectoral Annex. It will be responsible for the effective functioning of this Sectoral Annex. It will report to the Joint Committee as the Joint Committee will determine.

The Joint Sectoral Group will determine its own rules of procedure. It will take its decisions and adopt its recommendations by consensus. It may decide to delegate its tasks to subgroups.

### 14. Divergence of views

Both Parties will use their best endeavours to resolve any divergence of views concerning, inter alia, compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Joint Sectoral Group.

## SECTION IV

### CHANGES TO THE LIST OF OFFICIAL INSPECTION SERVICES

The Parties recognise the need for this Sectoral Annex to accommodate change, particularly with regard to the entry of new official inspection services or changes in the nature or role of established competent authorities. Where significant changes have occurred with regard to official inspection services, the Joint Sectoral Group will consider what, if any, additional information is required to verify programmes and establish or maintain mutual recognition of inspections, in accordance with point 7 of Section III.

11. The Sectoral Annex on medical devices is replaced by the following:

#### 'SECTORAL ANNEX ON MEDICAL DEVICES TO THE EUROPEAN COMMUNITY — NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

##### SCOPE AND COVERAGE

The provisions of this Sectoral Annex will apply to the following products:

Products for export to the European Union	Products for export to New Zealand
<p>(1) All medical devices:</p> <p>(a) manufactured in New Zealand; and</p> <p>(b) subject to third party conformity assessment procedures, both product and quality systems-related; and</p> <p>(c) provided for in Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended; and</p>	<p>(1) All medical devices:</p> <p>(a) manufactured in the European Union; and</p> <p>(b) subject to third party conformity assessment procedures, both product and quality systems-related, or subject to other requirements under the legislation listed in Section I, as amended.</p>

Products for export to the European Union	Products for export to New Zealand
<p>(d) provided for in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended.</p> <p>(2) For the purposes of paragraph 1:</p> <p>(a) medical devices provided for in the Appendix are excluded; and</p> <p>(b) unless otherwise provided for or by mutual arrangement by the Parties, 'manufacture' of a medical device does not include:</p> <p>(i) restoration or renovation processes such as repairing, re-conditioning, overhauling or refurbishing; or</p> <p>(ii) operations such as pressing, labelling, ticketing, packaging and preparation for sale, conducted alone or in combination with each other; or</p> <p>(iii) quality control inspections alone; or</p> <p>(iv) sterilisation alone.</p>	<p>(2) For the purposes of paragraph 1:</p> <p>(a) medical devices provided for in the Appendix are excluded; and</p> <p>(b) unless otherwise provided for or by mutual arrangement by the Parties, 'manufacture' of a medical device does not include:</p> <p>(i) restoration or renovation processes such as repairing, re-conditioning, overhauling or refurbishing; or</p> <p>(ii) operations such as pressing, labelling, ticketing, packaging and preparation for sale, conducted alone or in combination with each other; or</p> <p>(iii) quality control inspections alone; or</p> <p>(iv) sterilisation alone.</p>

## SECTION I

## LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Union with which New Zealand-designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Union-designated conformity assessment bodies will assess compliance
<p>— Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended</p> <p>— Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended</p> <p>— and any European Union legislation adopted on the basis of these Directives</p>	<p>— Radiocommunications Act 1989 and Regulations made pursuant to that Act</p> <p>— Electricity Act 1992 and Regulations made pursuant to that Act</p> <p>— Medicines Act 1981</p> <p>— Medicines Regulations 1984</p> <p>— Medicines (Database of Medical Devices) Regulations 2003</p> <p>— and any legislation adopted on the basis of, or that amends, the above legislation</p>

## SECTION II

## THE AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES UNDER THIS SECTORAL ANNEX

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
<p>— Ministry of Health</p>	<p>— <i>Belgium</i></p> <p>Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale</p> <p>Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie</p>

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
	<p>Agence Fédérale des Médicaments et des Produits de Santé – Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten</p> <p>— <i>Bulgaria</i></p> <p>Държавна агенция за метрологичен и технически надзор</p> <p>— <i>Czech Republic</i></p> <p>Úřad pro technickou normalizaci, metrologii a státní zkušebnictví</p> <p>— <i>Denmark</i></p> <p>Indenrigs- og Sundhedsministeriet</p> <p>Lægemiddelstyrelsen</p> <p>— <i>Germany</i></p> <p>ZLG — Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, Bonn</p> <p>ZLS — Zentralstelle der Länder für Sicherheitstechnik, München</p> <p>— <i>Estonia</i></p> <p>Majandus- ja Kommunikatsiooniministeerium</p> <p>— <i>Ireland</i></p> <p>Department of Health</p> <p>Irish Medicines Board</p> <p>— <i>Greece</i></p> <p>Υπουργείο Υγείας και Κοινωνικής Αλληλεγγύης</p> <p>Εθνικός Οργανισμός Φαρμάκων</p> <p>— <i>Spain</i></p> <p>Ministerio de Sanidad, Política Social e Igualdad</p> <p>Agencia Española de Medicamentos y Productos Sanitarios</p> <p>— <i>France</i></p> <p>Ministère de la Santé</p> <p>Agence Française de Sécurité Sanitaire des produits de Santé</p> <p>Agence Nationale du Médicament Vétérinaire</p> <p>— <i>Italy</i></p> <p>Ministero della Salute – Dipartimento dell' Innovazione – Direzione Generale Farmaci e Dispositivi Medici</p> <p>— <i>Cyprus</i></p> <p>The Drugs Council, Pharmaceutical Services (Ministry of Health)</p> <p>Veterinary Services (Ministry of Agriculture)</p>

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
	— <i>Latvia</i> Zāļu valsts aģentūra Veselības ministrija
	— <i>Lithuania</i> Lietuvos Respublikos sveikatos apsaugos ministerija
	— <i>Luxembourg</i> Ministère de la Santé Division de la Pharmacie et des Médicaments
	— <i>Hungary</i> Országos Gyógyszerészeti Intézet
	— <i>Malta</i> Direttorat tal-Affarijiet Regolatorji, Awtorità Maltija dwar l-iStandards
	— <i>Netherlands</i> Ministerie van Volksgezondheid, Welzijn en Sport Inspectie voor de Gezondheidszorg
	— <i>Austria</i> Bundesministerium für Gesundheit Bundesamt für Sicherheit im Gesundheitswesen
	— <i>Poland</i> Ministerstwo Zdrowia Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych
	— <i>Portugal</i> INFARMED:I.P. (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.)
	— <i>Romania</i> Ministerul Sănătății – Departament Dispozitive Medicale
	— <i>Slovenia</i> Ministrstvo za zdravje Javna agencija Republike Slovenije za zdravila in medicinske pripomočke
	— <i>Slovakia</i> Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky
	— <i>Finland</i> Sosiaali- ja terveystieteistö Sosiaali- ja terveystietealan lupa- ja valvontavirasto (Valvira)

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
	— <i>Sweden</i>  Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
	— <i>United Kingdom</i>  Medicines and Healthcare products Regulatory Agency

## SECTION III

## PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Union's requirements	The procedures to be followed by the European Union in designating conformity assessment bodies to assess products against New Zealand's requirements
<p>Conformity assessment bodies to be designated for the purposes of this Sectoral Annex will meet the requirements of the Directives listed in Section I, taking into account Annex II to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, as amended, and be designated on the basis of the procedures defined in the Annex to this Agreement. This may be demonstrated through:</p> <p>(a) Product certification bodies operating according to the requirements of EN 45011 or ISO Guides 28 and 40, and either:</p> <ul style="list-style-type: none"> <li>— accredited by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ), or</li> <li>— able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement.</li> </ul> <p>(b) Quality System certification bodies operating according to the requirements of EN 45012 or ISO Guide 62, and either:</p> <ul style="list-style-type: none"> <li>— accredited by JAS-ANZ, or</li> <li>— able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement.</li> </ul> <p>(c) Inspection bodies operating according to the requirements of ISO/IEC 17020, and either:</p> <ul style="list-style-type: none"> <li>— accredited by the Testing Laboratory Registration Council of New Zealand or any other body established by law in New Zealand which replaces it and which has the same functions, or</li> <li>— able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement.</li> </ul> <p>Pursuant to point 5.2 of Section IV, designation for high-risk devices listed in point 5.1 of that Section will occur on the basis of a confidence-building programme.</p>	<p>1. The procedures for designating conformity assessment bodies will be consistent with the principles and procedures set out in the Annex to this Agreement.</p> <p>2. The following procedures are deemed to be consistent with those set out in the Annex to this Agreement:</p> <p>(a) Certification bodies:</p> <ul style="list-style-type: none"> <li>— accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement (MLA) for certification of products,</li> <li>— members of the Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE) CB Scheme,</li> <li>— accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or</li> <li>— able to demonstrate competence by other means in accordance with Section A and B of the Annex to this Agreement.</li> </ul> <p>(b) Testing laboratories:</p> <ul style="list-style-type: none"> <li>— accredited by accreditation bodies which are signatories to the EA MLA for calibration and testing laboratories,</li> <li>— recognised within the IECEE CB Scheme, or</li> <li>— able to demonstrate competence by other means in accordance with Section A and B of the Annex to this Agreement.</li> </ul> <p>Pursuant to point 5.2 of Section IV, designation for high-risk devices listed in point 5.1 of that Section will occur on the basis of a confidence-building programme.</p>



## SECTION IV

## ADDITIONAL PROVISIONS

1. **New legislation**

The Parties note New Zealand's intention to introduce new legislation concerning medical devices, and jointly decide that the provisions of this Sectoral Annex will apply to this legislation upon its entry into force in New Zealand.

The Parties jointly declare their intention to extend the scope of this Sectoral Annex to in vitro diagnostic devices as soon as New Zealand's new legislation concerning medical devices is in place.

2. **Exchange of information**

The Parties will inform each other of incidents in the context of the medical device vigilance procedure, or with regard to matters concerning product safety. The Parties will also inform each other of:

- certificates withdrawn, suspended, restricted or revoked, and
- any legislation or amendment to existing legislation adopted on the basis of the legal texts listed in Section I.

The contact points through which the information can be passed are:

New Zealand:	<p>The Manager Medicines and Medical Devices Safety Authority (Medsafe) PO Box 5013 Wellington New Zealand Tel. 64-4-819 6874 Fax 64-4-819 6806</p> <p>and</p> <p>Group Manager Energy Safety and Radio Spectrum Management Ministry of Economic Development (MED) P.O. Box 1473 Wellington New Zealand Tel. 64-4-472-0030 Fax 64-4-471-0500</p>
European Union	<p>European Commission Directorate-General for Health and Consumers Rue de la Loi/Wetstraat 200 B-1049 Brussels Tel. 32-2-299 11 11</p>

The Parties may exchange information on the consequences of the establishment of the European Database on Medical Devices (Eudamed).

In addition, the Medicines and Medical Devices Safety Authority will advise of any certificates issued.

3. **Subcontracting**

Where required by New Zealand legislative, regulatory and administrative provisions, European Union conformity assessment bodies subcontracting all or part of the testing will subcontract only to testing laboratories accredited in accordance with point 2 of Section III.

4. **Recording of approvals granted**

In addition to the requirements imposed by the Annex to this Agreement on the designation of a conformity assessment body, the relevant European Union designating authority will provide to New Zealand, in respect of each designated conformity assessment body, details of the method that such conformity assessment body intends to adopt to record the fact that an approval required by the Secretary under the Electricity Act 1992 (and Regulations made pursuant to that Act) for fittings or appliances to be sold or offered for sale in New Zealand has been granted.

## 5. Confidence-building with respect to high-risk devices

- 5.1. A confidence-building process for the purpose of strengthening confidence in the designating systems of each of the Parties will apply for the following medical devices:
- active implantable devices as defined in the legislation referred to in Section I;
  - devices that are classified as class III devices under the legislation referred to in Section I;
  - medical devices that are implantable intra-ocular lenses;
  - medical devices that are intra-ocular visco elastic fluids, and
  - medical devices that are a barrier indicated for contraception or prevention of the sexual transmission of disease.
- 5.2. The Parties will establish a detailed programme to this effect involving the Medicines and Medical Devices Safety Authority and the European Union's competent authorities.
- 5.3. The confidence-building period will be reviewed after two years commencing from the date this Sectoral Annex, as amended, becomes effective.
- 5.4. Additional specific requirements for regulatory progress:
- 5.4.1. In pursuance of Articles 2, 7(1), 8(1) and 9(1) of this Agreement, either Party may request additional specific requirements in relation to the conformity assessment bodies for the purposes of demonstration of experience in the evolving regulatory systems.
- 5.4.2. These specific requirements may include training, observed conformity assessment body audits, visits and information and document exchange, including audit reports.
- 5.4.3. These requirements may likewise be applicable in relation to the designation of a conformity assessment body in accordance with this Agreement.

## 6. Joint Sectoral Group

A Joint Sectoral Group made up of representatives of the Parties will be established under this Sectoral Annex. It will be responsible for the effective functioning of this Sectoral Annex. It will report to the Joint Committee as the latter will determine.

The Joint Sectoral Group will determine its own rules of procedure. It will take its decisions and adopt its recommendations by consensus. It may decide to delegate its tasks to subgroups.

## 7. Divergence of views

Both Parties will use their best endeavours to resolve any divergence of views concerning, inter alia, compliance of manufacturers and conclusions of conformity assessment reports. Unresolved divergences of view will be referred to the Joint Sectoral Group.

### *Appendix*

The provisions of this Sectoral Annex will not apply to the following devices:

- medical devices that contain or are manufactured using cells, tissues or tissue derivatives of animal origin that have been rendered non-viable, where the safety with regard to viruses or other transferable agents requires validated methods for elimination or viral inactivation in the course of the manufacturing process;
- medical devices that contain tissues, cells or substances of microbial, bacterial or recombinant origin and are intended for use in or on the human body;
- medical devices incorporating tissues or tissue derivatives of human origin;
- medical devices incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;

- medical devices that incorporate, or intend to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device, and
- medical devices that are intended by the manufacturer specifically to be used for chemical disinfection of another medical device, except for sterilisers using dry heat, moist heat or ethylene oxide.

Both Parties may decide by common arrangement to extend the application of this Sectoral Annex to the aforementioned medical devices.’

#### *Article 2*

#### **Entry into force**

This Agreement shall enter into force on the first day of the second month following the date on which the Parties have exchanged diplomatic notes confirming the completion of their respective procedures for entry into force of this Agreement

Done at Brussels, in duplicate, on 23 February 2012 in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, each text being equally authentic.

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

За Нова Зеландия  
 Por Nueva Zelanda  
 Za Nový Zéland  
 For New Zealand  
 Für Neuseeland  
 Uus-Meremaa nimel  
 Για τη Νέα Ζηλανδία  
 For New Zealand  
 Pour la Nouvelle-Zélande  
 Per la Nuova Zelanda  
 Jaunzēlandes vārdā –  
 Naujosios Zelandijos vardu  
 Uj-Zéland részéről  
 Għal New Zealand  
 Voor Nieuw-Zeeland  
 W imieniu Nowej Zelandii  
 Pela Nova Zelândia  
 Pentru Noua Zeelandă  
 Za Nový Zéland  
 Za Novo Zelandijo  
 Uuden-Seelannin puolesta  
 För Nya Zeeland

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# REGULATIONS

## COUNCIL REGULATION (EU) No 1261/2012

of 20 December 2012

### fixing for 2013 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in the Black Sea

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) Article 43(3) of the Treaty provides that the Council, on a proposal from the Commission, is to adopt measures on the fixing and allocation of fishing opportunities.
- (2) Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy<sup>(1)</sup> requires that measures governing access to waters and resources and the sustainable pursuit of fishing activities be established taking into account available scientific advice and, in particular, the report drawn up by the Scientific, Technical and Economic Committee for Fisheries (STECF).
- (3) It is incumbent upon the Council to adopt measures on the fixing and allocation of fishing opportunities by fishery or group of fisheries, including certain conditions functionally linked thereto, as appropriate. Fishing opportunities should be distributed among Member States in such a way as to assure each Member State relative stability of fishing activities for each stock or fishery and having due regard to the objectives of the common fisheries policy established in Regulation (EC) No 2371/2002.
- (4) The total allowable catch (TACs) should be established on the basis of the available scientific advice, taking into account biological and socioeconomic aspects whilst ensuring fair treatment between fishing sectors, as well as in the light of the opinions expressed during the consultation of stakeholders.
- (5) The use of fishing opportunities set out in this Regulation should be subject to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy<sup>(2)</sup> and

in particular to Articles 33 and 34 thereof concerning respectively the recording of catches and fishing effort and the notification of data on the exhaustion of fishing opportunities. It is therefore necessary to specify the codes to be used by the Member States when sending data to the Commission relating to landings of stocks subject to this Regulation.

- (6) In accordance with Article 2 of Council Regulation (EC) No 847/96 of 6 May 1996 introducing additional conditions for year-to-year management of TACs and quotas<sup>(3)</sup>, the stocks that are subject to the various measures referred to therein must be identified.
- (7) In order to avoid interruption of fishing activities and to ensure the livelihood of Union fishermen, it is important to open these fisheries on 1 January 2013. For reasons of urgency, this Regulation should enter into force immediately after its publication,

HAS ADOPTED THIS REGULATION:

#### CHAPTER I

#### SCOPE AND DEFINITIONS

##### Article 1

##### Subject matter

This Regulation fixes the fishing opportunities for 2013 for certain fish stocks and groups of fish stocks in the Black Sea.

##### Article 2

##### Scope

This Regulation shall apply to EU vessels operating in the Black Sea.

##### Article 3

##### Definitions

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

- (a) 'GFCM' means General Fisheries Commission for the Mediterranean;

<sup>(1)</sup> OJ L 358, 31.12.2002, p. 59.

<sup>(2)</sup> OJ L 343, 22.12.2009, p. 1.

<sup>(3)</sup> OJ L 115, 9.5.1996, p. 3.

- (b) 'Black Sea' means geographical sub-area 29 as defined in Annex I to Regulation (EU) No 1343/2011 of the European Parliament and of the Council of 13 December 2011 on certain provisions for fishing in the GFCM (General Fisheries Commission for the Mediterranean) Agreement area <sup>(4)</sup> and in the resolution GFCM/33/2009/2;
- (c) 'EU vessel' means a fishing vessel flying the flag of a Member State and registered in the Union;
- (d) 'total allowable catch (TAC)' means the quantity that can be taken from each stock each year;
- (e) 'quota' means a proportion of the TAC allocated to the Union, a Member State or a third country.

## CHAPTER II

**FISHING OPPORTUNITIES***Article 4***TACs and allocations**

The TACs, the allocation of such TACs among Member States, and conditions functionally linked thereto, where appropriate, are set out in the Annex.

*Article 5***Special provisions on allocations**

The allocation of fishing opportunities among Member States as set out in this Regulation shall be without prejudice to:

- (a) exchanges made pursuant to Article 20(5) of Regulation (EC) No 2371/2002;
- (b) deductions and reallocations made pursuant to Article 37 of Regulation (EC) No 1224/2009;
- (c) additional landings allowed pursuant to Article 3 of Regulation (EC) No 847/96;

- (d) quantities withheld in accordance with Article 4 of Regulation (EC) No 847/96;
- (e) deductions made pursuant to Articles 105 and 107 of Regulation (EC) No 1224/2009.

*Article 6***Conditions for landing catches and by-catches**

Fish from stocks for which fishing opportunities are fixed by this Regulation shall be retained on board or landed only if:

- (a) the catches have been taken by vessels of a Member State having a quota and that quota is not exhausted; or
- (b) the catches consist of a share in a Union quota which has not been allocated by quota among Member States, and that Union quota has not been exhausted.

## CHAPTER III

**FINAL PROVISIONS***Article 7***Data transmission**

When, pursuant to Articles 33 and 34 of Regulation (EC) No 1224/2009, Member States send the Commission data relating to landings of quantities of stocks caught, they shall use the stock codes set out in the Annex to this Regulation.

*Article 8***Entry into force**

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

It shall apply from 1 January 2013.

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

Done at Brussels, 20 December 2012.

*For the Council*

*The President*

A. D. MAVROYIANNIS

<sup>(4)</sup> OJ L 347, 30.12.2011, p. 44.

## ANNEX

**TACs applicable to EU vessels in areas where TACs exist by species and by area**

The following tables set out the TACs and quotas (in tonnes live weight, except where otherwise specified) by stock, and conditions functionally linked thereto, where appropriate.

Fish stocks are referred to following the alphabetical order of the Latin names of the species. For the purposes of this Regulation, the following comparative table of Latin names and common names is provided:

Scientific name	Alpha-3 code	Common name
<i>Psetta maxima</i>	TUR	Turbot
<i>Sprattus sprattus</i>	SPR	Sprat

<b>Species:</b> Turbot <i>Psetta maxima</i>	<b>Zone:</b> EU waters in the Black Sea TUR/F37.4.2.C.
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Bulgaria	43,2
Romania	43,2
Union	86,4 <sup>(1)</sup>

TAC Not relevant

<p>Analytical TAC</p> <p>Article 3 of Regulation (EC) No 847/96 shall not apply.</p> <p>Article 4 of Regulation (EC) No 847/96 shall not apply.</p>
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<sup>(1)</sup> No fishing activity, including transshipment, taking on board, landing and first sale shall be permitted from 15 April to 15 June 2013.

<b>Species:</b> Sprat <i>Sprattus sprattus</i>	<b>Zone:</b> EU waters in the Black Sea SPR/F37.4.2.C
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Bulgaria	8 032,5
Romania	3 442,5
Union	11 475

TAC Not relevant

<p>Analytical TAC</p> <p>Article 3 of Regulation (EC) No 847/96 shall not apply.</p> <p>Article 4 of Regulation (EC) No 847/96 shall not apply.</p>
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**COUNCIL REGULATION (EU) No 1262/2012****of 20 December 2012****fixing for 2013 and 2014 the fishing opportunities for EU vessels for certain deep-sea fish stocks**

THE COUNCIL OF THE EUROPEAN UNION,

meetings with the Advisory Committee for Fisheries and Aquaculture and the Regional Advisory Councils concerned.

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) Article 43(3) of the Treaty provides that the Council, on a proposal from the Commission, is to adopt measures on the fixing and allocation of fishing opportunities.

(2) Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy<sup>(1)</sup> requires that measures governing access to waters and resources and the sustainable pursuit of fishing activities be established taking into account available scientific, technical and economic advice and in particular reports drawn up by the Scientific, Technical and Economic Committee for Fisheries (STECF), as well as in the light of any advice received from Regional Advisory Councils.

(3) It is incumbent upon the Council to adopt measures on the fixing and allocation of fishing opportunities by fishery or group of fisheries, including certain conditions functionally linked thereto, as appropriate. Fishing opportunities should be distributed among Member States in such a way as to assure each Member State relative stability of fishing activities for each stock or fishery and having due regard to the objectives of the Common Fisheries Policy established by Regulation (EC) No 2371/2002.

(4) The total allowable catches (TACs) should be established on the basis of available scientific advice, taking into account biological and socioeconomic aspects whilst ensuring fair treatment between fishing sectors, as well as in the light of the opinions expressed during the consultation of stakeholders, in particular at the

(5) Fishing opportunities should be in accordance with international agreements and principles, such as the 1995 United Nations agreement concerning the conservation and management of straddling stocks and highly migratory fish stocks<sup>(2)</sup>, and the detailed management principles laid down in the 2008 International Guidelines for the Management of Deep-sea Fisheries in the High Seas of the Food and Agriculture Organisation of the United Nations, according to which, in particular, a regulator should be more cautious when information is uncertain, unreliable or inadequate. The absence of adequate scientific information should not be used as a reason for postponing or failing to take conservation and management measures.

(6) The latest scientific advice from the International Council for the Exploration of the Sea (ICES) and from the STECF indicates that most deep-sea stocks are harvested unsustainably and that fishing opportunities for those stocks, in order to assure their sustainability, should be reduced until the evolution of the stock sizes show a positive trend. The ICES has further advised that no directed fishery should be allowed for orange roughy in all areas and for certain stocks of blue ling and red seabream.

(7) Concerning deep sea sharks, the main commercial species are considered depleted and, therefore, no directed fishing should take place.

(8) The fishing opportunities for deep-sea species as defined in Article 2(a) of Council Regulation (EC) No 2347/2002 of 16 December 2002 establishing specific access requirements and associated conditions applicable to fishing for deep-sea stocks<sup>(3)</sup> are decided on a bi-annual basis. Nevertheless, an exception is made for the stocks of greater silver smelt and the main fishery of blue ling for which the fishing opportunities depend on the outcome of the annual negotiations with Norway. The fishing opportunities for those stocks should be established in another relevant annual regulation fixing fishing opportunities.

<sup>(1)</sup> OJ L 358, 31.12.2002, p. 59.

<sup>(2)</sup> Agreement on the implementation of the provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 relating to the conservation and management of straddling fish stocks and highly migratory fish stocks (OJ L 189, 3.7.1998, p. 16).

<sup>(3)</sup> OJ L 351, 28.12.2002, p. 6.



- (9) In the interest of simplification, blue ling TACs autonomously decided by the Union should be regulated in the same legal instrument. Therefore, TACs for blue ling in international waters of II, III and IV should be included, together with the TACs for blue ling in international waters of XII, in the Regulation fixing the fishing opportunities available to EU vessels for certain fish stocks and groups of fish stocks which are not subject to international negotiations or agreements.
- (10) In accordance with Council Regulation (EC) No 847/96 of 6 May 1996 introducing additional conditions for year-to-year management of TACs and quotas<sup>(1)</sup> the stocks that are subject to various measures referred to therein should be identified. Precautionary TACs should apply for stocks for which no scientifically-based evaluation of fishing opportunities is available specifically for the year in which the TACs are to be set; analytical TACs should apply otherwise. In view of ICES and STECF advice for deep-sea stocks, those for which a science-based evaluation of the relevant fishing opportunities is not available should be subject to precautionary TACs in this Regulation.
- (11) In light of the scientific advice, the biological distribution of some stocks of roundnose grenadier does not necessarily correspond to the TAC areas in this Regulation. In order to facilitate the sustainable exploitation of these stocks, it is appropriate to allow for increased flexibility between TAC area Vb, VI, VII, on one hand, and TAC area VIII, IX, X, XII and XIV, on the other.
- (12) In order to avoid the interruption of fishing activities and to ensure the livelihood of the fishermen of the Union, this Regulation should apply from 1 January 2013. For reasons of urgency, this Regulation should enter into force immediately after its publication,
- (a) 'EU vessel' means a fishing vessel flying the flag of a Member State and registered in the Union;
- (b) 'EU waters' means the waters under the sovereignty or jurisdiction of the Member States with the exception of waters adjacent to the territories mentioned in Annex II to the Treaty;
- (c) 'total allowable catch' (TAC) means the quantity that can be taken and landed from each fish stock each year;
- (d) 'quota' means a proportion of the TAC allocated to the Union, a Member State or a third country;
- (e) 'international waters' means waters falling outside the sovereignty or jurisdiction of any State.
2. For the purposes of this Regulation, the following zone definitions shall apply:
- (a) ICES (International Council for the Exploration of the Sea) zones are the geographical areas specified in Annex III to Regulation (EC) No 218/2009 of the European Parliament and of the Council<sup>(2)</sup>;
- (b) CECAF (Committee for Eastern Central Atlantic Fisheries) zones are the geographical areas specified in Annex II to Regulation (EC) No 216/2009 of the European Parliament and of the Council<sup>(3)</sup>.

### Article 3

#### TACs and allocations

The TACs for deep-sea species caught by EU vessels in EU waters or in certain non-EU waters, the allocation of such TACs among Member States and the conditions functionally linked thereto, where appropriate, are set out in the Annex to this Regulation.

### Article 4

#### Special provisions on allocations of fishing opportunities

1. The allocation of fishing opportunities among Member States as set out in this Regulation shall be without prejudice to:

- (a) exchanges made pursuant to Article 20(5) of Regulation (EC) No 2371/2002;

<sup>(2)</sup> Regulation (EC) No 218/2009 of the European Parliament and of the Council of 11 March 2009 on the submission of nominal catch statistics by Member States fishing in the north-east Atlantic (OJ L 87, 31.3.2009, p. 70).

<sup>(3)</sup> Regulation (EC) No 216/2009 of the European Parliament and of the Council of 11 March 2009 on the submission of nominal catch statistics by Member States fishing in certain areas other than those of the North Atlantic (OJ L 87, 31.3.2009, p. 1).

HAS ADOPTED THIS REGULATION:

### Article 1

#### Subject matter

This Regulation fixes for the years 2013 and 2014 the annual fishing opportunities available to EU vessels for fish stocks of certain deep-sea species in EU waters and in certain non-EU waters where catch limits are required.

### Article 2

#### Definitions

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

<sup>(1)</sup> OJ L 115, 9.5.1996, p. 3.

- (b) deductions and reallocations made pursuant to Article 37 of Council Regulation (EC) No 1224/2009 <sup>(1)</sup> or pursuant to Article 10(4) of Council Regulation (EC) No 1006/2008 <sup>(2)</sup>;
- (c) additional landings allowed pursuant to Article 3 of Regulation (EC) No 847/96;
- (d) quantities withheld pursuant to Article 4 of Regulation (EC) No 847/96;
- (e) deductions made pursuant to Articles 105, 106 and 107 of Regulation (EC) No 1224/2009.

2. Article 3 of Regulation (EC) No 847/96 shall apply to stocks subject to precautionary TAC whereas Article 3(2) and

(3) and Article 4 of that Regulation shall apply to stocks subject to analytical TAC, except where otherwise specified in the Annex to this Regulation.

#### Article 5

##### Conditions for landing catches and by-catches

Fish from stocks for which TACs are established shall be retained on board or landed only if the catches have been taken by vessels flying the flag of a Member State having a quota and that quota is not exhausted.

#### Article 6

##### Entry into force

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

It shall apply from 1 January 2013.

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

Done at Brussels, 20 December 2012.

*For the Council*  
*The President*  
S. ALETRARIS

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<sup>(1)</sup> Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy (OJ L 343, 22.12.2009, p. 1).

<sup>(2)</sup> 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 (OJ L 286, 29.10.2008, p. 33).

## ANNEX

The references to fishing zones are references to ICES zones, unless otherwise specified.

## PART 1

## Definition of species and species groups

1. In the list set out in Part 2 of this Annex, fish stocks are referred to following the alphabetical order of the Latin names of the species. However, deep-sea sharks are placed at the beginning of that list. For the purposes of this Regulation, the following comparative table of common names and Latin names is provided:

Common name	Alpha-3 code	Scientific name
Black scabbardfish	BSF	<i>Aphanopus carbo</i>
Alfonsinos	ALF	<i>Beryx</i> spp.
Roundnose grenadier	RNG	<i>Coryphaenoides rupestris</i>
Orange roughy	ORY	<i>Hoplostethus atlanticus</i>
Red seabream	SBR	<i>Pagellus bogaraveo</i>
Greater Forkbeard	GFB	<i>Phycis blennoides</i>

2. For the purposes of this Regulation, 'deep-sea sharks' means the following list of species:

Common name	Alpha-3 code	Scientific name
Deep-water catsharks	API	<i>Apristurus</i> spp.
Friilled shark	HXC	<i>Chlamydoselachus anguineus</i>
Gulper shark	GUP	<i>Centrophorus granulosus</i>
Leafscale gulper shark	GUQ	<i>Centrophorus squamosus</i>
Portuguese dogfish	CYO	<i>Centroscymnus coelolepis</i>
Longnose velvet dogfish	CYP	<i>Centroscymnus crepidater</i>
Black dogfish	CFB	<i>Centroscyllium fabricii</i>
Birdbeak dogfish	DCA	<i>Deania calcea</i>
Kitefin shark	SCK	<i>Dalatias licha</i>
Greater lanternshark	ETR	<i>Etmopterus princeps</i>
Velvet belly	ETX	<i>Etmopterus spinax</i>
Blackmouth catshark (Blackmouth dogfish)	SHO	<i>Galeus melastomus</i>
Mouse catshark	GAM	<i>Galeus murinus</i>
Bluntnose six-gill shark	SBL	<i>Hexanchus griseus</i>
Sailfin roughshark (Sharpback shark)	OXN	<i>Oxynotus paradoxus</i>
Knifetooth dogfish	SYR	<i>Scymnodon ringens</i>
Greenland shark	GSK	<i>Somniosus microcephalus</i>

## PART 2

## Annual fishing opportunities applicable for EU vessels in areas where TACs exist by species and by area (in tonnes live weight)

<b>Species:</b> Deep-sea sharks		<b>Zone:</b> EU and international waters of V, VI, VII, VIII and IX (DWS/56789-)	
Year	2013	2014	
Germany	0	0	
Estonia	0	0	
Ireland	0	0	
Spain	0	0	
France	0	0	
Lithuania	0	0	
Poland	0	0	
Portugal	0	0	
United Kingdom	0	0	
Union	0	0	
TAC	0	0	Analytical TAC Article 3 of Regulation (EC) No 847/96 shall not apply. Article 4 of Regulation (EC) No 847/96 shall not apply.

  

<b>Species:</b> Deep-sea sharks		<b>Zone:</b> EU and international waters of X (DWS/10-)	
Year	2013	2014	
Portugal	0	0	
Union	0	0	
TAC	0	0	Analytical TAC Article 3 of Regulation (EC) No 847/96 shall not apply. Article 4 of Regulation (EC) No 847/96 shall not apply.

  

<b>Species:</b> Deep-sea sharks, <i>Deania hystricosa</i> and <i>Deania profundorum</i>		<b>Zone:</b> International waters of XII (DWS/12INT-)	
Year	2013	2014	
Ireland	0	0	
Spain	0	0	
France	0	0	
United Kingdom	0	0	
Union	0	0	
TAC	0	0	Analytical TAC Article 3 of Regulation (EC) No 847/96 shall not apply. Article 4 of Regulation (EC) No 847/96 shall not apply.

<b>Species:</b> Black scabbardfish <i>Aphanopus carbo</i>			<b>Zone:</b> EU and international waters of I, II, III and IV (BSF/1234-)
Year	2013	2014	
Germany	3	3	
France	3	3	
United Kingdom	3	3	
Union	9	9	
TAC	9	9	Precautionary TAC

<b>Species:</b> Black scabbardfish <i>Aphanopus carbo</i>			<b>Zone:</b> EU and international waters of V, VI, VII and XII (BSF/56712-)
Year	2013	2014	
Germany	35	46	
Estonia	17	22	
Ireland	87	113	
Spain	174	226	
France	2 440	3 172	
Latvia	113	147	
Lithuania	1	1	
Poland	1	1	
United Kingdom	174	226	
Others <sup>(1)</sup>	9	12	
Union	3 051	3 966	
TAC	3 051	3 966	Analytical TAC

<sup>(1)</sup> Exclusively for by-catches. No directed fisheries are permitted under this quota.

<b>Species:</b> Black scabbardfish <i>Aphanopus carbo</i>			<b>Zone:</b> EU and international waters of VIII, IX and X (BSF/8910-)
Year	2013	2014	
Spain	12	12	
France	29	29	
Portugal	3 659	3 659	
Union	3 700	3 700	
TAC	3 700	3 700	Analytical TAC

<b>Species:</b> Black scabbardfish <i>Aphanopus carbo</i>			<b>Zone:</b> EU and international waters of CECAF 34.1.2. (BSF/C3412-)
Year	2013	2014	
Portugal	3 674	3 490	
Union	3 674	3 490	
TAC	3 674	3 490	Precautionary TAC
<b>Species:</b> Alfonsinos <i>Beryx spp.</i>			<b>Zone:</b> EU and international waters of III, IV, V, VI, VII, VIII, IX, X, XII and XIV (ALF/3X14-)
Year	2013	2014	
Ireland	10	9	
Spain	70	67	
France	19	18	
Portugal	203	193	
United Kingdom	10	9	
Union	312	296	
TAC	312	296	Analytical TAC
<b>Species:</b> Roundnose grenadier <i>Coryphaenoides rupestris</i>			<b>Zone:</b> EU and international waters of I, II and IV (RNG/124-)
Year	2013	2014	
Denmark	1	1	
Germany	1	1	
France	10	10	
United Kingdom	1	1	
Union	13	13	
TAC	13	13	Precautionary TAC
<b>Species:</b> Roundnose grenadier <i>Coryphaenoides rupestris</i>			<b>Zone:</b> EU and international waters of III (RNG/03-) (1)
Year	2013	2014	
Denmark	643	515	
Germany	4	3	
Sweden	33	26	
Union	680	544	
TAC	680	544	Precautionary TAC

(1) No directed fishery for roundnose grenadier shall be conducted in ICES zone IIIa pending consultations between the European Union and Norway.

<b>Species:</b> Roundnose grenadier <i>Coryphaenoides rupestris</i>		<b>Zone:</b> EU and international waters of Vb, VI, VII (RNG/5B67-)	
Year	2013 <sup>(1)</sup>	2014 <sup>(1)</sup>	
Germany	8	8	
Estonia	63	63	
Ireland	279	279	
Spain	70	70	
France	3 539	3 539	
Lithuania	81	81	
Poland	41	41	
United Kingdom	208	208	
Others <sup>(2)</sup>	8	8	
Union	4 297	4 297	
TAC	4 297	4 297	Analytical TAC

<sup>(1)</sup> A maximum of 10 % of each quota may be fished in EU and international waters of VIII, IX, X, XII and XIV (RNG/\*8X14-).

<sup>(2)</sup> Exclusively for by-catches. No directed fisheries are permitted under this quota.

<b>Species:</b> Roundnose grenadier <i>Coryphaenoides rupestris</i>		<b>Zone:</b> EU and international waters of VIII, IX, X, XII and XIV (RNG/8X14-)	
Year	2013 <sup>(1)</sup>	2014 <sup>(1)</sup>	
Germany	23	21	
Ireland	5	4	
Spain	2 573	2 317	
France	119	107	
Latvia	41	37	
Lithuania	5	4	
Poland	805	724	
United Kingdom	10	9	
Union	3 581	3 223	
TAC	3 581	3 223	Analytical TAC

<sup>(1)</sup> A maximum of 10 % of each quota may be fished in EU and international waters of Vb, VI, VII (RNG/\*5B67-).

<b>Species:</b> Orange roughy <i>Hoplostethus atlanticus</i>		<b>Zone:</b> EU and international waters of VI (ORY/06-)	
Year	2013	2014	
Ireland	0	0	
Spain	0	0	
France	0	0	
United Kingdom	0	0	
Union	0	0	
TAC	0	0	Analytical TAC Article 3 of Regulation (EC) No 847/96 shall not apply. Article 4 of Regulation (EC) No 847/96 shall not apply.
<b>Species:</b> Orange roughy <i>Hoplostethus atlanticus</i>		<b>Zone:</b> EU and international waters of VII (ORY/07-)	
Year	2013	2014	
Ireland	0	0	
Spain	0	0	
France	0	0	
United Kingdom	0	0	
Others	0	0	
Union	0	0	
TAC	0	0	Analytical TAC Article 3 of Regulation (EC) No 847/96 shall not apply. Article 4 of Regulation (EC) No 847/96 shall not apply.
<b>Species:</b> Orange roughy <i>Hoplostethus atlanticus</i>		<b>Zone:</b> EU and international waters of I, II, III, IV, V, VIII, IX, X, XII and XIV (ORY/1CX14)	
Year	2013	2014	
Ireland	0	0	
Spain	0	0	
France	0	0	
Portugal	0	0	
United Kingdom	0	0	
Union	0	0	
TAC	0	0	Analytical TAC Article 3 of Regulation (EC) No 847/96 shall not apply. Article 4 of Regulation (EC) No 847/96 shall not apply.



<b>Species:</b> Red seabream <i>Pagellus bogaraveo</i>		<b>Zone:</b> EU and international waters of VI, VII and VIII (SBR/678-)	
Year	2013	2014	
Ireland	6	5	
Spain	156	143	
France	8	7	
United Kingdom	20	18	
Others <sup>(1)</sup>	6	5	
Union	196	178	
TAC	196	178	Analytical TAC

<sup>(1)</sup> Exclusively for by-catches. No directed fisheries are permitted under this quota.

<b>Species:</b> Red seabream <i>Pagellus bogaraveo</i>		<b>Zone:</b> EU and international waters of IX (SBR/09-)	
Year	2013 <sup>(1)</sup>	2014 <sup>(1)</sup>	
Spain	614	614	
Portugal	166	166	
Union	780	780	
TAC	780	780	Analytical TAC

<sup>(1)</sup> A maximum of 8 % of each quota may be fished in EU and international waters of VI, VII and VIII (SBR/\*678-).

<b>Species:</b> Red seabream <i>Pagellus bogaraveo</i>		<b>Zone:</b> EU and international waters of X (SBR/10-)	
Year	2013	2014	
Spain	9	8	
Portugal	1 004	904	
United Kingdom	9	8	
Union	1 022	920	
TAC	1 022	920	Analytical TAC

<b>Species:</b> Greater Forkbeard <i>Phycis blennoides</i>		<b>Zone:</b> EU and international waters of I, II, III and IV (GFB/1234-)	
Year	2013	2014	
Germany	9	9	
France	9	9	
United Kingdom	13	13	
Union	31	31	
TAC	31	31	Analytical TAC

<b>Species:</b> Greater Forkbeard <i>Phycis blennoides</i>		<b>Zone:</b> EU and international waters of V, VI and VII (GFB/567-)	
Year	2013 <sup>(1)</sup>	2014 <sup>(1)</sup>	
Germany	10	10	
Ireland	260	260	
Spain	588	588	
France	356	356	
United Kingdom	814	814	
Union	2 028	2 028	
TAC	2 028	2 028	Analytical TAC

<sup>(1)</sup> A maximum of 8 % of each quota may be fished in EU and international waters of VIII and IX (GFB/\*89-).

<b>Species:</b> Greater Forkbeard <i>Phycis blennoides</i>		<b>Zone:</b> EU and international waters of VIII and IX (GFB/89-)	
Year	2013 <sup>(1)</sup>	2014 <sup>(1)</sup>	
Spain	242	242	
France	15	15	
Portugal	10	10	
Union	267	267	
TAC	267	267	Analytical TAC

<sup>(1)</sup> A maximum of 8 % of each quota may be fished in EU and international waters of V, VI, VII (GFB/\*567-).

<b>Species:</b> Greater Forkbeard <i>Phycis blennoides</i>		<b>Zone:</b> EU and international waters of X and XII (GFB/1012-)	
Year	2013	2014	
France	9	9	
Portugal	36	36	
United Kingdom	9	9	
Union	54	54	
TAC	54	54	Analytical TAC

**COUNCIL REGULATION (EU) No 1263/2012****of 21 December 2012****amending Regulation (EU) No 267/2012 concerning restrictive measures against Iran**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215 thereof,

Having regard to Council Decision 2010/413/CFSP of 26 July 2010 concerning restrictive measures against Iran <sup>(1)</sup>,

Having regard to the joint proposals from the High Representative of the Union for Foreign Affairs and Security Policy and the European Commission,

Whereas:

- (1) Regulation (EU) No 267/2012 <sup>(2)</sup> gives effect to the measures provided for in Decision 2010/413/CFSP. On 15 October 2012, the Council adopted Decision 2012/635/CFSP <sup>(3)</sup> which amends Decision 2010/413/CFSP and provides for additional restrictive measures against Iran.
- (2) Those additional restrictive measures comprise, in particular, an export prohibition on key naval equipment and technology for ship-building, maintenance or refit. Moreover, trade in graphite, raw or semi-finished metals, such as aluminium and steel, and software for certain industrial processes should be prohibited.
- (3) The additional restrictive measures also include a ban on the import, purchase or transport of Iranian natural gas. Effective implementation of this prohibition requires that measures be taken to prohibit swaps of natural gas that are known to increase the export of natural gas from Iran in circumvention of the prohibition, or there is reasonable cause to suspect this. The contracts satisfied by use of a pipeline directly connected to the natural gas transmission grid of the Union without any inlet point intended to facilitate the purchase or increase export of natural gas originating in Iran should not be affected by the prohibition on natural gas imports.
- (4) Decision 2012/635/CFSP called for the review of restrictive measures concerning dual-use goods and technology set out in Annex I to Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items <sup>(4)</sup>, with a view to

including certain items in Part 2 of category 5 thereof which might be relevant to industries controlled directly or indirectly by the Islamic Revolutionary Guard Corps or which might be relevant to Iran's nuclear, military or ballistic missile programme while taking into account the need to avoid unintended effects on the civilian population in Iran.

- (5) In order to ensure the effective implementation of the prohibition on the sale, supply, transfer or export to Iran of additional key equipment or technology which could be used in the key sectors of the oil, natural gas and petrochemical industries, an additional list of such key equipment and technology should be provided.
- (6) For the same reason, lists of items subject to trade restrictions on natural gas, graphite, raw or semi-finished metals, such as aluminium and steel, and software for certain industrial processes should also be provided.
- (7) Decision 2012/635/CFSP also prohibits transactions between Union and Iranian banks and financial institutions, unless authorised in advance by the relevant Member State.
- (8) Furthermore, Decision 2012/635/CFSP provides for prohibitions on the provision of flagging and classification services to Iranian oil tankers and cargo vessels as well as regarding the supply of vessels designed for the transport or storage of oil and petrochemical products to Iranian persons and entities or to other persons and entities for the purpose of transporting or storing Iranian oil and petrochemical products.
- (9) In order to protect the environment and the health and safety of workers, it is necessary to provide that the competent authorities of Member States may take all action they deem necessary to ensure that legal obligations concerning the health and safety of workers and environment protection are respected. In cases of urgency, a Member State should be allowed to take such action without prior notification provided that it notifies the other Member States and the Commission as soon as possible afterwards.
- (10) Where a Member State had granted a license to engage in the activities of exploitation of hydrocarbons to a designated person, entity or body before that person, entity or body was designated, the competent authority of that Member State may authorise derogation from certain prohibitions provided for in Regulation (EU) No 267/2012 where such derogation is needed to avoid or remediate environmental damage or permanent destruction of the license's value.

<sup>(1)</sup> OJ L 195, 27.7.2010, p. 39.

<sup>(2)</sup> OJ L 88, 24.3.2012, p. 1.

<sup>(3)</sup> OJ L 282, 16.10.2012, p. 58.

<sup>(4)</sup> OJ L 134, 29.5.2009, p. 1.

- (11) These measures fall within the scope of the Treaty and regulatory action at the level of the Union is therefore necessary in order to implement them, in particular with a view to ensuring their uniform application by economic operators in all Member States.
- (12) Regulation (EU) No 267/2012 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Regulation (EU) No 267/2012 is amended as follows:

- (1) Article 2, is amended as follows:

- (a) paragraph 2 is replaced by the following:

"2. Annex I shall include goods and technology, including software, which are dual-use items or technology as defined in Regulation (EC) No 428/2009, except for certain goods and technology as specified in part A of Annex I to this Regulation.";

- (b) the following paragraph is inserted:

"2a. The Member State concerned shall inform the other Member States and the Commission, within four weeks, of authorisations granted in accordance with Regulation (EC) No 428/2009, in respect of the goods and technology as specified in part A of Annex I to this Regulation.".

- (2) In Article 6, the following points are added:

"(d) the execution, until 15 April 2013, of contracts concluded before 22 December 2012 for the sale, supply, transfer or export of goods and technology as specified in Part C of Annex I to this Regulation or ancillary contracts necessary for the execution of such contracts.

(e) the execution, until 15 April 2013, of contracts concluded before 22 December 2012 for the provision of technical assistance or financing or financial assistance related to goods and technology as specified in Part C of Annex I to this Regulation."

With regard to point (d), the Member State concerned shall inform the other Member States and the Commission, within four weeks, of authorisations granted in accordance with Regulation (EC) No 428/2009.

- (3) Article 8 is replaced by the following:

*"Article 8*

1. It shall be prohibited to sell, supply, transfer or export key equipment or technology listed in Annexes VI and VIA, directly or indirectly, to any Iranian person, entity or body, or for use in Iran.

2. Annexes VI and VIA shall include key equipment and technology for the following key sectors of the oil and gas industry in Iran:

- (a) exploration of crude oil and natural gas;
- (b) production of crude oil and natural gas;
- (c) refining;
- (d) liquefaction of natural gas.

3. Annexes VI and VIA shall also include key equipment and technology for the petrochemical industry in Iran.

4. Annexes VI and VIA shall not include items included in the Common Military List, or in Annex I, II or III."

- (4) Article 9 is replaced by the following:

*"Article 9*

It shall be prohibited:

- (a) to provide, directly or indirectly, technical assistance or brokering services related to the key equipment and technology listed in Annexes VI and VIA, or related to the provision, manufacture, maintenance and use of goods listed in Annexes VI and VIA, to any Iranian person, entity or body, or for use in Iran;
- (b) to provide, directly or indirectly, financing or financial assistance related to the key equipment and technology listed in Annexes VI and VIA, to any Iranian person, entity or body, or for use in Iran."

- (5) Article 10 is replaced by the following:

*"Article 10*

1. The prohibitions in Articles 8 and 9 shall not apply to:

- (a) the execution, until 15 April 2013, of transactions required by a trade contract concerning key equipment or technology in the exploration of crude oil and natural gas, production of crude oil and natural gas, refining, liquefaction of natural gas as listed in Annex VI concluded before 27 October 2010, or ancillary contracts necessary for the execution of such contracts, or by a contract or agreement concluded before 26 July 2010 and relating to an investment in Iran made before 26 July 2010, nor shall they prevent the execution of an obligation arising therefrom;
- (b) the execution, until 15 April 2013, of transactions required by a trade contract concerning key equipment or technology for the petrochemical industry as listed in Annex VI concluded before 24 March 2012, or of ancillary contracts necessary for the execution of such contracts, or by a contract or agreement concluded before 23 January 2012 and relating to an investment in Iran made before 23 January 2012, nor shall they prevent the execution of an obligation arising therefrom;

(c) the execution, until 15 April 2013, of transactions required by a trade contract concerning key equipment or technology in the exploration of crude oil and natural gas, production of crude oil and natural gas, refining, liquefaction of natural gas and for the petrochemical industry as listed in Annex VIA concluded before 16 October 2012 and relating to an investment in Iran in the exploration of crude oil and natural gas, production of crude oil and natural gas, and the refining, liquefaction of natural gas made before 26 July 2010, or relating to an investment in Iran in the petrochemical industry made before 23 January 2012, nor shall they prevent the execution of an obligation arising therefrom; or

(d) the provision of technical assistance intended solely for the installation of equipment or technology delivered in accordance with points (a), (b) and (c),

provided that the natural or legal person, entity or body seeking to engage in such transactions, or to provide assistance to such transactions, has notified, at least 20 working days in advance, the transaction or assistance to the competent authority of the Member State in which it is established.

2. Prohibitions in Articles 8 and 9 shall be without prejudice to the execution of obligations arising from contracts referred to in Article 12(1)(b) and 14(1)(b) provided that those obligations arise from service contracts or ancillary contracts necessary for their execution and provided that the execution of those obligations has been authorised in advance by the competent authority concerned and the Member State concerned has informed the other Member States and the Commission of its intention to grant an authorisation."

(6) The following Articles are inserted:

*"Article 10a*

1. It shall be prohibited to sell, supply, transfer or export key naval equipment or technology listed in Annex VIB, directly or indirectly, to any Iranian person, entity or body, or for use in Iran.

2. Annex VIB shall include key naval equipment or technology for ship building, maintenance or refit, including equipment or technology used in the construction of oil tankers.

*Article 10b*

1. It shall be prohibited:

(a) to provide, directly or indirectly, technical assistance or brokering services related to the key equipment and technology listed in Annex VIB, or related to the provision, manufacture, maintenance and use of

goods listed in Annex VIB, to any Iranian person, entity or body, or for use in Iran;

(b) to provide, directly or indirectly, financing or financial assistance related to the key equipment and technology listed in Annex VIB, to any Iranian person, entity or body, or for use in Iran.

*Article 10c*

1. The prohibitions in Articles 10a and 10b shall be without prejudice to the supply of key naval equipment and technology to a vessel which is not owned or controlled by an Iranian person, entity or body and which has been forced into a port in Iran, or into Iranian territorial waters, under force majeure.

2. The prohibitions in Articles 10a and 10b shall not apply to the execution, until 15 February 2013, of contracts concluded before 22 December 2012 or ancillary contracts necessary for the execution of such contracts.

*Article 10d*

1. It shall be prohibited to sell, supply, transfer or export software as listed in Annex VIIA, directly or indirectly, to any Iranian person, entity or body, or for use in Iran.

2. Annex VIIA shall include software for integrating industrial processes which is relevant to industries controlled directly or indirectly by the Islamic Revolutionary Guard Corps or which is relevant to Iran's nuclear, military or ballistic missile programme.

*Article 10e*

1. It shall be prohibited:

(a) to provide, directly or indirectly, technical assistance or brokering services related to the software listed in Annex VIIA, or related to the provision, manufacture, maintenance and use of goods listed in Annex VIIA, to any Iranian person, entity or body, or for use in Iran;

(b) to provide, directly or indirectly, financing or financial assistance related to the software listed in Annex VIIA, to any Iranian person, entity or body, or for use in Iran.

*Article 10f*

1. The prohibitions in Articles 10d and 10e shall not apply to the execution, until 15 January 2013, of contracts concluded before 22 December 2012 or ancillary contracts necessary for the execution of such contracts."

(7) Article 12(1) is replaced by the following:

"1. The prohibitions in Article 11 shall not apply to:

- (a) the execution until 1 July 2012, of trade contracts concluded before 23 January 2012, or of ancillary contracts necessary for the execution of such contracts;
- (b) the execution of contracts concluded before 23 January 2012, or of ancillary contracts, necessary for the execution of such contracts, where such a contract specifically provides that the supply of Iranian crude oil and petroleum products or the proceeds derived from their supply are for the reimbursement of outstanding amounts to persons, entities or bodies under the jurisdiction of Member States;
- (c) crude oil or petroleum products, which had been exported from Iran prior to 23 January 2012, or where the export was made pursuant to point (a) on or prior to 1 July 2012; or where the export was made pursuant to point (b);
- (d) the purchase of bunker oil produced and supplied by a third country other than Iran, intended for the propulsion of the engines of vessels;
- (e) the purchase of bunker oil for the propulsion of the engines of a vessel which has been forced into a port in Iran, or into Iranian territorial waters, under force majeure,

provided that the person, entity or body seeking to perform the contract referred to in points (a), (b) and (c) has notified, at least 20 working days in advance, the activity or transaction to the competent authority of the Member State in which it is established."

- (8) In Article 14(1), point (c) is replaced by the following:

"(c) petrochemical products which had been exported from Iran prior to 23 January 2012, or where the export was made pursuant to point (a) on or prior to 1 May 2012, or where the export was made pursuant to point (b)."

- (9) The following Article is inserted:

*"Article 14a*

1. It shall be prohibited:

- (a) to purchase, transport, or import into the Union natural gas which originates in Iran or has been exported from Iran;
- (b) to swap natural gas which originates in Iran or has been exported from Iran;
- (c) to provide, directly or indirectly, brokering services, financing or financial assistance, including financial derivatives, as well as insurance and re-insurance and brokering services relating to insurance and re-insurance, in respect of the activities in points (a) or (b).

2. The prohibitions in paragraph 1 shall not apply to:

- (a) natural gas that has been exported from a State other than Iran when the exported gas has been combined

with gas originating from Iran within the infrastructure of a State other than Iran;

- (b) the purchase of natural gas within Iran by nationals of Member States for civilian purposes, including residential heating or power, or for the maintenance of diplomatic missions; or
- (c) the execution of contracts for the delivery of natural gas originating in a State other than Iran into the Union.

3. "Natural gas" means the products listed in Annex IVA.

4. For the purpose of paragraph 1, "to swap" means to exchange natural gas streams of different origins."

- (10) The following Articles are inserted:

*"Article 15a*

1. It shall be prohibited to sell, supply, transfer or export graphite and raw or semi-finished metals as listed in Annex VIIB, directly or indirectly, to any Iranian person, entity or body, or for use in Iran.

2. Annex VIIB shall include graphite and raw or semi-finished metals, such as aluminium and steel, which are relevant to industries controlled directly or indirectly by the Islamic Revolutionary Guard Corps or which are relevant to Iran's nuclear, military or ballistic missile programme.

3. The prohibition in paragraph 1 shall not apply to the goods listed in Annexes I, II and III.

*Article 15b*

1. It shall be prohibited:

- (a) to provide, directly or indirectly, technical assistance or brokering services related to the goods as listed in Annex VIIB, or related to the provision, manufacture, maintenance and use of goods listed in Annex VIIB, to any Iranian person, entity or body, or for use in Iran;
- (b) to provide, directly or indirectly, financing or financial assistance related to the goods listed Annex VIIB, to any Iranian person, entity or body, or for use in Iran.

2. The prohibitions in paragraph 1 shall not apply in relation to the goods listed in Annexes I, II and III.

*Article 15c*

The prohibitions in Article 15a shall not apply to the execution, until 15 April 2013, of contracts concluded before 22 December 2012 or ancillary contracts necessary for the execution of such contracts."

- (11) Article 23 is amended as follows:

- (a) in paragraph 2, points (c) and (d) are replaced by the following:

"(c) being a member of the Islamic Revolutionary Guard Corps or a legal person, entity or body owned or controlled by the Islamic Revolutionary Guard Corps or by one or more of its members, or natural or legal persons acting on their behalf or providing insurance or other essential services to them;

(d) being other persons, entities or bodies that provide support, such as material, logistical or financial support, to the Government of Iran and entities owned or controlled by them, or persons and entities associated with them;"

(b) paragraph 4 is replaced by the following:

"4. Without prejudice to the derogations provided for in Article 24, 25, 26, 27, 28, 28a or 29, it shall be prohibited to supply specialised financial messaging services, which are used to exchange financial data to the natural or legal persons, entities or bodies listed in Annexes VIII and IX."

(12) In Article 25, point (a)(ii) is replaced by the following:

"(ii) the payment will not contribute to an activity prohibited under this Regulation. If the payment serves as consideration for a trade activity that has already been performed and the competent authority of another Member State had given prior confirmation that the activity was not prohibited at the time it was performed, it shall be deemed, *prima facie*, that the payment will not contribute to a prohibited activity; and".

(13) In Article 26(1), point (a) is replaced by the following:

"(a) the competent authority concerned has determined that the funds or economic resources are:

(i) necessary to satisfy the basic needs of persons listed in Annex VIII or IX and their dependent family members, including payments for food-stuffs, rent or mortgage, medicines and medical treatment, taxes, insurance premiums, and public utility charges;

(ii) intended exclusively for payment of reasonable professional fees and reimbursement of incurred expenses associated with the provision of legal services;

(iii) intended exclusively for payment of fees or service charges for routine holding or maintenance of frozen funds or economic resources; or

(iv) intended exclusively for the payment of fees due in connection with the de-flagging of vessels; and".

(14) Article 28 is replaced by the following:

"Article 28

By way of derogation from Article 23(2), the competent authorities may also authorise, under such conditions as they deem appropriate:

(a) the release of certain frozen funds or economic resources of the Central Bank of Iran, after having determined that the funds or economic resources are necessary for the purpose of providing credit or financial institutions with liquidity for the financing of trade, or the servicing of trade loans; or

(b) the release of certain frozen funds or economic resources held by the Central Bank of Iran, after having determined that the funds or economic resources are necessary for the reimbursement of a claim due under a contract or agreement concluded by an Iranian person, entity or body before 16 October 2012 where such a contract or agreement provides for the reimbursement of outstanding amounts to persons, entities or bodies under the jurisdiction of Member States;

provided that the Member State concerned has notified the other Member States and the Commission of its intention to grant an authorisation at least ten working days prior to the authorisation."

(15) Article 30 is replaced by the following Articles:

"Article 30

1. It shall be prohibited to transfer funds between, on the one hand, financial and credit institutions falling within the scope of this Regulation as defined in Article 49, and, on the other hand:

(a) credit and financial institutions and bureaux de change domiciled in Iran;

(b) branches and subsidiaries, where they fall within the scope of this Regulation, of credit and financial institutions and bureaux de change domiciled in Iran;

(c) branches and subsidiaries, where they do not fall within the scope of this Regulation, of credit and financial institutions and bureaux de change domiciled in Iran; and

(d) credit and financial institutions and bureaux de change that are not domiciled in Iran but are controlled by persons, entities or bodies domiciled in Iran,

unless such transfers fall within the scope of paragraph 2 and have been processed in accordance with paragraph 3.

2. The following transfers may be authorised in accordance with paragraph 3:



- (a) transfers regarding foodstuffs, healthcare, medical equipment, or for agricultural or humanitarian purposes;
- (b) transfers regarding personal remittances;
- (c) transfers in connection with a specific trade contract provided that such transfer is not prohibited under this Regulation;
- (d) transfers regarding diplomatic missions or consular posts or international organisations enjoying immunities in accordance with international law, insofar as such transfers are intended to be used for official purposes of the diplomatic missions or consular posts or organisations enjoying immunities in accordance with international law;
- (e) transfers regarding payment to satisfy claims by or against an Iranian person, entity or body, or transfers of similar nature provided that they do not contribute to the activities prohibited under this Regulation, on a case-by-case basis, if the Member State concerned has notified the other Member States and the Commission at least ten days in advance of its intention to grant an authorisation;
- (f) transfers necessary for the execution of the obligations arising from contracts referred to in Article 12(1)(b).

3. Transfers of funds which may be authorised under paragraph 2 shall be processed as follows:

- (a) transfers due on transactions regarding foodstuffs, healthcare, medical equipment, or for agricultural or humanitarian purposes, below EUR 100 000 or equivalent, and transfers due on transactions regarding personal remittances, below EUR 40 000 or equivalent, shall be carried out without any prior authorisation.

The transfer shall be notified in advance in writing to the competent authority of the Member State concerned if equal to or above EUR 10 000 or equivalent;

- (b) transfers due on transactions regarding foodstuffs, healthcare, medical equipment, or for agricultural or humanitarian purposes, equal to or above EUR 100 000 or equivalent, and transfers due on transactions regarding personal remittances, equal to or above EUR 40 000 or equivalent, shall require prior authorisation of the competent authority of the Member State concerned pursuant to paragraph 2.

Member States shall inform each other of any authorisation granted at three-monthly intervals;

- (c) any other transfer equal to or above EUR 10 000 or equivalent shall require prior authorisation of the competent authority of the Member State concerned pursuant to paragraph 2.

Member States shall inform each other of any authorisation granted at three-monthly intervals.

4. Transfers of funds below EUR 10 000 or equivalent shall not require any prior authorisation or notification.

5. Notifications and requests for authorisations relating to the transfer of funds to an entity falling within the scope of paragraph 1(a) to (d) shall be addressed by or on behalf of the payment service provider of the payer to the competent authorities of the Member States where the payment service provider is established.

Notifications and requests for authorisations relating to the transfer of funds from an entity falling within the scope of paragraph 1(a) to (d) shall be addressed by or on behalf of the payment service provider of the payee to the competent authorities of the Member States where the payment service provider is established.

If the payment service provider of the payer or of the payee does not fall under the scope of this Regulation, notifications and requests for authorisation shall be addressed, in the case of a transfer to an entity falling within the scope of paragraph 1(a) to (d), by the payer, and in the case of a transfer from an entity falling within the scope of paragraph 1(a) to (d), by the payee, to the competent authorities of the Member State in which, respectively, the payer or payee is resident.

6. Credit and financial institutions falling within the scope of this Regulation shall, in their activities with entities referred to in paragraph 1(a) to (d) and in order to prevent infringements of the provisions of this Regulation, conduct enhanced vigilance as follows:

- (a) exercise continuous vigilance over account activity, particularly through their programmes on customer due diligence;
- (b) require that in payment instructions all information fields which relate to the originator and beneficiary of the transaction in question be completed and if that information is not supplied, refuse the transaction;
- (c) maintain all records of transactions for a period of five years and make them available to national authorities on request;
- (d) if they have reasonable grounds to suspect that activities with credit and financial institutions may be in breach of the provisions of this Regulation, report without delay their suspicions to the financial intelligence unit (FIU) or to another competent authority designated by the Member State concerned, without prejudice to Articles 5 and 23. The FIU or such other competent authority will serve as a national centre for receiving and analysing suspicious transaction reports regarding potential breaches of this

Regulation. The FIU or such other competent authority shall have access, directly or indirectly, on a timely basis to the financial, administrative and law enforcement information that it requires to properly undertake this function, including the analysis of suspicious transaction reports.

#### Article 30a

1. Transfers of funds to and from an Iranian person, entity or body which do not fall within the scope of Article 30(1) shall be processed as follows:

- (a) transfers due on transactions regarding foodstuffs, healthcare, medical equipment, or for agricultural or humanitarian purposes shall be carried out without any prior authorisation.

The transfer shall be notified in advance in writing to the competent authority of the Member State concerned if equal to or above EUR 10 000 or equivalent;

- (b) any other transfer below EUR 40 000 or equivalent shall be carried out without any prior authorisation.

The transfer shall be notified in advance in writing to the competent authority of the Member State concerned if equal to or above EUR 10 000 or equivalent;

- (c) any other transfer equal to or above EUR 40 000 or equivalent shall require a prior authorisation of the competent authority of the Member State concerned.

Member States shall inform each other of any authorisation rejected at three-monthly intervals.

2. Transfers of funds below EUR 10 000 or equivalent shall not require any prior authorisation or notification.

3. Notifications and requests for authorisation relating to the transfer of funds shall be processed as follows:

- (a) in the case of electronic transfers of funds processed by credit or financial institutions:

- (i) notifications and requests for authorisation relating to the transfer of funds to an Iranian person, entity or body which is located outside the Union, shall be addressed by or on behalf of the payment service provider of the payer to the competent authorities of the Member State in which the payment service provider is established;

- (ii) notifications and requests for authorisation relating to the transfer of funds from an Iranian person, entity or body which is located outside the Union, shall be addressed by or on

behalf of the payment service provider of the payee to the competent authorities of the Member State in which the payment service provider is established;

- (iii) if, in cases (i) and (ii), the payment service provider of the payer or of the payee does not fall under the scope of this Regulation, notifications and requests for authorisation shall be addressed, in the case of a transfer to an Iranian person, entity or body, by the payer, and in the case of a transfer from an Iranian person, entity or body by the payee to the competent authorities of the Member State in which, respectively, the payer or payee is resident;

- (iv) notifications and requests for authorisation relating to the transfer of funds to an Iranian person, entity or body which is located within the Union, shall be addressed by or on behalf of the payment service provider of the payee to the competent authorities of the Member States in which the payment service provider is established;

- (v) notifications and requests for authorisation relating to the transfer of funds from an Iranian person, entity or body which is located within the Union, shall be addressed by or on behalf of the payment service provider of the payer to the competent authorities of the Member States in which the payment service provider is established;

- (vi) if, in cases (iv) and (v), the payment service provider of the payer or of the payee does not fall under the scope of this Regulation, notifications and requests for authorisation shall be addressed, in the case of a transfer to an Iranian person, entity or body, by the payer, and in the case of a transfer from an Iranian person, entity or body by the payee to the competent authorities of the Member State in which, respectively, the payee or payer is resident;

- (vii) in relation to a transfer of funds to or from an Iranian person, entity or body where neither the payer nor the payee, nor their respective payment service providers, fall under the scope of this Regulation but a payment service provider which does fall under the scope of this Regulation acts as an intermediary, then that payment service provider must comply with the obligation to notify or seek authorisation, as applicable, if it knows or has reasonable cause to suspect that the transfer is to or from an Iranian person, entity or body. Where there is more than one payment service provider acting

as an intermediary, only the first payment service provider to process the transfer is required to comply with the obligation to notify or seek authorisation, as applicable. Any notification or request for authorisation must be addressed to the competent authorities of the Member State in which the payment service provider is established;

(viii) where there is more than one payment service provider involved in a series of linked transfers of funds, transfers within the Union shall include a reference to the authorisation granted under this Article;

(b) in the case of transfers of funds which are made by non-electronic means, notifications and requests for authorisation relating to the transfer of funds shall be processed as follows:

(i) notifications and requests for authorisation relating to transfers to an Iranian person, entity or body shall be addressed by the payer to the competent authorities of the Member State where the payer is resident;

(ii) notifications and requests for authorisation relating to the transfers from an Iranian person, entity or body shall be addressed by the payee to the competent authorities of the Member State in which the payee is resident.

#### Article 30b

1. Where an authorisation has been granted in accordance with Articles 24, 25, 26, 27, 28 or 28a, Articles 30 and 30a shall not apply.

The requirement for prior authorisation of transfers of funds as provided for in Articles 30(3)(b) and (c), shall be without prejudice to the execution of transfers of funds notified to or authorised by the competent authority in advance before 22 December 2012. Such transfers of funds shall be executed before 15 April 2013.

Articles 30 and 30a shall not apply with regard to transfers of funds provided for in Article 29.

2. Articles 30(3) and 30a(1) shall apply regardless of whether the transfer of funds is executed in a single operation or in several operations which appear to be linked. For the purpose of this Regulation, "operations which appear to be linked" includes:

(a) a series of consecutive transfers from or to the same financial or credit institutions within the scope of Article 30(1)(a) to (d) or from or to the same Iranian person, entity or body which are made in connection with a single obligation to a transfer of funds, where each individual transfer falls below the relevant threshold set out in Articles 30 and 30a but which, in the aggregate, meet the criteria for notification or authorisation; or

(b) a chain of transfers involving different payment service providers or natural or legal persons which effects a single obligation to make a transfer of funds.

3. For the purposes of Article 30(3)(b) and 30(3)(c) and Article 30a(1)(c), the competent authorities shall grant the authorisation, under such terms and conditions as they deem appropriate, unless they have reasonable grounds to determine that the transfer of funds for which the authorisation is requested could be in breach of any of the prohibitions or obligations in this Regulation.

A competent authority may charge a fee for the assessment of requests for authorisation.

4. For the purposes of Article 30a(1)(c), an authorisation shall be deemed granted if a competent authority has received a request in writing for authorisation and, within four weeks, the competent authority has not objected in writing to the transfer of funds. If the objection is raised because an investigation is pending, the competent authority shall state this and communicate its decision without delay. The competent authorities shall have access, directly or indirectly, on a timely basis to the financial, administrative and law enforcement related information necessary for carrying out the investigation.

5. The following persons, entities or bodies do not fall within the scope of Articles 30 and 30a:

(a) persons, entities or bodies who merely convert paper documents into electronic data and are acting under a contract with a credit institution or a financial institution;

(b) persons, entities or bodies who provide credit or financial institutions solely with a message or other support system for transmitting funds; or

(c) persons, entities or bodies who provide credit or financial institutions solely with clearing and settlement systems."

(16) Article 31 is replaced by the following:

#### "Article 31

1. Branches and subsidiaries, falling within the scope of this Regulation as defined in Article 49, of credit and financial institutions domiciled in Iran shall notify the competent authority of the Member State where they are established of all transfers of funds carried out or received by them, the names of the parties and the amount and the date of the transaction, within five working days after carrying out or receiving the transfer of funds concerned. If the information is available, the notification must specify the nature of the transaction and, where appropriate, the nature of the goods covered by the transaction and must, in particular, state whether the goods are covered by Annex I, II, III, IV, IVA, V, VI, VIA, VIB, VII, VIIA or VIIB of this Regulation and, if their export is subject to authorisation, indicate the number of the licence granted.

2. Subject to and in accordance with the information-sharing arrangements, the notified competent authorities shall without delay transmit the information on notifications referred to in paragraph 1, as necessary, in order to prevent any transaction that could contribute to proliferation-sensitive nuclear activities or to the development of nuclear weapons delivery systems, to the competent authorities of other Member States where the counterparts to such transactions are established."

(17) Article 32 is deleted.

(18) In Articles 33 and 34, references to Article 32(2) are replaced by references to Article 30(1).

(19) The following Articles are inserted:

*"Article 37a*

1. The provision of the following services in respect of oil tankers and cargo vessels flying the flag of the Islamic Republic of Iran or owned, chartered, or operated, directly or indirectly, by an Iranian person, entity or body shall be prohibited:

(a) the provision of classification services of any kind, including but not limited to:

(i) the production and application of classification rules or technical specifications concerning the design, construction, equipment and maintenance of ships, as well as shipboard management systems;

(ii) the carrying out of surveys and inspections in accordance with classification rules and procedures;

(iii) the assignment of a class notation and the delivery, endorsement or renewal of certificates of compliance with classification rules or specifications;

(b) the supervision of and participation in the design, construction and repair of ships and their parts including blocks, elements, machinery, electrical installations and control installation, as well as related technical assistance, financing or financial assistance;

(c) the inspection, testing and certification of marine equipment, materials and components as well as the supervision of the installation on board and the supervision of system integration;

(d) the carrying out of surveys, inspections, audits and visits and the issuance, renewal or endorsement of the relevant certificates and documents of compliance, on behalf of the flag State administration, in accordance with the International Convention for the Safety of Life at Sea, 1974, as amended (SOLAS 1974) and its 1988 Protocol; the International Convention for the Prevention of Pollution from Ships, 1973, as

modified by the Protocol of 1978 relating thereto, as amended (MARPOL 73/78); the Convention on the International Regulations for Preventing Collisions at Sea, 1972, as amended (COLREG 1972); the International Convention on Load Lines, 1966 (LL 1966) and its 1988 Protocol; the International Convention on Standards of Training, Certification and Watch-keeping for Seafarers, 1978, as amended (STCW); and the International Convention on Tonnage Measurement of Ships, 1969 (TONNAGE 1969).

2. The prohibition in paragraph 1 shall apply from 15 January 2013.

*Article 37b*

1. It shall be prohibited to make available vessels designed for the transport or storage of oil and petrochemical products:

(i) to any Iranian person, entity or body; or

(ii) to any other person, entity or body, unless the providers of vessels have taken appropriate action to prevent the vessel from being used to carry or store oil or petrochemical products that originate in Iran or have been exported from Iran.

2. The prohibition in paragraph 1 shall be without prejudice to the execution of obligations arising from contracts and ancillary contracts referred to in Article 12(1)(b) and (c) and in Article 14(1)(b) and (c), provided that the import and transport of Iranian crude oil, petroleum or petrochemical products have been notified to the competent authority pursuant to Article 12(1) or 14(1)."

(20) Article 41 is replaced by the following:

*"Article 41*

It shall be prohibited to participate, knowingly and intentionally, in activities the object or effect of which is to circumvent the measures in Article 2, 5(1), 8, 9, 10a, 10b, 10d, 10e, 11, 13, 14a, 15a, 15b, 17, 22, 23, 30, 30a, 34, 35, 37a or 37b."

(21) In Article 43, paragraph 3 is replaced by the following:

"3. The Member State concerned shall notify the other Member States and the Commission of the determination referred to in paragraph 1 and its intention to grant an authorisation at least ten working days prior to the authorisation. In case of threat to the environment and/or to the health and safety of workers in the Union requiring urgent action, the Member State concerned may grant an authorisation without prior notification and shall notify the other Member States and the Commission within three working days after having granted the authorisation."

(22) The following Article is inserted:

"Article 43a

1. By way of derogation from Articles 8, 9, Article 17(1) as regards an Iranian person, entity or body referred to in Article 17(2)(b), Articles 23(2) and (3) insofar as they refer to persons, entities and bodies listed in Annex IX, Article 30 and 35, the competent authorities of a Member State may authorise, under such conditions as they deem appropriate, activities related to the exploration for, or exploitation of, hydrocarbons within the Union undertaken pursuant to a licence for such exploration or exploitation issued by a Member State to a person, entity or body listed in Annex IX, if the following conditions are met:

- (a) the licence for the exploration for, or exploitation of, hydrocarbons within the Union was issued prior to the date on which the person, entity or body listed in Annex IX was designated; and
- (b) the authorisation is necessary to avoid or remediate environmental damage in the Union or to prevent permanent destruction of the licence's value, including by securing the pipeline and infrastructure used in connection with the licensed activity, on a temporary basis. Such authorisation may include measures taken under national legislation.

2. The derogation provided for in paragraph 1 shall only be granted for such period as necessary and its validity shall not exceed the validity of the licence issued to the person, entity or body listed in Annex IX. In case the competent authority considers that subrogation to contracts or the provision of indemnities is necessary, the period of validity of the derogation shall not exceed five years.

3. The Member State concerned shall notify the other Member States and the Commission of its intention to grant an authorisation at least ten working days prior to

the authorisation. In case of threat to the environment in the Union requiring urgent action to prevent damage to the environment, the Member State concerned may grant an authorisation without prior notification and shall notify the other Member States and the Commission within three working days after having granted the authorisation."

(23) A reference to Article 43a is added in the Title of Annex X.

(24) In Article 45, point (b) is replaced by the following:

"(b) amend Annexes III, IV, IVA, V, VI, VIA, VIB, VII, VIIA, VIIB and X on the basis of information supplied by Member States."

(25) Annex I is replaced by the text set out in Annex I to this Regulation.

(26) The text set out in Annex II of this Regulation is inserted as Annex IVA.

(27) The text set out in Annex III of this Regulation is inserted as Annex VIA.

(28) The text set out in Annex IV of this Regulation is inserted as Annex VIB.

(29) The text set out in Annex V of this Regulation is inserted as Annex VIIA.

(30) The text set out in Annex VI of this Regulation is inserted as Annex VIIB.

*Article 2*

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

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

Done at Brussels, 21 December 2012.

*For the Council*

*The President*

A. D. MAVROYIANNIS

## ANNEX I

## "ANNEX I

## PART A

**Goods and technology referred to in Articles 2(1), (2) and (4), 3(3), 5(1), 6, 8(4), 17(2) and 31(1)**

This Annex comprises all goods and technology listed in Annex I to Regulation (EC) No 428/2009, as defined therein, with the exception of those specified in Part A as well as with the exception, until 15 April 2013, of those specified in Part C.

	Description
1.	<p>"Information security" systems and equipment for final use for public telecommunication services and internet service providing or for the protection by the network operator of these services, including components necessary for operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing services related to those systems and equipment as follows:</p> <p>a. Systems, equipment, application specific "electronic assemblies", modules and integrated circuits for "information security" related to networks such as wifi, 2G, 3G, 4G or fixed networks (classical, ADSL or optic fiber), as follows, and components therefor specially designed for "information security":</p> <p><i>N.B.: For the control of Global Navigation Satellite Systems (GNSS) receiving equipment containing or employing decryption (i.e., GPS or GLONASS), see 7A005 of Annex I to Regulation (EC) No 428/2009.</i></p> <p>1. Designed or modified to use "cryptography" employing digital techniques performing any cryptographic function other than authentication or digital signature and having any of the following:</p> <p><i>Technical Notes:</i></p> <p>1. Authentication and digital signature functions include their associated key management function.</p> <p>2. Authentication includes all aspects of access control where there is no encryption of files or text except as directly related to the protection of passwords, Personal Identification Numbers (PINs) or similar data to prevent unauthorised access.</p> <p>3. "Cryptography" does not include "fixed" data compression or coding techniques.</p> <p><i>Note:</i> 1.a.1. includes equipment designed or modified to use "cryptography" employing analogue principles when implemented with digital techniques.</p> <p>a. A "symmetric algorithm" employing a key length in excess of 56 bits; or</p> <p>b. An "asymmetric algorithm" where the security of the algorithm is based on any of the following:</p> <p>1. Factorisation of integers in excess of 512 bits (e.g., RSA);</p> <p>2. Computation of discrete logarithms in a multiplicative group of a finite field of size greater than 512 bits (e.g., Diffie-Hellman over <math>Z/pZ</math>); or</p> <p>3. Discrete logarithms in a group other than mentioned in 1.a.1.b.2. in excess of 112 bits</p> <p>(e.g., Diffie-Hellman over an elliptic curve);</p>

	Description
2.	<p>"Software" as follows, for final use for public telecommunication services, internet service providing or for the protection by the network operator of these services:</p> <p>a. "Software" specially designed or modified for the "use" of equipment specified in 1.a.1 or "software" specified in 2.b.1;</p> <p>b. Specific "software", as follows:</p> <p>1. "Software" having the characteristics, or performing or simulating the functions of the equipment, specified in 5A002.a.1;</p>
3.	<p>"Technology" according to the General Technology Note for the "use" of equipment specified in 1.a.1 or "software" specified in 2.a. or 2.b.1 of this list, for final use for public telecommunication services and internet service providing or for the protection by the network operator of these services.</p>

## PART B

Article 6 applies to the following goods:

Item from Annex I to Regulation (EC) No 428/2009	Description
0A001	<p>"Nuclear reactors" and specially designed or prepared equipment and components therefor, as follows:</p> <p>a. "Nuclear reactors";</p> <p>b. Metal vessels, or major shop-fabricated parts therefor, including the reactor vessel head for a reactor pressure vessel, specially designed or prepared to contain the core of a "nuclear reactor";</p> <p>c. Manipulative equipment specially designed or prepared for inserting or removing fuel in a "nuclear reactor";</p> <p>d. Control rods specially designed or prepared for the control of the fission process in a "nuclear reactor", support or suspension structures therefor, rod drive mechanisms and rod guide tubes;</p> <p>e. Pressure tubes specially designed or prepared to contain fuel elements and the primary coolant in a "nuclear reactor" at an operating pressure in excess of 5.1 MPa;</p> <p>f. Zirconium metal and alloys in the form of tubes or assemblies of tubes in which the ratio of hafnium to zirconium is less than 1:500 parts by weight, specially designed or prepared for use in a "nuclear reactor";</p> <p>g. Coolant pumps specially designed or prepared for circulating the primary coolant of "nuclear reactors";</p> <p>h. 'Nuclear reactor internals' specially designed or prepared for use in a "nuclear reactor", including support columns for the core, fuel channels, thermal shields, baffles, core grid plates, and diffuser plates;</p> <p><i>Note: In 0A001.h. 'nuclear reactor internals' means any major structure within a reactor vessel which has one or more functions such as supporting the core, maintaining fuel alignment, directing primary coolant flow, providing radiation shields for the reactor vessel, and guiding in-core instrumentation.</i></p>

Item from Annex I to Regulation (EC) No 428/2009	Description
	i. Heat exchangers (steam generators) specially designed or prepared for use in the primary coolant circuit of a "nuclear reactor"; j. Neutron detection and measuring instruments specially designed or prepared for determining neutron flux levels within the core of a "nuclear reactor".
0C002	Low enriched uranium covered by 0C002 when it is incorporated in assembled nuclear fuels elements

## PART C

Item from Annex I to Regulation (EC) No 428/2009	Description
5A002	<p>"Information security" systems, equipment and components therefor, as follows:</p> <p>a. Systems, equipment, application specific "electronic assemblies", modules and integrated circuits for "information security", as follows and other specially designed components therefor:</p> <p><i>N.B.: For the control of Global Navigation Satellite Systems (GNSS) receiving equipment containing or employing decryption (i.e., GPS or GLONASS), see 7A005.</i></p> <p>1. Designed or modified to use "cryptography" employing digital techniques performing any cryptographic function other than authentication or digital signature and having any of the following:</p> <p><i>Technical Notes:</i></p> <p>1. Authentication and digital signature functions include their associated key management function.</p> <p>2. Authentication includes all aspects of access control where there is no encryption of files or text except as directly related to the protection of passwords, Personal Identification Numbers (PINs) or similar data to prevent unauthorised access.</p> <p>3. "Cryptography" does not include "fixed" data compression or coding techniques.</p> <p><i>Note:</i> 5A002.a.1. includes equipment designed or modified to use "cryptography" employing analogue principles when implemented with digital techniques.</p> <p>a. A "symmetric algorithm" employing a key length in excess of 56 bits; or</p> <p>b. An "asymmetric algorithm" where the security of the algorithm is based on any of the following:</p> <p>1. Factorisation of integers in excess of 512 bits (e.g., RSA);</p> <p>2. Computation of discrete logarithms in a multiplicative group of a finite field of size greater than 512 bits (e.g., Diffie-Hellman over <math>Z/pZ</math>); or</p> <p>3. Discrete logarithms in a group other than mentioned in 5A002.a.1.b.2. in excess of 112 bits</p> <p>(e.g., Diffie-Hellman over an elliptic curve);</p>



Item from Annex I to Regulation (EC) No 428/2009	Description
5D002	<p>"Software" as follows:</p> <ul style="list-style-type: none"><li>a. "Software" specially designed or modified for the "use" of equipment specified in 5A002.a.1 or "software" specified in 5D002.c.1;</li><li>c. Specific "software", as follows:<ul style="list-style-type: none"><li>1. "Software" having the characteristics, or performing or simulating the functions of the equipment, specified in 5A002.a.1;</li></ul></li></ul> <p><i>Note: 5D002 does not control "software" as follows:</i></p> <ul style="list-style-type: none"><li>a. "Software" required for the "use" of equipment excluded from control by the Note to 5A002;</li><li>b. "Software" providing any of the functions of equipment excluded from control by the Note to 5A002.</li></ul>
5E002	<p>"Technology" according to the General Technology Note for the "use" of equipment specified in 5A002.a.1 or "software" specified in 5D002.a. or 5D002.c.1 of this list".</p>

## ANNEX II

## "ANNEX IVA

**Products referred to in Articles 14a and 31(1)****Natural gas and other gaseous hydrocarbons**

HS code	Description
2709 00 10	Natural gas condensates
2711 11 00	Natural Gas – in liquefied state
2711 21 00	Natural Gas – in gaseous state
2711 12	Propane
2711 13	Butanes
2711 19 00	Other".

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## ANNEX III

## "ANNEX VIA

**Key equipment and technology referred to Articles 8, 10(1)(c) and 31(1)**

HS code	Description
	- Casing, tubing and drill pipe, of a kind used in drilling for oil or gas:
7304 22	- Drill pipe of stainless steel
7304 23	-- Other drill pipe
7304 24	-- Other, of stainless steel
7304 29	-- Other
ex 7305	Other tubes and pipes (for example, welded, riveted or similarly closed), having circular cross-sections, the external diameter of which exceeds 406,4 mm, of iron or steel, with a chrome content of 1 % or more and with a cold resistance that can go below -120°C
	- Line pipe of a kind used for oil or gas pipelines:
7306 11	-- Welded, of stainless steel
7306 19	-- Other
	- Casing and tubing of a kind used in drilling for oil or gas:
7306 21 00	-- Welded, of stainless steel
7306 29 00	-- Other
	Containers for compressed or liquefied gas, of iron or steel:
7311 00 99	- Other, of a capacity of 1 000 l or more
ex 7613	Aluminium containers for compressed or liquefied gas, of a capacity of 1 000 l or more".

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## ANNEX IV

## "ANNEX VIB

**Key equipment and technology referred to in Articles 10a, 10b, 10c and 31(1)**

HS code	Description
8406 10 00	Steam turbines for marine propulsion
ex 8406 90	Parts of steam turbines for marine propulsion
8407 21	Marine propulsion engines, outboard motors
ex 8407 29	Marine propulsion engines, other
8408 10	Marine propulsion engines
ex 8409 91 00	Parts suitable for use solely or principally with machines of subheadings 8407 21 or 8407 29
ex 8409 99 00	Parts suitable for use solely or principally with machines of subheading 8408 10
ex 8411 81	Other gas turbine of a power not exceeding 5 000 kW, for marine propulsion
ex 8411 82	Other gas turbines of a power exceeding 5 000 kW, for marine propulsion
ex 8468	Machinery and apparatus for soldering, brazing or welding whether or not capable of cutting, other than those of heading 8515; gas-operated surface tempering machines and appliances:
ex 8483	Transmission shafts (including cam shafts and crank shafts) and cranks; bearing housings and plain shaft bearings; gears and gearing; ball or roller screws; gear boxes and other speed changers, including torque converters; flywheels and pulleys, including pulley blocks; clutches and shaft couplings (including universal joints), designed for the propulsion of vessels at the maximum possible dead-weight tonnage at scantling draught of 55 000 dwt or more
8487 10	Ships' or boats' propellers and blades therefor
ex 8515	Electric (including electrically heated gas), laser or other light or photon beam, ultrasonic, electron beam, magnetic pulse or plasma arc soldering, brazing or welding machines and apparatus, whether or not capable of cutting; electric machines and apparatus for hot spraying of metals or cermets:
ex 9014 10 00	Direction finding compasses, solely for the maritime industry
ex 9014 80 00	Other navigational instruments and appliances, solely for the maritime industry
ex 9014 90 00	Parts and accessories of subheadings 9014 10 00 and 9014 80 00, solely for the maritime industry
ex 9015	Surveying (including photogram metrical surveying), hydro graphic, oceanographic, hydrological, meteorological or geophysical instruments and appliances, excluding compasses; rangefinders, solely for the maritime industry "

## ANNEX V

## "ANNEX VIIA

**Software for integrating industrial processes referred to in Article 10d, 10e, 10f and 31(1)**

1. Enterprise Resource Planning software, designed specifically for use in nuclear, military, gas, oil, navy, aviation, financial and construction industries.

*Explanatory note: Enterprise Resource Planning software is software used for financial accounting, management accounting, human resources, manufacturing, supply chain management, project management, customer relationship management, data services, or access control."*

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## ANNEX VI

## "ANNEX VIIB

**Graphite and raw or semi-finished metals referred to in Articles 15a, 15b, 15c and 31(1)**

Introductory note: The inclusion of goods in this Annex is without prejudice to the rules applicable to the goods included in Annexes I, II and III.

## 1. Graphite

HS code	Description
2504	Natural graphite
3801	Artificial graphite; colloidal or semi-colloidal graphite; preparations based on graphite or other carbon in the form of pastes, blocks, plates or other semi-manufactures
6815 10	Non-electrical articles of graphite or other carbon, incl. carbon fibres
6903 10	Retorts, crucibles, mufflers, nozzles, plugs, supports, cupels, tubes, pipes, sheaths, rods and other refractory ceramic goods. Other than those of siliceous fossil meals or of similar siliceous earths, containing, by weight, more than 50 % of graphite, or other carbon or of a mixture of these products
8545	Carbon electrodes, carbon brushes, lamp carbons, battery carbons and other articles of graphite or other carbon, with or without metal, of a kind used for electrical purposes

## 2. Iron and Steel

HS code	Description
7201	Pig iron and spiegeleisen in pigs, blocks or other primary forms
7202	Ferro-alloys
7203	Ferrous products obtained by direct reduction of iron ore and other spongy ferrous products, in lumps, pellets or similar forms; iron having a minimum purity by weight of 99,94 %, in lumps, pellets or similar forms
7204	Ferrous waste and scrap; remelting scrap ingots of iron or steel
7205	Granules and powders, of pig iron, spiegeleisen, iron or steel
7206	Iron and non-alloy steel in ingots or other primary forms
7207	Semi-finished products of iron or non-alloy steel
7218	Stainless steel in ingots or other primary forms; semi-finished products of stainless steel
7224	Other alloy steel in ingots or other primary forms; semi-finished products of other alloy steel

## 3. Copper and articles thereof

HS code	Description
7401 00 00	Copper mattes; cement copper (precipitated copper)
7402 00 00	Unrefined copper; copper anodes for electrolytic refining
7403	Refined copper and copper alloys, unwrought
7404 00	Copper waste and scrap

7405 00 00	Master alloys of copper
7406	Copper powders and flakes
7407	Copper bars, rods and profiles
7410	Copper foil (whether or not printed or backed with paper, paperboard, plastics or similar backing materials) of a thickness (excluding any backing) not exceeding 0,15 mm
7413 00 00	Stranded wire, cables, plaited bands and the like, of copper, not electrically insulated

#### 4. Nickel and articles thereof

HS code	Description
7501	Nickel mattes, nickel oxide sinters and other intermediate products of nickel metallurgy
7502	Unwrought nickel
7503 00	Nickel waste and scrap
7504 00 00	Nickel powders and flakes
7505	Nickel bars, rods, profiles and wire
7506	Nickel plates, sheets, strip and foil
7507	Nickel tubes, pipes and tube or pipe fittings (for example, couplings, elbows, sleeves)

#### 5. Aluminium

HS code	Description
7601	Unwrought aluminium
7602	Aluminium waste and scrap
7603	Aluminium powders and flakes
7605	Aluminium wire
7606	Aluminium plates, sheets and strip, of a thickness exceeding 0,2 mm
7609 00 00	Aluminium tube or pipe fittings (for example, couplings, elbows, sleeves)
7614	Stranded wire, cables, plaited bands and the like, of aluminium, not electrically insulated

#### 6. Lead

HS code	Description
7801	Unwrought lead
7802 00 00	Lead waste and scrap
7804	Lead plates, sheets, strip and foil; lead powders and flakes

#### 7. Zinc

HS code	Description
7901	Unwrought zinc
7902 00 00	Zinc waste and scrap

7903	Zinc dust, powders and flakes
7904 00 00	Zinc bars, rods, profiles and wire
7905 00 00	Zinc plates, sheets, strip and foil

## 8. Tin

HS code	Description
8001	Unwrought tin
8002 00 00	Tin waste and scrap
8003 00 00	Tin bars, rods, profiles and wire

## 9. Other base metals, cermets, articles thereof

HS code	Description
ex 8101	Tungsten (wolfram) and articles thereof, including waste and scrap, other than anti-cathodes for x-ray tubes
ex 8102	Molybdenum and articles thereof, including waste and scrap, other than articles specifically designed for use in dentistry
ex 8103	Tantalum and articles thereof, including waste and scrap, other than dental instruments and surgical tools and articles specially designed for orthopaedic and surgical purposes
8104	Magnesium and articles thereof, including waste and scrap
8105	Cobalt mattes and other intermediate products of cobalt metallurgy; cobalt and articles thereof, including waste and scrap
ex 8106 00	Bismuth and articles thereof, including waste and scrap, other than that specially prepared for the preparation of chemical compounds for pharmaceutical use
8107	Cadmium and articles thereof, including waste and scrap
8108	Titanium and articles thereof, including waste and scrap
8109	Zirconium and articles thereof, including waste and scrap
8110	Antimony and articles thereof, including waste and scrap
8111 00	Manganese and articles thereof, including waste and scrap
ex 8112	Beryllium, chromium, germanium, vanadium, gallium, hafnium, indium, niobium (columbium), rhenium and thallium, and articles of these metals, including waste and scrap, other than windows for X-ray tubes
8113 00	Cermets and articles thereof, including waste and scrap".

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**COUNCIL IMPLEMENTING REGULATION (EU) No 1264/2012****of 21 December 2012****implementing Regulation (EU) No 267/2012 concerning restrictive measures against Iran**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) No 267/2012 of 23 March 2012 concerning restrictive measures against Iran <sup>(1)</sup>, and in particular Article 46(2) thereof,

Whereas:

- (1) On 23 March 2012, the Council adopted Regulation (EU) No 267/2012.
- (2) In view of the situation in Iran, and in accordance with Decision 2012/829/CFSP <sup>(2)</sup>, additional persons and entities should be included in the list of natural and legal persons, entities and bodies subject to restrictive measures set out in Annex IX to Regulation (EU) No 267/2012.

- (3) Furthermore, certain entities should be removed from the list of natural and legal persons, entities and bodies subject to restrictive measures as set out in Annex IX to Regulation (EU) No 267/2012, while the entries for certain entities should be amended.

- (4) In order to ensure that the measures provided for in this Regulation are effective, it should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex IX to Regulation (EU) No 267/2012 shall be amended as set out in the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the date of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 21 December 2012.

*For the Council*  
*The President*  
A. D. MAVROYIANNIS

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<sup>(1)</sup> OJ L 88, 24.3.2012, p. 1.

<sup>(2)</sup> See page 71 of this Official Journal.

## ANNEX

I. The person and entities listed below shall be added to the list set out in Annex IX to Regulation (EU) No 267/2012:

"I. Persons and entities involved in nuclear or ballistic missile activities and persons and entities providing support to the Government of Iran

**Person**

	Name	Identifying information	Reasons	Date of listing
1.	Babak Zanjani	Date of birth: 12 March 1971	Babak Zanjani is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. Zanjani is a key facilitator for Iranian oil deals and transferring oil-related money. Zanjani owns and operates the UAE-based Sorinet Group, and some of its companies are used by Zanjani to channel oil-related payments.	22.12.2012

**Entities**

	Name	Identifying information	Reasons	Date of listing
1.	National Iranian Oil Products Distribution Company (NIOPCD)	No.1, Tehran, Iranshahr Ave.Shadab.St, P.O.Box: 79145/3184 Tel: +98-21-77606030 Website: www.niopdc.ir	Subsidiary of the National Iranian Oil Refining and Distribution Company (NIORDC)	22.12.2012
2.	Iranian Oil Pipelines and Telecommunications Company (IOPTC)	No.194, Tehran, Sepahbod Gharani Ave. Tel: +98-21-88801960/ +98-21-66152223 Fax: +98-21-66154351 Website: www.ioptc.com	Subsidiary of the National Iranian Oil Refining and Distribution Company (NIORDC)	22.12.2012
3.	National Iranian Oil Engineering and Construction Company (NIOEC)	No.263, Tehran, Ostad Nejatollahi Ave. P.O.Box: 11365/6714 Tel: +98-21-88907472 Fax: +98-21-88907472 Website: www.nioec.org	Subsidiary of the National Iranian Oil Refining and Distribution Company (NIORDC)	22.12.2012
4.	Iran Composites Institute	Iran Composites Institute, Iranian University of Science and Technology, 16845-188, Tehran, Iran, Telephone: 98 217 3912858 Fax: 98 217 7491206 E-mail: ici@iust.ac.ir Website: <a href="http://www.irancomposites.org">http://www.irancomposites.org</a>	Iranian Composites Institute (ICI, aka Composite Institute of Iran) is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. As of 2011 ICI had been contracted to provide EU-designated Iran Centrifuge Technology Company (TESA) with IR-2M centrifuge rotors.	22.12.2012

	Name	Identifying information	Reasons	Date of listing
5.	Jelvesazan Company	22 Bahman St., Bozorgmehr Ave, 84155666, Esfahan, Iran Tel: 98 0311 2658311 15 Fax: 98 0311 2679097	Jelvesazan Company is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. As of early 2012 Jelvesazan intended to supply controlled vacuum pumps to EU-designated Iran Centrifuge Technology Company (TESA).	22.12.2012
6.	Iran Aluminium Company	Arak Road Km 5, Tehran Road, 38189-8116, Arak, Iran Tel: 98 861 4130430 Fax: 98 861 413023 Website: www.iralco.net	The Iran Aluminium Company (aka IRALCO, Iranian Aluminium Company) is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. As of mid-2012 IRALCO had a contract to supply aluminium to EU-designated Iran Centrifuge Technology Company (TESA).	22.12.2012
7.	Simatec Development Company		Simatec Development Company is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. As of early 2010 Simatec was contracted by UN-designated Kalaye Electric Company (KEC) to procure Vacon inverters to power uranium enrichment centrifuges. As of mid-2012 Simatec was attempting to procure EU-controlled inverters.	22.12.2012
8.	Aluminat	1. Parcham St, 13 <sup>th</sup> Km of Qom Rd 38135 Arak (Factory) 2. Unit 38, 5 <sup>th</sup> Fl, Bldg No 60, Golfam St, Jordan, 19395-5716, Tehran Tel: 98 212 2049216 / 22049928 / 22045237 Fax: 98 21 22057127 Website: www.aluminat.com	Aluminat is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. In early 2012 Aluminat had a contract to supply 6061-T6 aluminium to EU-designated Iran Centrifuge Technology Company (TESA).	22.12.2012
9.	Organisation of Defensive Innovation and Research		The Organisation of Defensive Innovation and Research (SPND) is assisting designated persons and entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. The IAEA has identified SPND with their concerns over possible military dimensions (PMD) to Iran's nuclear programme over which Iran continues to refuse to co-operate. SPND is run by UN-designated Mohsen Fakhrizadeh and is part of the Ministry of Defence For Armed Forces Logistics (MODAFL, designated	22.12.2012

	Name	Identifying information	Reasons	Date of listing
			by the EU in May 2011). Davoud Babaei was designated by the EU in December 2011 in his role as SPND's head of security, in which he is responsible for preventing the disclosure of information including to the IAEA.	
10.	First Islamic Investment Bank	<p>Branch: 19A-31-3A, Level 31 Business Suite, Wisma UOA, Jalan Pinang 50450, Kuala Lumpur; Kuala Lumpur; Wilayah Persekutuan; 50450 Tel: 603-21620361/2/3/4, +6087417049/ 417050, +622157948110</p> <p>Branch: Unit 13 (C), Main Office Tower, Financial Park Labuan Complex, Jalan Merdeka, 87000 Federal Territory of Labuan, Malaysia; Labuan F.T; 87000</p> <p>Investor Relations: Menara Prima 17<sup>th</sup> floor Jalan Lingkar, Mega Kuningan Blok 6.2 Jakarta 12950 – Indonesia; South Jakarta; Jakarta; 12950</p>	First Islamic Investment Bank (FIIB) is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. FIIB is part of the Sorinet Group owned and operated by Babak Zanjani. It is being used to channel Iranian oil-related payments.	22.12.2012
11.	International Safe Oil		International Safe Oil (ISO) is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. ISO is part of the Sorinet Group owned and operated by Babak Zanjani. It is being used to channel Iranian oil-related payments.	22.12.2012
12.	Sorinet Commercial Trust	<p>SCT Bankers Company Branch: No.1808, 18th Floor, Grosvenor House Commercial Tower, Sheik Zayed Road, Dubai, UAE, P.O.Box 31988 Tel: 0097 14 3257022-99 E-mail: INFO@SCTBankers.com Dubai SWIFT Code: SCTSAEA1</p> <p>Branch: No.301, 3<sup>rd</sup> Floor Sadaf Building Kish Island, Iran, P.O.Box 1618 Tel: +98 764 444 32 341-2 Fax: +98 764 444 50 390-1</p>	Sorinet Commercial Trust (SCT) is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. SCT is part of the Sorinet Group owned and operated by Babak Zanjani. It is being used to channel Iranian oil-related payments.	22.12.2012
13.	Hong Kong Intertrade Company Ltd	Hong Kong Intertrade Company, Hong Kong	Hong Kong Intertrade Company Ltd (HKICO) is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. HKICO is a front company controlled by EU-designated National Iranian Oil	22.12.2012

	Name	Identifying information	Reasons	Date of listing
			Company (NIOC). In mid-2012 HKICO was scheduled to receive millions of dollars from NIOC oil sales.	
14.	Petro Suisse	Petro Suisse Avenue De la Tour-Halimand 6, 1009 Pully, Switzerland	Petro Suisse is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. It is a front company controlled by EU-designated NIOC. NIOC set up Petro Suisse as a company and would use Petro Suisse accounts to make and receive payments. Petro Suisse continued to be in contact with NIOC in 2012.	22.12.2012
15.	Oil Industry Pension Fund Investment Company	No 234, Taleghani St, Tehran Iran	Iran's Oil Industry Pension Fund Investment Company (OPIC, aka the Oil Pension Fund, NIOC Pension Fund, Petroleum Ministry Pension Fund) is providing financial support to the government of Iran. OPIC operates under the Iranian Ministry of Petroleum and the National Iranian Oil Company (NIOC), both of which are EU-designated. It holds shares in a number of EU-designated entities.	22.12.2012
16.	CF Sharp and Company Private Limited		This entity has been assisting the Irano-Hind Shipping Company (IHSC) (designated by the United Nations on 9 June 2010) in circumventing the sanctions adopted against it. Following its designation, IHSC has tried to conceal its ownership of three tankers, by placing them under the management of Noah Ship Management and then Marian Ship Management. CF Sharp and Co. has contributed to this arrangement by concluding a personnel management contract with IHSC covering the crew of those three tankers. That contract was performed by Noah Ship Management and Marian Ship Management.	22.12.2012
17.	Sharif University of Technology	Azadi Ave, 11365-8639, Tehran, Iran Tel: 98 21 66022727 Fax: 98 21 66036005 Website: www.sharif.ir	Sharif University of Technology (SUT) is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is providing support to Iran's proliferation sensitive nuclear activities. As of late 2011 SUT had provided laboratories for use by UN-designated Iranian	22.12.2012

	Name	Identifying information	Reasons	Date of listing
			nuclear entity Kalaye Electric Company (KEC) and EU-designated Iran Centrifuge Technology Company (TESA).	
18.	Moallem Insurance Company (also known as: Moallem Insurance; Moallem Insurance Co.; M.I.C; Export and Investment Insurance Co.)	No. 56, Haghani Boulevard, Vanak Square, Tehran 1517973511, Iran PO Box 19395-6314, 11/1 Sharif Ave, Vanaq Square, Tehran 19699, Iran Phone: (98-21) 886776789, 887950512, 887791835 Fax: (98-21) 88771245 Website: www.mic-ir.com	Main insurer of IRISL	22.12.2012"

II. The entries for the entities set out in Annex IX to Regulation (EU) No 267/2012 listed below shall be replaced by the entries below:

**"B. Entities**

	Name	Identifying information	Reasons	Date of listing
1.	Technology Cooperation Office (TCO) of the Iranian President's Office (a.k.a. Center for Innovation and Technology (CITC))	Tehran, Iran	Responsible for Iran's technological advancement through relevant foreign procurement and training links. Supports the nuclear and missile programmes.	26.07.2010
2.	Sureh (a.k.a. Soreh) Nuclear Reactors Fuel Company (a.k.a. Nuclear Fuel Reactor Company; Sookht Atomi Reactorhaye Iran; Soukht Atomi Reactorha-ye Iran)	Head Office: 61 Shahid Abtahi St, Karegar e Shomali, Tehran Complex: Persian Gulf Boulevard, Km20 SW Esfahan Road, Esfahan	A company subordinate to the UN-sanctioned Atomic Energy Organisation of Iran (AEOI) consisting of the Uranium Conversion Facility, the Fuel Manufacturing Plant and the Zirconium Production Plant.	23.05.2011
3.	Tidewater (a.k.a. Tidewater Middle East Co; Faraz Royal Qeshm Company LLC)	Postal address: No 80, Tidewater Building, Vozara Street, Next to Saie Park, Tehran, Iran	Owned or controlled by IRGC	23.01.2012"

III. The entities listed below shall be deleted from the list set out in Annex IX to Regulation (EU) No 267/2012:

1. CF Sharp Shipping Agencies Pte Ltd
2. Soreh (Nuclear Fuel Reactor Company).

## COMMISSION IMPLEMENTING REGULATION (EU) No 1265/2012

of 17 December 2012

amending Implementing Regulation (EU) No 837/2012 as regards the minimum activity of a preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 22594) as feed additive for poultry, weaned piglets, pigs for fattening and sows (holder of authorisation DSM Nutritional Products)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition<sup>(1)</sup>, and in particular Article 13(3) thereof,

Whereas:

- (1) The use of a preparation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* (DSM 22594), belonging to the additive category of 'zootechnical additives', was authorised for 10 years as a feed additive for use on poultry, weaned piglets, pigs for fattening and sows by Commission Implementing Regulation (EU) No 837/2012<sup>(2)</sup>.
- (2) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of the preparation concerned by adding a new solid formulation with a minimum activity of 10 000 FYT/g. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').
- (3) The Authority concluded in its opinion of 24 May 2012<sup>(3)</sup> that the new enzyme solid formulation is not

expected to introduce hazards to the target species, consumers, users or the environment not already considered and it is efficacious at the minimum activity of 10 000 FYT/g. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (4) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (5) Implementing Regulation (EU) No 837/2012 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Implementing Regulation (EU) No 837/2012 is amended in accordance with the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 17 December 2012.

For the Commission

The President

José Manuel BARROSO

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> OJ L 252, 19.9.2012, p. 7.

<sup>(3)</sup> EFSA Journal 2012; 10(6):2730.

## ANNEX

The Annex to Implementing Regulation (EU) No 837/2012 is replaced by the following:

## 'ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
<b>Category of zootechnical additives. Functional group: digestibility enhancers</b>									
4a18	DSM Nutritional Products	6-phytase (EC 3.1.3.26)	<p><i>Additive composition</i></p> <p>Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Aspergillus oryzae</i> (DSM 22594) with a minimum activity of: 10 000 FYT <sup>(1)</sup>/g in solid form 20 000 FYT/g in liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>6-phytase (EC 3.1.3.26) produced by <i>Aspergillus oryzae</i> (DSM 22594)</p> <p><i>Analytical method</i> <sup>(2)</sup></p> <p>For quantification of 6-phytase in feed:</p> <p>Colorimetric method measuring the inorganic phosphate released by the 6-phytase from phytate (ISO 30024:2009)</p>	<p>Poultry</p> <p>Pigs for fattening</p> <p>Piglets (weaned)</p> <p>Sows</p>	—	500 FYT	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</p> <p>2. Recommended dose per kilogram of complete feed for:</p> <p>— poultry, piglets (weaned) and pigs for fattening: 500-4 000 FYT,</p> <p>— sows: 1 000-4 000 FYT.</p> <p>3. For use in feed containing more than 0,23 % phytin-bound phosphorus.</p> <p>4. For safety: breathing protection, glasses and gloves shall be used during handling.</p> <p>5. For use in weaned piglets up to 35 kg.</p>	9 October 2022

<sup>(1)</sup> 1 FYT is the amount of enzyme which liberates 1 µmol of inorganic phosphate from phytate per minute under reaction conditions with a phytate concentration of 5,0 mM at pH 5,5 and 37 °C.

<sup>(2)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: [http://irmm.jrc.ec.europa.eu/EURLs/EURL\\_feed\\_additives/Pages/index.aspx](http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx)



**COMMISSION IMPLEMENTING REGULATION (EU) No 1266/2012****of 21 December 2012****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors <sup>(2)</sup>, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

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

HAS ADOPTED THIS REGULATION:

*Article 1*

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

*Article 2*

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

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

Done at Brussels, 21 December 2012.

*For the Commission,  
On behalf of the President,  
José Manuel SILVA RODRÍGUEZ  
Director-General for Agriculture and  
Rural Development*

<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> OJ L 157, 15.6.2011, p. 1.

## ANNEX

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

<i>(EUR/100 kg)</i>		
CN code	Third country code <sup>(1)</sup>	Standard import value
0702 00 00	AL	56,9
	MA	79,5
	TN	111,9
	TR	123,6
	ZZ	93,0
0707 00 05	AL	87,0
	TR	136,9
	ZZ	112,0
0709 93 10	MA	110,2
	TR	137,7
	ZZ	124,0
0805 10 20	MA	61,3
	TR	63,0
	ZA	51,2
	ZZ	58,5
0805 20 10	MA	69,9
	ZZ	69,9
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	86,6
	JM	129,1
	MA	98,7
	TR	84,1
	ZZ	99,6
0805 50 10	TR	79,2
	ZZ	79,2
0808 10 80	BA	56,8
	CA	156,3
	CN	174,8
	MK	40,0
	US	132,7
	ZA	123,7
	ZZ	114,4
0808 30 90	CN	72,9
	TR	135,1
	US	182,0
	ZZ	130,0

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

**COMMISSION IMPLEMENTING REGULATION (EU) No 1267/2012****of 21 December 2012****fixing the import duties in the cereals sector applicable from 1 January 2013**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) <sup>(1)</sup>,Having regard to Commission Regulation (EU) No 642/2010 of 20 July 2010 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of import duties in the cereals sector <sup>(2)</sup>, and in particular Article 2(1) thereof,

Whereas:

(1) Article 136(1) of Regulation (EC) No 1234/2007 states that the import duty on products covered by CN codes 1001 19 00, 1001 11 00, ex 1001 91 20 (common wheat seed), ex 1001 99 00 (high quality common wheat other than for sowing), 1002 10 00, 1002 90 00, 1005 10 90, 1005 90 00, 1007 10 90 and 1007 90 00 is to be equal to the intervention price valid for such products on importation and increased by 55 %, minus the cif import price applicable to the consignment in question. However, that duty may not exceed the rate of duty in the Common Customs Tariff.

(2) Article 136(2) of Regulation (EC) No 1234/2007 lays down that, in order to calculate the import duty

referred to in paragraph 1 of that Article, representative cif import prices are to be established on a regular basis for the products in question.

(3) Under Article 2(2) of Regulation (EU) No 642/2010, the price to be used for the calculation of the import duty on products covered by CN codes 1001 19 00, 1001 11 00, ex 1001 91 20 (common wheat seed), ex 1001 99 00 (high quality common wheat other than for sowing), 1002 10 00, 1002 90 00, 1005 10 90, 1005 90 00, 1007 10 90 and 1007 90 00 is the daily cif representative import price determined as specified in Article 5 of that Regulation.

(4) Import duties should be fixed for the period from 1 January 2013 and should apply until new import duties are fixed and enter into force.

(5) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

*Article 1*

From 1 January 2013, the import duties in the cereals sector referred to in Article 136(1) of Regulation (EC) No 1234/2007 shall be those fixed in Annex I to this Regulation on the basis of the information contained in Annex II.

*Article 2*

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

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

Done at Brussels, 21 December 2012.

*For the Commission,  
On behalf of the President,  
José Manuel SILVA RODRÍGUEZ  
Director-General for Agriculture and  
Rural Development*

<sup>(1)</sup> OJ L 299, 16.11.2007, p. 1.

<sup>(2)</sup> OJ L 187, 21.7.2010, p. 5.

## ANNEX I

**Import duties on the products referred to in Article 136(1) of Regulation (EC) No 1234/2007 applicable from 1 January 2013**

CN code	Description	Import duties <sup>(1)</sup> (EUR/t)
1001 19 00 1001 11 00	Durum wheat, high quality	0,00
	medium quality	0,00
	low quality	0,00
ex 1001 91 20	Common wheat seed	0,00
ex 1001 99 00	High quality common wheat other than for sowing	0,00
1002 10 00 1002 90 00	Rye	0,00
1005 10 90	Maize seed other than hybrid	0,00
1005 90 00	Maize other than seed <sup>(2)</sup>	0,00
1007 10 90 1007 90 00	Grain sorghum other than hybrids for sowing	0,00

<sup>(1)</sup> The importer may benefit, under Article 2(4) of Regulation (EU) No 642/2010, from a reduction in the duty of:

- EUR 3/t, where the port of unloading is located on the Mediterranean Sea (beyond the Strait of Gibraltar) or on the Black Sea, for goods arriving in the Union via the Atlantic Ocean or the Suez Canal,
- EUR 2/t, where the port of unloading is located in Denmark, Estonia, Ireland, Latvia, Lithuania, Poland, Finland, Sweden, the United Kingdom or on the Atlantic coast of the Iberian Peninsula, for goods arriving in the Union via the Atlantic Ocean.

<sup>(2)</sup> The importer may benefit from a flat-rate reduction of EUR 24/t where the conditions laid down in Article 3 of Regulation (EU) No 642/2010 are met.

## ANNEX II

## Factors for calculating the duties laid down in Annex I

14.12.2012-20.12.2012

## 1. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

(EUR/t)

	Common wheat <sup>(1)</sup>	Maize	Durum wheat, high quality	Durum wheat, medium quality <sup>(2)</sup>	Durum wheat, low quality <sup>(3)</sup>
Exchange	Minnéapolis	Chicago	—	—	—
Quotation	263,55	213,34	—	—	—
Fob price USA	—	—	259,19	249,19	229,19
Gulf of Mexico premium	—	18,17	—	—	—
Great Lakes premium	25,89	—	—	—	—

<sup>(1)</sup> Premium of EUR 14/t incorporated (Article 5(3) of Regulation (EU) No 642/2010).<sup>(2)</sup> Discount of EUR 10/t (Article 5(3) of Regulation (EU) No 642/2010).<sup>(3)</sup> Discount of EUR 30/t (Article 5(3) of Regulation (EU) No 642/2010).

## 2. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

Freight costs: Gulf of Mexico-Rotterdam: 14,52 EUR/t

Freight costs: Great Lakes-Rotterdam: 46,05 EUR/t

# DIRECTIVES

## COMMISSION IMPLEMENTING DIRECTIVE 2012/52/EU

of 20 December 2012

### laying down measures to facilitate the recognition of medical prescriptions issued in another Member State

(Text with EEA relevance)

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<sup>(1)</sup>, and in particular points (a), (c) and (d) of Article 11(2) thereof,

Whereas:

- (1) Pursuant to Article 11(2) of Directive 2011/24/EU, the Commission has an obligation to adopt measures to facilitate the recognition of medical prescriptions issued in a Member State other than the Member State where the prescriptions are dispensed.
- (2) Pursuant to point (a) of Article 11(2) of Directive 2011/24/EU, the Commission is to adopt a non-exhaustive list of elements to be included in those prescriptions. That list should enable the dispensing health professional to verify the authenticity of the prescription and whether it was issued by a member of a regulated health profession who is legally entitled to do so.
- (3) The elements to be included in the prescriptions should facilitate the correct identification of medicinal products or medical devices as referred to in point (c) of Article 11(2) of Directive 2011/24/EU.
- (4) Medicinal products should therefore be indicated using the common name in order to facilitate the correct identification of products which are marketed under different brand names across the Union and of products that are not marketed in all Member States. That common name to be used should be either the International Non-proprietary name recommended by the World Health Organisation or, if such name does not exist, the usual common name. In contrast, the brand name of a medicinal product should only be used to ensure clear identification of biological medicinal products as defined in point 3.2.1.1.(b) of Annex I to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products

for human use<sup>(2)</sup>, because of the special characteristics of those products, or of other medicinal products in cases where the prescribing professional considers it medically necessary.

- (5) Medical devices do not have common names as medicinal products. Therefore the prescription should also include direct contact details of the prescriber which enable the dispensing professional, where necessary, to enquire about the prescribed medical device and correctly identify it.
- (6) The non-exhaustive list of elements to appear on the prescriptions should facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, as referred to in point (d) of Article 11(2) of Directive 2011/24/EU. The Commission will regularly review the situation in order to assess whether additional measures are necessary to help patients understand the instructions concerning the use of the product.
- (7) To enable patients to request appropriate prescriptions, it is important that national contact points referred to in Article 6 of Directive 2011/24/EU provide patients with adequate information on the content and purpose of the non-exhaustive list of elements that should appear in those prescriptions.
- (8) As the overall impact of cross-border healthcare is limited, the non-exhaustive list of elements should apply only to prescriptions intended to be used in another Member State.
- (9) As the principle of mutual recognition of prescriptions derives from Article 56 of the Treaty on the Functioning of the European Union, this Directive does not preclude the Member States from applying the principle of mutual recognition to prescriptions that do not contain the elements set out in the non-exhaustive list. At the same time, nothing in this Directive prevents the Member States from providing that prescriptions drafted on their territory, with a view to be used in another Member State, contain additional elements that are provided for under the rules applicable on their territory, as long as these rules are compatible with Union law.

<sup>(1)</sup> OJ L 88, 4.4.2011, p. 45–65

<sup>(2)</sup> OJ L 311, 28.11.2001, p. 67.

(10) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 16(1) of Directive 2011/24/EU

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

**Subject matter**

This Directive lays down measures for the uniform implementation of Article 11(1) of Directive 2011/24/EU concerning the recognition of medical prescriptions issued in another Member State.

*Article 2*

**Scope**

This Directive shall apply to prescriptions, as defined in point (k) of Article 3 of Directive 2011/24/EU, which are issued further to a request of a patient who intends to use them in another Member State.

*Article 3*

**Content of prescriptions**

Member States shall ensure that prescriptions contain at least the elements set out in the Annex.

*Article 4*

**Information requirements**

Member States shall ensure that the national contact points referred to in Article 6 of Directive 2011/24/EU inform patients about the elements to be included, pursuant to this Directive, in prescriptions issued in a Member State other than the Member State where they are dispensed.

*Article 5*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 25 October 2013 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

*Article 6*

**Entry into force**

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

*Article 7*

**Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 20 December 2012.

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX

**Non-exhaustive list of elements to be included in medical prescriptions**

*Headings appearing in bold in this Annex are not required to feature in prescriptions*

**Identification of the patient**

Surname(s)

First name(s) (written out in full, i.e. no initials)

Date of Birth

**Authentication of the prescription**

Issue date

**Identification of the prescribing health professional**

Surname(s)

First name(s) (written out in full, i.e. no initials)

Professional qualification

Details for direct contact (email and telephone or fax, the latter both with international prefix)

Work address (including the name of the relevant Member State)

Signature (written or digital, depending on the medium chosen for issuing the prescription)

**Identification of the prescribed product, where applicable**

'Common name' as defined by Article 1 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

The brand name if:

- (a) the prescribed product is a biological medicinal product, as defined in point 3.2.1.1.(b) of Annex I (Part I) to Directive 2001/83; or
- (b) the prescribing health professional deems it medically necessary; in that case the prescription shall shortly state the reasons justifying the use of the brand name

Pharmaceutical formulation (tablet, solution, etc.)

Quantity

Strength, as defined in Article 1 of Directive 2001/83/EC

Dosage regimen

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# DECISIONS

## COUNCIL DECISION 2012/829/CFSP

of 21 December 2012

### amending Decision 2010/413/CFSP concerning restrictive measures against Iran

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Whereas:

- (1) On 26 July 2010, the Council adopted Decision 2010/413/CFSP <sup>(1)</sup>.
- (2) A provision concerning enhanced monitoring over all activities of financial institutions within the Union with Iranian financial institutions should be inserted in Decision 2010/413/CFSP.
- (3) In addition, a provision in Decision 2010/413/CFSP concerning the freezing of funds and economic resources should also be amended.
- (4) Furthermore, additional persons and entities should be included in the list of persons and entities subject to restrictive measures as set out in Annex II to Decision 2010/413/CFSP, certain entities should be removed from that list and the entries concerning certain entities should be amended.
- (5) Decision 2010/413/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

#### Article 1

Decision 2010/413/CFSP is hereby amended as follows:

- (1) In Article 10, the following paragraph is inserted:

"3a. Financial institutions shall be required, in their activities with banks and financial institutions as set out in paragraph 1, to:

- (a) exercise continuous vigilance over account activity including through their programmes on customer due diligence and under their obligations relating to money-laundering and financing of terrorism;

(b) require that all information fields of payment instructions which relate to the originator and beneficiary of the transaction in question be completed and, if that information is not supplied, refuse the transaction;

(c) maintain all records of transactions for a period of five years and make them available to national authorities on request;

(d) if they suspect, or have reasonable grounds to suspect, that funds are related to proliferation financing, promptly report their suspicions to the FIU or another competent authority designated by the Member State concerned. The FIU or such other competent authority shall have access, directly or indirectly, on a timely basis to the financial, administrative and law enforcement information that it requires to properly undertake this function, including the analysis of suspicious transaction reports."

- (2) Article 20(1)(b) is replaced by the following:

"(b) persons and entities not covered by Annex I that are engaged in, directly associated with, or providing support for, Iran's proliferation-sensitive nuclear activities or for the development of nuclear weapon delivery systems, including through the involvement in procurement of the prohibited items, goods, equipment, materials and technology, or persons or entities acting on their behalf or at their direction, or entities owned or controlled by them, including through illicit means, or persons and entities that have assisted designated persons or entities in evading or violating the provisions of UNSCR 1737 (2006), UNSCR 1747 (2007), UNSCR 1803 (2008) and UNSCR 1929 (2010) or this Decision, as well as other members and entities of IRGC and IRISL and entities owned or controlled by them or acting on their behalf or providing insurance or other essential services to them, as listed in Annex II."

#### Article 2

Annex II to Decision 2010/413/CFSP shall be amended as set out in the Annex to this Decision.

<sup>(1)</sup> OJ L 195, 27.7.2010, p. 39.

*Article 3*

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

Done at Brussels, 21 December 2012.

*For the Council*  
*The President*  
A. D. MAVROYIANNIS

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## ANNEX

I. The person and entities listed below shall be added to the list set out in Annex II to Decision 2010/413/CFSP:

"I. Persons and entities involved in nuclear or ballistic missile activities and persons and entities providing support to the Government of Iran

**Person**

	Name	Identifying information	Reasons	Date of listing
1.	Babak Zanjani	Date of birth: 12 March 1971	Babak Zanjani is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. Zanjani is a key facilitator for Iranian oil deals and transferring oil-related money. Zanjani owns and operates the UAE-based Sorinet Group, and some of its companies are used by Zanjani to channel oil-related payments.	22.12.2012

**Entities**

	Name	Identifying information	Reasons	Date of listing
1.	National Iranian Oil Products Distribution Company (NIOPCD)	No.1, Tehran, Iranshahr Ave.Shadab.St, P.O.Box: 79145/3184 Tel: +98-21-77606030 Website: www.niopdc.ir	Subsidiary of the National Iranian Oil Refining and Distribution Company (NIORDC)	22.12.2012
2.	Iranian Oil Pipelines and Telecommunications Company (IOPTC)	No.194, Tehran, Sepahbod Gharani Ave. Tel: +98-21-88801960/ +98-21-66152223 Fax: +98-21-66154351 Website: www.ioptc.com	Subsidiary of the National Iranian Oil Refining and Distribution Company (NIORDC)	22.12.2012
3.	National Iranian Oil Engineering and Construction Company (NIOEC)	No.263, Tehran, Ostad Nejatollahi Ave. P.O.Box: 11365/6714 Tel: +98-21-88907472 Fax: +98-21-88907472 Website: www.nioec.org	Subsidiary of the National Iranian Oil Refining and Distribution Company (NIORDC)	22.12.2012
4.	Iran Composites Institute	Iran Composites Institute, Iranian University of Science and Technology, 16845-188, Tehran, Iran, Telephone: 98 217 3912858 Fax: 98 217 7491206 E-mail: ici@iust.ac.ir Website: <a href="http://www.irancomposites.org">http://www.irancomposites.org</a>	Iranian Composites Institute (ICI, aka Composite Institute of Iran) is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. As of 2011 ICI had been contracted to provide EU-designated Iran Centrifuge Technology Company (TESA) with IR-2M centrifuge rotors.	22.12.2012

	Name	Identifying information	Reasons	Date of listing
5.	Jelvezazan Company	22 Bahman St., Bozorgmehr Ave, 84155666, Esfahan, Iran Tel: 98 0311 2658311 15 Fax: 98 0311 2679097	Jelvezazan Company is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. As of early 2012 Jelvezazan intended to supply controlled vacuum pumps to EU-designated Iran Centrifuge Technology Company (TESA).	22.12.2012
6.	Iran Aluminium Company	Arak Road Km 5, Tehran Road, 38189-8116, Arak, Iran Tel: 98 861 4130430 Fax: 98 861 413023 Website: www.iralco.net	The Iran Aluminium Company (aka IRALCO, Iranian Aluminium Company) is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. As of mid-2012 IRALCO had a contract to supply aluminium to EU-designated Iran Centrifuge Technology Company (TESA).	22.12.2012
7.	Simatec Development Company		Simatec Development Company is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. As of early 2010 Simatec was contracted by UN-designated Kalaye Electric Company (KEC) to procure Vacon inverters to power uranium enrichment centrifuges. As of mid-2012 Simatec was attempting to procure EU-controlled inverters.	22.12.2012
8.	Aluminat	1. Parcham St, 13 <sup>th</sup> Km of Qom Rd 38135 Arak (Factory) 2. Unit 38, 5 <sup>th</sup> Fl, Bldg No 60, Golfam St, Jordan, 19395-5716, Tehran Tel: 98 212 2049216 / 22049928 / 22045237 Fax: 98 21 22057127 Website: www.aluminat.com	Aluminat is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. In early 2012 Aluminat had a contract to supply 6061-T6 aluminium to EU-designated Iran Centrifuge Technology Company (TESA).	22.12.2012
9.	Organisation of Defensive Innovation and Research		The Organisation of Defensive Innovation and Research (SPND) is assisting designated persons and entities to violate the provisions of UN and EU sanctions on Iran and is directly supporting Iran's proliferation sensitive nuclear activities. The IAEA has identified SPND with their concerns over possible military dimensions (PMD) to Iran's nuclear programme over which Iran continues to refuse to co-operate. SPND is run by UN-designated Mohsen Fakhrizadeh and is part of the Ministry of Defence For Armed Forces Logistics (MODAFL, designated	22.12.2012

	Name	Identifying information	Reasons	Date of listing
			by the EU in May 2011). Davoud Babaei was designated by the EU in December 2011 in his role as SPND's head of security, in which he is responsible for preventing the disclosure of information including to the IAEA.	
10.	First Islamic Investment Bank	<p>Branch: 19A-31-3A, Level 31 Business Suite, Wisma UOA, Jalan Pinang 50450, Kuala Lumpur; Kuala Lumpur; Wilayah Persekutuan; 50450 Tel: 603-21620361/2/3/4, +6087417049/ 417050, +622157948110</p> <p>Branch: Unit 13 (C), Main Office Tower, Financial Park Labuan Complex, Jalan Merdeka, 87000 Federal Territory of Labuan, Malaysia; Labuan F.T; 87000</p> <p>Investor Relations: Menara Prima 17<sup>th</sup> floor Jalan Lingkar, Mega Kuningan Blok 6.2 Jakarta 12950 – Indonesia; South Jakarta; Jakarta; 12950</p>	First Islamic Investment Bank (FIIB) is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. FIIB is part of the Sorinet Group owned and operated by Babak Zanjani. It is being used to channel Iranian oil-related payments.	22.12.2012
11.	International Safe Oil		International Safe Oil (ISO) is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. ISO is part of the Sorinet Group owned and operated by Babak Zanjani. It is being used to channel Iranian oil-related payments.	22.12.2012
12.	Sorinet Commercial Trust	<p>SCT Bankers Company Branch: No.1808, 18th Floor, Grosvenor House Commercial Tower, Sheik Zayed Road, Dubai, UAE, P.O.Box 31988 Tel: 0097 14 3257022-99 E-mail: INFO@SCTBankers.com Dubai SWIFT Code: SCTSAEA1</p> <p>Branch: No.301, 3<sup>rd</sup> Floor Sadaf Building Kish Island, Iran, P.O.Box 1618 Tel: +98 764 444 32 341-2 Fax: +98 764 444 50 390-1</p>	Sorinet Commercial Trust (SCT) is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. SCT is part of the Sorinet Group owned and operated by Babak Zanjani. It is being used to channel Iranian oil-related payments.	22.12.2012
13.	Hong Kong Intertrade Company Ltd	Hong Kong Intertrade Company, Hong Kong	Hong Kong Intertrade Company Ltd (HKICO) is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. HKICO is a front company controlled by EU-designated National Iranian Oil	22.12.2012

	Name	Identifying information	Reasons	Date of listing
			Company (NIOC). In mid-2012 HKICO was scheduled to receive millions of dollars from NIOC oil sales.	
14.	Petro Suisse	Petro Suisse Avenue De la Tour-Halimand 6, 1009 Pully, Switzerland	Petro Suisse is assisting designated entities to violate the provisions of the EU regulation on Iran and is providing financial support to the government of Iran. It is a front company controlled by EU-designated NIOC. NIOC set up Petro Suisse as a company and would use Petro Suisse accounts to make and receive payments. Petro Suisse continued to be in contact with NIOC in 2012.	22.12.2012
15.	Oil Industry Pension Fund Investment Company	No 234, Taleghani St, Tehran Iran	Iran's Oil Industry Pension Fund Investment Company (OPIC, aka the Oil Pension Fund, NIOC Pension Fund, Petroleum Ministry Pension Fund) is providing financial support to the government of Iran. OPIC operates under the Iranian Ministry of Petroleum and the National Iranian Oil Company (NIOC), both of which are EU-designated. It holds shares in a number of EU-designated entities.	22.12.2012
16.	CF Sharp and Company Private Limited		This entity has been assisting the Irano-Hind Shipping Company (IHSC) (designated by the United Nations on 9 June 2010) in circumventing the sanctions adopted against it. Following its designation, IHSC has tried to conceal its ownership of three tankers, by placing them under the management of Noah Ship Management and then Marian Ship Management. CF Sharp and Co. has contributed to this arrangement by concluding a personnel management contract with IHSC covering the crew of those three tankers. That contract was performed by Noah Ship Management and Marian Ship Management.	22.12.2012
17.	Sharif University of Technology	Azadi Ave, 11365-8639, Tehran, Iran Tel: 98 21 66022727 Fax: 98 21 66036005 Website: www.sharif.ir	Sharif University of Technology (SUT) is assisting designated entities to violate the provisions of UN and EU sanctions on Iran and is providing support to Iran's proliferation sensitive nuclear activities. As of late 2011 SUT had provided laboratories for use by UN-designated Iranian	22.12.2012

	Name	Identifying information	Reasons	Date of listing
			nuclear entity Kalaye Electric Company (KEC) and EU-designated Iran Centrifuge Technology Company (TESA).	
18.	Moallem Insurance Company (also known as: Moallem Insurance; Moallem Insurance Co.; M.I.C; Export and Investment Insurance Co.)	No. 56, Haghani Boulevard, Vanak Square, Tehran 1517973511, Iran PO Box 19395-6314, 11/1 Sharif Ave, Vanaq Square, Tehran 19699, Iran Phone: (98-21) 886776789, 887950512, 887791835 Fax: (98-21) 88771245 Website: www.mic-ir.com	Main insurer of IRISL	22.12.2012"

II. The entries for entities set out in Annex II to Decision 2010/413/CFSP listed below shall be replaced by the entries below:

**"B. Entities**

	Name	Identifying information	Reasons	Date of listing
1.	Technology Cooperation Office (TCO) of the Iranian President's Office (a.k.a. Center for Innovation and Technology (CITC))	Tehran, Iran	Responsible for Iran's technological advancement through relevant foreign procurement and training links. Supports the nuclear and missile programmes.	26.07.2010
2.	Sureh (a.k.a. Soreh) Nuclear Reactors Fuel Company (a.k.a. Nuclear Fuel Reactor Company; Sookht Atomi Reactorhaye Iran; Soukht Atomi Reactorha-ye Iran)	Head Office: 61 Shahid Abtahi St, Karegar e Shomali, Tehran Complex: Persian Gulf Boulevard, Km20 SW Esfahan Road, Esfahan	A company subordinate to the UN-sanctioned Atomic Energy Organisation of Iran (AEOI) consisting of the Uranium Conversion Facility, the Fuel Manufacturing Plant and the Zirconium Production Plant.	23.05.2011
3.	Tidewater (a.k.a. Tidewater Middle East Co.; Faraz Royal Qeshm Company LLC)	Postal address: No 80, Tidewater Building, Vozara Street, next to Saie Park, Tehran, Iran	Owned or controlled by IRGC	23.01.2012"

III. The entities listed below shall be deleted from the list set out in Annex II to Decision 2010/413/CFSP:

1. CF Sharp Shipping Agencies Pte Ltd
2. Soreh (Nuclear Fuel Reactor Company).

## COMMISSION IMPLEMENTING DECISION

of 7 December 2012

**on an additional financial contribution towards Member States' fisheries control, inspection and surveillance programmes for 2012***(notified under document C(2012) 8967)***(Only the Bulgarian, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Spanish and Swedish texts are authentic)**

(2012/830/EU)

THE EUROPEAN COMMISSION,

by operators and/or Member States carrying out investments in traceability projects were defined by the Commission in its letter of 14 May 2012.

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

Having regard to Council Regulation (EC) No 861/2006 of 22 May 2006 establishing Community financial measures for the implementation of the common fisheries policy and in the area of the Law of the Sea <sup>(1)</sup>, and in particular Article 21 thereof,

Whereas:

(1) Based upon the requests for Union co-financing that have been submitted by Member States in their fisheries control programmes for 2012, the Commission has adopted Implementing Decision 2012/294/EU of 25 May 2012 on a Union financial contribution towards Member States' fisheries control, inspection and surveillance programmes for 2012 <sup>(2)</sup>, which has left some of the 2012 budget available unused.

(2) That unused part of the 2012 budget should now be allocated by a new Decision.

(3) In conformity with Article 21(2) of Regulation (EC) No 861/2006, Member States have been asked to submit programmes related to additional funding in the priority areas defined by the Commission in its letter to Member States of 25 April 2012, i.e. projects aiming at improvements in the control system of a Member State as jointly identified by the Member State and the Commission, measurement of engine power, and traceability of fishery products. Requirements to be met

(4) On that basis and given budgetary constraints, requests in the programmes for Union funding related to actions such as pilot projects, the construction or modernisation of patrol vessels and aircrafts, and those training projects having no link with improvements to be brought in the control systems of Member States have been rejected since they were not dedicated to the priority areas defined above. Within the priority areas indicated by the Commission, not all the projects in the programmes could be retained, due to budgetary restraints. The Commission had to select the projects to be co-financed on the basis of the improvements to be brought in the control systems of Member States and of the requirements defined by the Commission for traceability. Applications concerning actions listed in Article 8(1)(a) of Regulation (EC) No 861/2006 may qualify for Union funding.

(5) As to traceability projects, it is important to ensure that they are developed on the basis of internationally recognised standards, as required by Article 67(8) of Commission Implementing Regulation (EU) No 404/2011 <sup>(3)</sup>.

(6) The applications for Union funding have been assessed with regard to their compliance with the rules set out in Commission Regulation (EC) No 391/2007 of 11 April 2007 laying down detailed rules for the implementation of Council Regulation (EC) No 861/2006 as regards the expenditure incurred by Member States in implementing the monitoring and control systems applicable to the Common Fisheries Policy <sup>(4)</sup>.

<sup>(1)</sup> OJ L 160, 14.6.2006, p. 1.

<sup>(2)</sup> OJ L 150, 9.6.2012, p. 86.

<sup>(3)</sup> OJ L 112, 30.4.2011, p. 1.

<sup>(4)</sup> OJ L 97, 12.4.2007, p. 30.



- (7) The Commission has assessed the projects whose cost does not exceed EUR 40 000 VAT excluded, and has retained those for which it is justified to provide for Union co-financing in the light of the improvements they are likely to bring to the control system of the applicant Member States.
- (8) It is appropriate to fix the maximum amounts and the rate of the Union financial contribution within the limits set by Article 15 of Regulation (EC) No 861/2006 and to lay down the conditions under which such contribution may be granted.
- (9) In order to encourage investment in the priority actions defined by the Commission and in view of the negative impact of the financial crisis on Member States' budgets, expenditure related to the abovementioned priority areas should benefit from a high co-financing rate, within the limits laid down in Article 15 of Regulation (EC) No 861/2006.
- (10) In order to qualify for the contribution, projects co-financed on the basis of this Regulation should comply with all the relevant provision of Union legislation and, in particular with Implementing Regulation (EU) No 404/2011.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS DECISION:

#### Article 1

##### Subject matter

This Decision provides for an additional Union financial contribution towards expenditure incurred by Member States for 2012 in implementing monitoring and control systems applicable to the common fisheries policy (CFP), as referred to in Article 8(1)(a) of Regulation (EC) No 861/2006. It establishes the amount of the Union financial contribution for each Member State, the rate of the Union financial contribution and the conditions on which such contribution may be granted.

#### Article 2

##### Closure of outstanding commitments

All payments in respect of which a reimbursement is claimed shall be made by the Member State concerned by 30 June 2016. Payments made by a Member State after that deadline shall not be eligible for reimbursement. Unused budgetary appropriations related to this Decision shall be de-committed at the latest by 31 December 2017.

#### Article 3

##### New technologies & IT networks

1. Expenditure incurred, in respect of projects referred to in Annex I, on the setting up of new technologies and IT networks in order to allow efficient and secure collection and management of data in connection with monitoring, control and surveillance of fisheries activities, shall qualify for a financial contribution of 90 % of the eligible expenditure, within the limits laid down in that Annex.

2. As far as traceability projects are concerned, the EU contribution shall be limited to EUR 1 000 000 in case of investments carried out by Member State authorities, and to EUR 250 000 in case of private investments. The total number of traceability projects carried out by private operators shall be limited to 8 per Member State and per financing decision.

3. In order to qualify for the financial contribution referred to in paragraph 2, all projects co-financed according to this Decision shall satisfy the applicable requirements laid down in Council Regulation (EC) No 1224/2009<sup>(1)</sup> and Implementing Regulation (EU) No 404/2011.

#### Article 4

##### Automatic localisation devices

1. Expenditure incurred, in respect of projects referred to in Annex II, on the purchase and fitting on board of fishing vessels of automatic localisation devices enabling vessels to be monitored at a distance by a fisheries monitoring centre through a vessel monitoring system (VMS) shall qualify for a financial contribution of 90 % of the eligible expenditure, within the limits established in that Annex.

2. The financial contribution referred to in paragraph 1 shall be calculated on the basis of a price capped at EUR 2 500 per vessel.

3. In order to qualify for the financial contribution referred to in paragraph 1, automatic localisation devices shall satisfy the requirements laid down in Implementing Regulation (EU) No 404/2011.

#### Article 5

##### Electronic recording and reporting systems

Expenditure incurred, in respect of projects referred to in Annex III, on the development, purchase, and installation of, as well as technical assistance for, the components necessary for electronic recording and reporting systems (ERS), in order to allow efficient and secure data exchange related to monitoring, control and surveillance of fisheries activities, shall qualify for a financial contribution of 90 % of the eligible expenditure, within the limits laid down in that Annex.

<sup>(1)</sup> OJ L 343, 22.12.2009, p. 1.

## Article 6

**Electronic recording and reporting devices**

1. Expenditure incurred, in respect of projects referred to in Annex IV, on the purchase and fitting on board of fishing vessels of ERS devices enabling vessels to record and report electronically to a Fisheries Monitoring Centre data on fisheries activities, shall qualify for a financial contribution of 90 % of the eligible expenditure, within the limits established in that Annex.

2. The financial contribution referred to in paragraph 1 shall be calculated on the basis of a price capped at EUR 3 000 per vessel, without prejudice of paragraph 4.

3. In order to qualify for a financial contribution, ERS devices shall satisfy the requirements established in Implementing Regulation (EU) No 404/2011.

4. In case of devices combining ERS and VMS functions and fulfilling the requirements laid down in Implementing Regulation (EU) No 404/2011 the financial contribution referred to in paragraph 1 of this Article shall be calculated on the basis of a price capped at EUR 4 500 per vessel.

## Article 7

**Total maximum Union contribution per Member State**

The planned expenditure, the eligible share thereof, and the maximum Union contribution per Member State are as follows:

(EUR)			
Member State	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
<b>Belgium</b>	194 250	94 250	84 825
<b>Bulgaria</b>	30 678	30 678	27 610
<b>Denmark</b>	5 055 113	3 522 171	2 941 347
<b>Germany</b>	4 511 100	425 000	382 500
<b>Ireland</b>	52 005 000	1 000 000	900 000
<b>Greece</b>	1 246 750	1 246 750	1 122 075
<b>Spain</b>	10 528 653	7 029 087	6 326 179
<b>France</b>	4 815 437	3 349 587	3 014 628
<b>Italy</b>	9 299 000	2 880 000	2 592 000
<b>Latvia</b>	76 355	76 355	68 719
<b>Lithuania</b>	150 462	150 462	135 416
<b>Malta</b>	1 098 060	951 860	856 674
<b>Netherlands</b>	2 639 439	250 000	225 000
<b>Austria</b>	409 102	128 179	115 361
<b>Poland</b>	4 771 695	1 516 741	1 365 067
<b>Portugal</b>	2 013 500	1 863 500	1 677 150
<b>Finland</b>	2 560 000	2 280 000	2 052 000
<b>Sweden</b>	2 980 000	2 900 000	2 610 000
<b>United Kingdom</b>	1 284 738	545 284	490 755
<b>Total</b>	<b>105 669 332</b>	<b>30 239 904</b>	<b>26 987 307</b>

*Article 8***Addressees**

This Decision is addressed to the Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the Federal Republic of Germany, Ireland, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Latvia, the Republic of Lithuania, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, the Republic of Finland, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 7 December 2012.

*For the Commission*

Maria DAMANAKI

*Member of the Commission*

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## ANNEX I

## NEW TECHNOLOGIES &amp; IT NETWORKS

(EUR)

Member State & project code	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
<b>Belgium:</b>			
BE/12/08	30 000	30 000	27 000
BE/12/09	4 250	4 250	3 825
BE/12/10	100 000	0	0
<b>Subtotal</b>	<b>134 250</b>	<b>34 250</b>	<b>30 825</b>
<b>Bulgaria:</b>			
BG/12/02	30 678	30 678	27 610
<b>Subtotal</b>	<b>30 678</b>	<b>30 678</b>	<b>27 610</b>
<b>Denmark:</b>			
DK/12/20	336 419	0	0
DK/12/22	269 136	0	0
DK/12/23	538 271	0	0
DK/12/24	134 568	134 568	121 111
DK/12/25	95 637	0	0
DK/12/26	158 911	0	0
DK/12/27	275 864	275 864	248 278
DK/12/28	272 500	272 500	245 250
DK/12/29	281 265	281 265	250 000
DK/12/30	282 592	282 592	250 000
DK/12/31	280 439	280 439	250 000
DK/12/32	296 049	296 049	250 000
DK/12/33	262 407	262 407	235 870
DK/12/34	269 136	269 136	242 222
DK/12/35	22 000	22 000	19 800
DK/12/36	405 000	405 000	250 000
DK/12/37	375 000	375 000	250 000
DK/12/38	163 500	163 500	147 150
<b>Subtotal</b>	<b>4 718 694</b>	<b>3 320 319</b>	<b>2 759 681</b>
<b>Germany:</b>			
DE/12/23	400 000	400 000	360 000
DE/12/24	165 000	0	0
DE/12/25	250 000	0	0
DE/12/27	358 000	0	0
DE/12/28	110 000	0	0
DE/12/29	350 000	0	0
DE/12/30	95 000	0	0
DE/12/31	443 100	0	0
DE/12/32	650 000	0	0
DE/12/33	970 000	0	0

(EUR)			
Member State & project code	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
DE/12/34	275 000	0	0
DE/12/35	420 000	0	0
<b>Subtotal</b>	<b>4 486 100</b>	<b>400 000</b>	<b>360 000</b>
<b>Ireland:</b>			
IE/12/06	20 000	0	0
IE/12/08	70 000	0	0
<b>Subtotal</b>	<b>90 000</b>	<b>0</b>	<b>0</b>
<b>Greece:</b>			
EL/12/11	180 000	180 000	162 000
EL/12/12	750 000	750 000	675 000
EL/12/13	180 000	180 000	162 000
EL/12/14	26 750	26 750	24 075
EL/12/15	110 000	110 000	99 000
<b>Subtotal</b>	<b>1 246 750</b>	<b>1 246 750</b>	<b>1 122 075</b>
<b>Spain:</b>			
ES/12/02	939 263	939 263	845 336
ES/12/03	974 727	974 727	877 255
ES/12/05	795 882	795 883	716 294
ES/12/06	759 305	759 305	683 375
ES/12/08	163 250	163 250	146 925
ES/12/09	72 000	72 000	64 800
ES/12/10	100 000	100 000	90 000
ES/12/11	379 000	379 000	341 100
ES/12/12	490 000	490 000	441 000
ES/12/13	150 000	150 000	135 000
ES/12/15	150 000	0	0
ES/12/18	54 000	54 000	48 600
ES/12/19	290 440	290 440	261 396
ES/12/21	17 500	17 500	15 750
ES/12/22	681 000	0	0
ES/12/23	372 880	372 880	335 592
ES/12/24	415 254	0	0
<b>Subtotal</b>	<b>6 804 501</b>	<b>5 558 247</b>	<b>5 002 423</b>
<b>France:</b>			
FR/12/08	777 600	777 600	699 840
FR/12/09	870 730	870 730	783 656
FR/12/10	229 766	229 766	206 789
FR/12/11	277 395	277 395	249 656
FR/12/12	230 363	230 363	207 327
FR/12/13	197 403	197 403	177 663
FR/12/14	450 000	450 000	405 000
FR/12/15	211 500	0	0
FR/12/16	274 330	274 330	246 897

				(EUR)
Member State & project code	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution	
FR/12/17	254 350	0	0	
<b>Subtotal</b>	<b>3 773 437</b>	<b>3 307 587</b>	<b>2 976 828</b>	
<b>Italy:</b>				
IT/12/13	135 000	135 000	121 500	
IT/12/15	125 000	125 000	112 500	
IT/12/16	withdrawn	0	0	
IT/12/17	250 000	250 000	225 000	
IT/12/18	250 000	0	0	
IT/12/19	630 000	630 000	567 000	
IT/12/21	1 500 000	1 500 000	1 350 000	
IT/12/22	311 000	0	0	
IT/12/23	38 000	0	0	
IT/12/24	1 900 000	0	0	
<b>Subtotal</b>	<b>5 139 000</b>	<b>2 640 000</b>	<b>2 376 000</b>	
<b>Latvia:</b>				
LV/12/02	6 732	6 732	6 058	
LV/12/03	58 350	58 350	52 515	
<b>Subtotal</b>	<b>65 082</b>	<b>65 082</b>	<b>58 573</b>	
<b>Lithuania:</b>				
LT/12/04	150 462	150 462	135 416	
<b>Subtotal</b>	<b>150 462</b>	<b>150 462</b>	<b>135 416</b>	
<b>Malta:</b>				
MT/12/04	30 000	30 000	27 000	
MT/12/07	261 860	261 860	235 674	
<b>Subtotal</b>	<b>291 860</b>	<b>291 860</b>	<b>262 674</b>	
<b>Netherlands:</b>				
NL/12/07	250 000	250 000	225 000	
NL/12/08	278 172	0	0	
NL/12/09	277 862	0	0	
NL/12/10	286 364	0	0	
NL/12/11	276 984	0	0	
NL/12/12	129 398	0	0	
NL/12/13	129 500	0	0	
NL/12/14	200 000	0	0	
NL/12/15	230 000	0	0	
NL/12/16	136 329	0	0	
NL/12/17	19 300	0	0	
NL/12/18	36 120	0	0	
NL/12/19	89 860	0	0	
NL/12/20	299 550	0	0	
<b>Subtotal</b>	<b>2 639 439</b>	<b>250 000</b>	<b>225 000</b>	
<b>Austria:</b>				
AT/12/01	128 179	128 179	115 361	

(EUR)			
Member State & project code	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
AT/12/02	280 923	0	0
<b>Subtotal</b>	<b>409 102</b>	<b>128 179</b>	<b>115 361</b>
<b>Poland:</b>			
PL/12/08	103 936	0	0
PL/12/10	41 028	0	0
PL/12/11	15 955	0	0
PL/12/07	40 500	0	0
PL/12/08	1 000 000	1 000 000	900 000
PL/12/09	172 600	0	0
PL/12/10	1 505 000	0	0
PL/12/11	208 760	0	0
PL/12/12	227 350	0	0
PL/12/13	240 300	0	0
PL/12/14	323 000	323 000	290 700
PL/12/15	181 000	0	0
PL/12/16	416 000	0	0
<b>Subtotal</b>	<b>4 475 429</b>	<b>1 323 000</b>	<b>1 190 700</b>
<b>Portugal:</b>			
PT/12/08	25 000	25 000	22 500
PT/12/10	105 000	150 000	135 000
PT/12/11	150 000	0	0
<b>Subtotal</b>	<b>325 000</b>	<b>175 000</b>	<b>157 500</b>
<b>Finland:</b>			
FI/12/11	1 000 000	1 000 000	900 000
FI/12/12	1 000 000	1 000 000	900 000
FI/12/13	280 000	280 000	252 000
FI/12/14	280 000	0	0
<b>Subtotal</b>	<b>2 560 000</b>	<b>2 280 000</b>	<b>2 052 000</b>
<b>Sweden:</b>			
SE/12/07	850 000	850 000	765 000
SE/12/08	750 000	750 000	675 000
SE/12/09	300 000	300 000	270 000
SE/12/10	1 000 000	1 000 000	900 000
SE/10/11	80 000	0	0
<b>Subtotal</b>	<b>2 980 000</b>	<b>2 900 000</b>	<b>2 610 000</b>
<b>United Kingdom:</b>			
UK/12/51	122 219	122 219	109 997
UK/12/52	564 086	0	0
UK/12/54	50 141	50 141	45 127
UK/12/55	43 873	43 873	39 486
UK/12/56	122 219	122 219	109 997
UK/12/73	12 535	12 535	11 282
UK/12/74	162 958	162 958	146 662
<b>Subtotal</b>	<b>1 078 032</b>	<b>513 945</b>	<b>462 551</b>
<b>Total</b>	<b>41 397 816</b>	<b>24 615 360</b>	<b>21 925 217</b>

## ANNEX II

## AUTOMATIC LOCALISATION DEVICES

(EUR)			
Member State & project code	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
<b>Germany:</b>			
DE/12/22	25 000	25 000	22 500
<b>Subtotal</b>	<b>25 000</b>	<b>25 000</b>	<b>22 500</b>
<b>Spain:</b>			
ES/12/17	1 256 340	0	0
ES/12/20	326 124	0	0
<b>Subtotal</b>	<b>1 582 464</b>	<b>0</b>	<b>0</b>
<b>Italy:</b>			
IT/12/12	240 000	240 000	216 000
IT/12/14	130 000	0	0
IT/12/20	3 400 000	0	0
<b>Subtotal</b>	<b>3 770 000</b>	<b>240 000</b>	<b>216 000</b>
<b>Malta:</b>			
MT/12/03	146 200	0	0
MT/12/05	400 000	400 000	360 000
<b>Subtotal</b>	<b>546 200</b>	<b>400 000</b>	<b>360 000</b>
<b>Total</b>	<b>5 923 664</b>	<b>665 000</b>	<b>598 500</b>



## ANNEX III

## ELECTRONIC RECORDING AND REPORTING SYSTEMS

(EUR)			
Member State & project code	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
<b>Belgium:</b>			
BE/12/07	60 000	60 000	54 000
<b>Subtotal</b>	<b>60 000</b>	<b>60 000</b>	<b>54 000</b>
<b>Denmark:</b>			
DK/12/19	201 852	201 852	181 666
DK/12/21	134 567	0	0
<b>Subtotal</b>	<b>336 419</b>	<b>201 852</b>	<b>181 666</b>
<b>Ireland:</b>			
IE/12/05	1 000 000	1 000 000	900 000
<b>Subtotal</b>	<b>1 000 000</b>	<b>1 000 000</b>	<b>900 000</b>
<b>Spain:</b>			
ES/12/14	1 207 352	1 207 352	1 086 617
ES/12/25	263 488	263 488	237 139
<b>Subtotal</b>	<b>1 470 840</b>	<b>1 470 840</b>	<b>1 323 756</b>
<b>France:</b>			
FR/12/18	42 000	42 000	37 800
<b>Subtotal</b>	<b>42 000</b>	<b>42 000</b>	<b>37 800</b>
<b>Latvia:</b>			
LT/12/01	11 273	11 273	10 146
<b>Subtotal</b>	<b>11 273</b>	<b>11 273</b>	<b>10 146</b>
<b>Malta:</b>			
MT/12/06	260 000	260 000	234 000
<b>Subtotal</b>	<b>260 000</b>	<b>260 000</b>	<b>234 000</b>
<b>Poland:</b>			
PL/12/03	170 948	170 948	153 853
PL/12/05	22 793	22 793	20 514
<b>Subtotal</b>	<b>193 741</b>	<b>193 741</b>	<b>174 367</b>
<b>Portugal:</b>			
PT/12/09	75 000	75 000	67 500
<b>Subtotal</b>	<b>75 000</b>	<b>75 000</b>	<b>67 500</b>
<b>Total</b>	<b>3 449 274</b>	<b>3 314 706</b>	<b>2 983 235</b>

## ANNEX IV

## ELECTRONIC RECORDING AND REPORTING DEVICES

(EUR)

Member State & project code	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
<b>Portugal:</b>			
PT/12/07	1 613 500	1 613 500	1 452 150
<b>Total</b>	<b>1 613 500</b>	<b>1 613 500</b>	<b>1 452 150</b>

## ANNEX V

## TRAINING &amp; EXCHANGE PROGRAMMES

(EUR)

Member State & project code	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
<b>Ireland:</b>			
IE/12/07	15 000	0	0
<b>Subtotal</b>	<b>15 000</b>	<b>0</b>	<b>0</b>
<b>Spain:</b>			
ES/12/16	40 000	0	0
<b>Subtotal</b>	<b>40 000</b>	<b>0</b>	<b>0</b>
<b>United Kingdom:</b>			
UK/12/58	2 507	0	0
UK/12/59	14 416	0	0
UK/12/60	1 253	0	0
UK/12/61	877	0	0
UK/12/62	2 507	0	0
UK/12/63	3 384	0	0
UK/12/64	11 282	0	0
UK/12/65	17 549	0	0
UK/12/66	11 282	0	0
UK/12/67	9 401	9 401	8 461
UK/12/68	9 401	0	0
UK/12/69	11 281	0	0
UK/12/70	9 401	9 401	8 461
UK/12/71	9 401	0	0
UK/12/72	12 535	12 536	11 282
<b>Subtotal</b>	<b>144 030</b>	<b>31 338</b>	<b>28 204</b>
<b>Total</b>	<b>199 030</b>	<b>31 338</b>	<b>28 204</b>

## ANNEX VI

**AMOUNTS RELATED TO PILOT PROJECTS AND TO THE ACQUISITION OR MODERNISATION OF PATROL  
VESSELS AND AIRCRAFT THAT WERE REJECTED**

(EUR)

Type of expenditure	Expenditure planned in the national fisheries control additional programme	Expenditure for projects selected under this Decision	Maximum Union contribution
<b>Pilot projects:</b>			
<i>Subtotal</i>	<b>693 523</b>	<b>0</b>	<b>0</b>
		<b>0</b>	<b>0</b>
<b>Patrol vessels and aircraft</b>			
<i>Subtotal</i>	<b>52 392 525</b>	<b>0</b>	<b>0</b>
<i>Total</i>	<b>53 086 048</b>	<b>0</b>	<b>0</b>

## COMMISSION DECISION

of 20 December 2012

**authorising Spain to extend the temporary suspension of the application of Articles 1 to 6 of Regulation (EU) No 492/2011 of the European Parliament and of the Council on freedom of movement for workers within the Union with regard to Romanian workers**

(2012/831/EU)

THE EUROPEAN COMMISSION,

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

Having regard to the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded <sup>(1)</sup>, and in particular Article 23 and paragraph 7 second subparagraph of Annex VII, Part 1. 'Freedom of movement for persons', thereof,

Having regard to the request from Spain of 13 December 2012,

Whereas:

(1) Spain had been fully applying Articles 1 to 6 of Regulation (EEC) No 1612/68 of the Council of 15 October 1968 on freedom of movement for workers within the Community <sup>(2)</sup> to Romanian nationals since 1 January 2009 when it notified the Commission on 22 July 2011, with reference to a serious disturbance of the Spanish labour market, pursuant to paragraph 7 third subparagraph of Annex VII Part 1 to the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded (hereinafter 'the 2005 Act of Accession'), that it had decided on that day to re-introduce restrictions on labour market access for Romanian workers. Regulation (EEC) No 1612/68 was codified and replaced by Regulation (EU) No 492/2011 of the European Parliament and of the Council of 5 April 2011 on freedom of movement for workers within the Union <sup>(3)</sup>, which entered into force on 16 June 2011.

(2) In response to a request by Spain on 28 July 2011 to the Commission pursuant to paragraph 7 second subparagraph of Annex VII Part 1 to the 2005 Act of Accession to state that Articles 1 to 6 of Regulation (EU) No 492/2011 be wholly suspended in respect of Romanian workers throughout Spain and in all sectors, the Commission authorised Spain by Decision 2011/503/EU <sup>(4)</sup> to limit the free access of Romanian workers to the Spanish labour market until 31 December 2012, subject to certain conditions. This Decision entered into force on 12 August 2011.

(3) Spain asked the Commission by letter of 13 December 2012 to extend the suspension of Articles 1-6 of Regulation (EU) No 492/2011 in respect of Romanian workers until 31 December 2013.

(4) Spain justifies its request by the fact that the two reasons underlying Decision 2011/503/EU remain: the serious disturbance of the Spanish labour market, affecting all regions and sectors; and the labour market situation of Romanian citizens residing in Spain as well as the risk that an unrestricted inflow of Romanian workers would increase pressure on the Spanish labour market.

(5) Spain provides statistical evidence indicating that the economic and labour market situation has further worsened since mid-2011, leading to record levels in unemployment and youth unemployment, and that the economic forecasts point to a contraction of the GDP in 2012 and 2013 and a further increase of unemployment. Moreover, Spain states that the disturbance of the Spanish labour market which seriously threatens levels of employment is of a general nature and not limited to a particular region or sector.

(6) Spain further provides statistical data indicating that the number of Romanian residents in Spain has continued to increase (despite restrictions on free access to the labour market for Romanian workers) and that they numbered 913 405 in September 2012; that the share of Romanian nationals who contribute to the social security system is decreasing; that the numbers of Romanian nationals registered as jobseekers and of those receiving unemployment benefits are relatively high, albeit decreasing, and that their unemployment rate is higher than the average. Spain concludes that the current labour market situation affects its capacity to absorb new inflows of Romanian workers.

(7) According to Paragraph 7 second subparagraph of Annex VII Part 1 to the 2005 Act of Accession a Member State may request the Commission to state within two weeks that the application of Articles 1-6 of Regulation (EU) No 492/2011 be wholly or partially suspended in a given region or occupation.

(8) Analysis in 2011 of the economic data underlying Decision 2011/503/EU showed that Spain was indeed facing a serious labour market disturbance, characterised by the by far highest unemployment rate in the EU (Eurostat monthly unemployment data show 21,0 %, against 9,4 % on average in the EU and 9,9 % in the euro area in June 2011), a particularly dramatic

<sup>(1)</sup> OJ L 157, 21.6.2005, p. 203.

<sup>(2)</sup> OJ L 257, 19.10.1968, p. 2.

<sup>(3)</sup> OJ L 141, 27.5.2011, p. 1.

<sup>(4)</sup> OJ L 207, 12.8.2011, p. 22.

- unemployment among youth (45,7 % in June 2011) and a slow economic recovery (Eurostat figures show GDP growth first quarter 2011 compared with the previous quarter was only 0,3 %, against 0,8 % for the EU and the euro area), hampered in addition by the international financial turbulence requiring Spain to introduce further budget cuts aiming at fiscal consolidation, which could have further short-term negative effects on its scope for economic growth. The impact of the employment decline had been a general one affecting all regions and all sectors of production. Labour force survey data for the period between 2008 and 2010 also showed a general fall in the employment level of 9 %, in the construction sector even of 33 %, affecting all regions, varying between 6 % in the Basque country to 13 % in the Valenciana Autonomous Community.
- (9) Consequently the Commission considered that Spain provided evidence that it was undergoing a labour market disturbance in a generalised way which seriously affected the level of employment in all regions and all sectors and was liable to persist in the near future.
- (10) Moreover, the analysis in 2011 by the Commission established that: Romanian nationals living in Spain were strongly affected by unemployment at a rate of more than 30 % (source: Eurostat Labour force survey data, first quarter 2011). The inflows of Romanian nationals arriving in Spain, despite a certain decrease due to the economic recession, remained at substantial levels, even though there was a low labour demand in Spain. The number of Romanian nationals usually resident in Spain increased from 388 000 on 1 January 2006 to 823 000 on 1 January 2010 (source: Eurostat migration statistics).
- (11) The analysis of the currently available economic data show that the labour market in Spain remains seriously disturbed. The economic downturn continues to have a greater impact on employment in Spain than in other Member States and the data shows that the trend became more pronounced throughout 2011 and the first quarters of 2012. In October 2012, the unemployment rate was around 26,2 %, compared to 21,3 % in June 2011, against 10,7 % on average in the EU in October 2012 (and 9,5 % in June 2011). Moreover, the unemployment rate among young persons is dramatically high at 55,9 % in October 2012, compared to 23,4 % on average in the EU (source: Eurostat monthly unemployment data).
- (12) The adverse economic situation and the resulting labour market disturbances are likely to persist. According to the European Commission economic forecasts, the Spanish GDP is expected to contract in 2012 and 2013 (- 1,4 % for both years) before recovering slightly in 2014 (+ 0,8 %) and the unemployment rate is foreseen to continue to increase and reach 26,6 % in 2013 (and decrease to 26,1 % in 2014). The decline in employment has continued to affect all economic sectors. Between the second quarter 2011 and the third quarter 2012, employment in Spain has contracted by around 980 000 (or - 5,4 %) (source: Eurostat Labour Force Survey). While the construction sector displayed the largest drop (- 293 000 or - 20,5 %), employment in agriculture, manufacturing and the services sector have also decreased. Moreover, all regions are affected by high levels of unemployment (from 12,0 % in Basque country to 30,4 % in Andalusia in 2011, source: Eurostat Labour Force Survey data) and the labour market disturbance is therefore not limited to a particular region.
- (13) Consequently, the Commission considers that Spain has provided evidence that it is still undergoing a labour market disturbance in a generalised way which seriously affects the level of employment in all regions and all sectors and is liable to persist in the near future.
- (14) Moreover, the analysis by the Commission shows that, since Spain re-introduced restrictions on labour market access for Romanian workers, the number of Romanian nationals in Spain has continued to increase, albeit at a slower pace than before: according to Spanish migration statistics, it increased by 11 970 (or + 1,3 %) between 30 September 2011 (901 435) and 30 September 2012 (913 405) whereas it had increased by 83 975 (or + 10,3 %) between 30 September 2010 (817 460) and 30 September 2011 (901 435). Romanian nationals in Spain still experience very high levels of unemployment: 36,4 % in the third quarter 2012 (source: Eurostat Labour Force Survey data).
- (15) It is therefore likely that the full application of EU law on free movement of workers would still be a factor in increasing pressure on the Spanish labour market as it allows for the unrestricted inflow of Romanian workers.
- (16) Therefore, in order to restore the situation of the Spanish labour market to normal, it is appropriate to authorise Spain to continue to temporarily limit the free access of Romanian workers to that labour market. As the transitional arrangements in the 2005 Act of Accession that allow for restrictions on labour market access of Romanian nationals, of which the safeguard clause forms part, are limited in time until 31 December 2013, the authorisation cannot extend beyond that date.
- (17) Restrictions on access to the labour market constitute a derogation from a fundamental principle of the Treaty on the Functioning of the European Union, namely the free movement of workers. In accordance with the well-established case-law of the Court of Justice, such measures should be restrictively interpreted and applied.
- (18) It is at this time appropriate that restrictions should continue to apply for employed activities in the entire territory of Spain and to all sectors in view of the specific current situation in the Spanish labour market and the displacement and other potential spill-over effects between regions and sectors caused by a selective restriction. However, the scope of the derogation can

be reduced, should the Commission ascertain that the relevant particulars underlying such derogation have changed or that its effects prove to be more restrictive than its purpose requires, in particular for employed activities requiring a university degree or equivalent qualifications.

- (19) Equally, though in order for the restrictions authorised by this Decision to have the envisaged effect on the Spanish labour market, it is now considered appropriate that these restrictions remain in place until the end of the transitional period on 31 December 2013, this time-frame may be shortened if the Commission determines that the relevant particulars which led to the adoption of this Decision have changed or that its effects prove to be more restrictive than its purpose requires.
- (20) To that effect, Spain is to provide quarterly to the Commission such statistical data, as will be required to ascertain the evolution of the labour market per sector of activity and occupation. The first quarterly report is to be presented before 31 March 2013.
- (21) The Decision to authorise Spain to continue its restrictions on the free access of Romanian nationals to the Spanish labour market is subject to certain conditions to ensure that those restrictions are strictly limited to what is necessary to the envisaged purpose.
- (22) It is therefore not appropriate to authorise the re-introduction of restrictions in respect of Romanian nationals and their family members who were already employed in the Spanish labour market or who were already registered as jobseekers by the Public Employment Services in Spain on 22 July 2011, that is on the date of notification by Spain of the measures referred to in recital 1.
- (23) The principles governing restrictions on access to the labour market, as laid down in Annex VII Part 1 to the 2005 Act of Accession, such as the standstill clause and the principle of Union preference mentioned in paragraph 14 of Part 1 of that Annex, should also be respected.
- (24) The right of family members of Romanian workers to take up employment in Spain should be governed *mutatis mutandis* by paragraph 8 of Annex VII Part 1 to the 2005 Act of Accession.
- (25) The restrictions on the rights of Romanian nationals and their family members to access the Spanish labour market authorised by this Decision are strictly limited to the scope of this Decision and can in no way affect any other rights that Romanian nationals and their family members enjoy under Union law.
- (26) For monitoring purposes, an obligation to provide the Commission with details of the measures that Spain has taken on the basis of this Decision should be laid down,

HAS ADOPTED THIS DECISION:

*Article 1*

Spain is hereby authorised under the conditions specified in Articles 2 to 4 of this Decision to suspend Articles 1 to 6 of Regulation (EU) No 492/2011 with regard to Romanian nationals until 31 December 2013.

*Article 2*

Without prejudice to the measures introduced by Spain on 22 July 2011 pursuant to paragraph 7 third subparagraph of Annex VII Part 1 to the 2005 Act of Accession, this Decision shall not affect the Romanian nationals and their family members:

who were employed in Spain on 12 August 2011, or

who were registered as jobseekers by the Public Employment Services in Spain on 12 August 2011.

*Article 3*

The application of this Decision shall be subject *mutatis mutandis* to the conditions on transitional arrangements as laid down in Annex VII Part 1 to the 2005 Act of Accession.

*Article 4*

Spain shall take all necessary measures to continue to closely monitor the development of the labour market. It shall provide the Commission with quarterly statistical data evidencing the evolution of the labour market per sector of activity and occupation. The first quarterly report shall be presented before 31 March 2013.

In case of any significant change in the labour market, Spain shall provide the Commission and the Member States without delay with an update of the relevant particulars it has supplied in respect of its request for a Commission decision and in respect of which this Decision is adopted.

*Article 5*

This Decision may be amended or repealed in particular if the relevant particulars referred to in Article 4 and which led to its adoption have changed or that its effects prove to be more restrictive than its purpose requires.

*Article 6*

Spain shall provide the Commission with details of the measures it has taken on the basis of this Decision within two months of receipt thereof.

*Article 7*

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

Done at Brussels, 20 December 2012.

For the Commission

The President

José Manuel BARROSO

**DECISION OF THE EUROPEAN CENTRAL BANK**  
**of 10 December 2012**  
**amending Decision ECB/2010/21 on the annual accounts of the European Central Bank**  
**(ECB/2012/30)**  
**(2012/832/EU)**

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

HAS ADOPTED THIS DECISION:

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Article 26.2 thereof,

*Article 1*

**Amendment**

Whereas:

Article 3 of Decision ECB/2010/21 is replaced by the following:

- (1) Decision ECB/2010/21 of 11 November 2010 on the annual accounts of the European Central Bank <sup>(1)</sup> lays down the rules for drawing up the annual accounts of the European Central Bank (ECB).
- (2) Article 3 of Decision ECB/2010/21 specifies that the basic accounting assumptions defined in Article 3 of Guideline ECB/2010/20 of 11 November 2010 on the legal framework for accounting and financial reporting in the European System of Central Banks <sup>(2)</sup> also apply for the purposes of Decision ECB/2010/21. This applies, inter alia, to Article 3(c) of Guideline ECB/2010/20 in relation to post-balance sheet events, which provides that assets and liabilities are adjusted for events that occur between the annual balance sheet date and the date on which the financial statements are approved by the relevant bodies if they affect the condition of assets or liabilities at the balance sheet date.
- (3) It needs to be clarified for the ECB's annual accounts that post-balance sheet events should only be taken into account until the date when the financial statements are authorised for issue, i.e. the date on which the Executive Board authorises the submission of the ECB's annual accounts to the Governing Council for approval.
- (4) Decision ECB/2010/21 should be amended accordingly,

*'Article 3*

**Basic accounting assumptions**

The basic accounting assumptions defined in Article 3 of Guideline ECB/2010/20 shall also apply for the purposes of this Decision. In derogation from the first sentence of Article 3(c) of Guideline ECB/2010/20, post-balance sheet events shall only be taken into account until the date on which the Executive Board authorises the submission of the ECB's annual accounts to the Governing Council for approval.'

*Article 2*

**Entry into force**

This Decision shall enter into force on 31 December 2012.

Done at Frankfurt am Main, 10 December 2012.

*The President of the ECB*

Mario DRAGHI

<sup>(1)</sup> OJ L 35, 9.2.2011, p. 1.

<sup>(2)</sup> OJ L 35, 9.2.2011, p. 31.

# GUIDELINES

## GUIDELINE OF THE EUROPEAN CENTRAL BANK

of 10 December 2012

### amending Guideline ECB/2010/20 on the legal framework for accounting and financial reporting in the European System of Central Banks

(ECB/2012/29)

(2012/833/EU)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Articles 12.1, 14.3 and 26.4 thereof,

Having regard to the contribution of the General Council of the European Central Bank pursuant to the second and third indents of Article 46.2 of the Statute of the European System of Central Banks and of the European Central Bank,

Whereas:

(1) Guideline ECB/2010/20 of 11 November 2010 on the legal framework for accounting and financial reporting in the European System of Central Banks <sup>(1)</sup> lays down the rules for standardising the accounting and financial reporting of operations undertaken by the national central banks.

(2) Annex IV to Guideline ECB/2010/20 already provides, in non-mandatory terms, under liability item 13 'Provisions' the possibility of establishing provisions for foreign exchange rate, interest rate, credit and gold price risks. In view of the importance of ensuring that national central banks have sufficient financial resources to cover the significant risks arising from their activities and without prejudice to national accounting rules on risk provisions, it is considered necessary to strengthen this option by inserting it in the enacting terms of Guideline ECB/2010/20. The recommendation does not prevent national central banks from maintaining or creating provisions for additional risks according to their national accounting rules.

(3) The financial reporting of emergency liquidity assistance operations should be harmonised and claims resulting

from such operations should be mentioned in Annex IV to Guideline ECB/2010/20 under asset item 6 'Other claims on euro area credit institutions denominated in euro'.

(4) Guideline ECB/2010/20 needs to be amended accordingly,

HAS ADOPTED THIS GUIDELINE:

#### Article 1

#### Amendments

Guideline ECB/2010/20 is amended as follows:

1. The following is added as Article 6a:

#### 'Article 6a

#### **Provision for foreign exchange rate, interest rate, credit and gold price risks**

Taking into due consideration the nature of the activities of the NCBs, an NCB may establish a provision for foreign exchange rate, interest rate, credit and gold price risks on its balance sheet. The NCB shall decide on the size and use of the provision on the basis of a reasoned estimate of the NCB's risk exposure.'

2. Annex IV to Guideline ECB/2010/20 is replaced by the Annex to this Guideline.

#### Article 2

#### Entry into force

This Guideline shall enter into force on 31 December 2012.

<sup>(1)</sup> OJ L 35, 9.2.2011, p. 31.



*Article 3***Addressees**

This Guideline applies to all Eurosystem central banks.

Done at Frankfurt am Main, 10 December 2012.

*For the Governing Council of the ECB*

*The President of the ECB*

Mario DRAGHI

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## ANNEX

## 'ANNEX IV

COMPOSITION AND VALUATION RULES FOR THE BALANCE SHEET <sup>(1)</sup>

## ASSETS

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
1	1	<b>Gold and gold receivables</b>	Physical gold, i.e. bars, coins, plates, nuggets in storage or "under way". Non-physical gold, such as balances in gold sight accounts (unallocated accounts), term deposits and claims to receive gold arising from the following transactions: (a) upgrading or downgrading transactions; and (b) gold location or purity swaps where there is a difference of more than one business day between release and receipt	Market value	Mandatory
2	2	<b>Claims on non-euro area residents denominated in foreign currency</b>	Claims on counterparties resident outside the euro area including international and supranational institutions and central banks outside the euro area denominated in foreign currency		
2.1	2.1	<b>Receivables from the International Monetary Fund (IMF)</b>	<p>(a) <i>Drawing rights within the reserve tranche (net)</i> National quota minus balances in euro at the disposal of the IMF. The No 2 account of the IMF (euro account for administrative expenses) may be included in this item or under the item "Liabilities to non-euro area residents denominated in euro"</p> <p>(b) <i>SDRs</i> Holdings of SDRs (gross)</p> <p>(c) <i>Other claims</i> General arrangements to borrow, loans under special borrowing arrangements, deposits made to trusts under the management of the IMF</p>	<p>(a) <i>Drawing rights within the reserve tranche (net)</i> Nominal value, translation at the foreign exchange market rate</p> <p>(b) <i>SDRs</i> Nominal value, translation at the foreign exchange market rate</p> <p>(c) <i>Other claims</i> Nominal value, translation at the foreign exchange market rate</p>	Mandatory  Mandatory  Mandatory
2.2	2.2	<b>Balances with banks and security investments, external loans and other external assets</b>	<p>(a) <i>Balances with banks outside the euro area other than those under asset item 11.3 "Other financial assets"</i> Current accounts, fixed-term deposits, day-to-day money, reverse repo transactions</p>	<p>(a) <i>Balances with banks outside the euro area</i> Nominal value, translation at the foreign exchange market rate</p>	Mandatory

<sup>(1)</sup> Disclosure relating to euro banknotes in circulation, remuneration of net intra-Eurosystem claims/liabilities resulting from the allocation of euro banknotes within the Eurosystem, and monetary income should be harmonised in NCBs published annual financial statements. The items to be harmonised are indicated with an asterisk in Annexes IV, VIII and IX.

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>
		<p>(b) <i>Security investments outside the euro area other than those under asset item 11.3 "Other financial assets"</i></p> <p>Notes and bonds, bills, zero bonds, money market paper, equity instruments held as part of the foreign reserves, all issued by non-euro area residents</p>	<p>(b) (i) <i>Marketable securities other than held-to-maturity</i></p> <p>Market price and foreign exchange market rate</p> <p>Any premiums or discounts are amortised</p>	Mandatory
			<p>(ii) <i>Marketable securities classified as held-to-maturity</i></p> <p>Cost subject to impairment and foreign exchange market rate</p> <p>Any premiums or discounts are amortised</p>	Mandatory
			<p>(iii) <i>Non-marketable securities</i></p> <p>Cost subject to impairment and foreign exchange market rate</p> <p>Any premiums or discounts are amortised</p>	Mandatory
			<p>(iv) <i>Marketable equity instruments</i></p> <p>Market price and foreign exchange market rate</p>	Mandatory
		<p>(c) <i>External loans (deposits) outside the euro area other than those under asset item 11.3 "Other financial assets"</i></p>	<p>(c) <i>External loans</i></p> <p>Deposits at nominal value translated at the foreign exchange market rate</p>	Mandatory
		<p>(d) <i>Other external assets</i></p> <p>Non-euro area banknotes and coins</p>	<p>(d) <i>Other external assets</i></p> <p>Nominal value, translation at the foreign exchange market rate</p>	Mandatory
3	3	<p><b>Claims on euro area residents denominated in foreign currency</b></p> <p>(a) <i>Security investments inside the euro area other than those under asset item 11.3 "Other financial assets"</i></p> <p>Notes and bonds, bills, zero bonds, money market paper, equity instruments held as part of the foreign reserves, all issued by euro area residents</p>	<p>(a) (i) <i>Marketable securities other than held-to-maturity</i></p> <p>Market price and foreign exchange market rate</p> <p>Any premiums or discounts are amortised</p>	Mandatory
			<p>(ii) <i>Marketable securities classified as held-to-maturity</i></p> <p>Cost subject to impairment and foreign exchange market rate</p> <p>Any premiums or discounts are amortised</p>	Mandatory
			<p>(iii) <i>Non-marketable securities</i></p> <p>Cost subject to impairment and foreign exchange market rate</p> <p>Any premiums or discounts are amortised</p>	Mandatory

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>
			(iv) <i>Marketable equity instruments</i> Market price and foreign exchange market rate	Mandatory
		(b) <i>Other claims on euro area residents other than those under asset item 11.3 "Other financial assets"</i>  Loans, deposits, reverse repo transactions, sundry lending	(b) <i>Other claims</i>  Deposits and other lending at nominal value, translated at the foreign exchange market rate	Mandatory
4	4	<b>Claims on non-euro area residents denominated in euro</b>		
4.1	4.1	<b>Balances with banks, security investments and loans</b>		
		(a) <i>Balances with banks outside the euro area other than those under asset item 11.3 "Other financial assets"</i>  Current accounts, fixed-term deposits, day-to-day money. Reverse repo transactions in connection with the management of securities denominated in euro	(a) <i>Balances with banks outside the euro area</i>  Nominal value	Mandatory
		(b) <i>Security investments outside the euro area other than those under asset item 11.3 "Other financial assets"</i>  Equity instruments, notes and bonds, bills, zero bonds, money market paper, all issued by non-euro area residents	(b) (i) <i>Marketable securities other than held-to-maturity</i>  Market price  Any premiums or discounts are amortised	Mandatory
			(ii) <i>Marketable securities classified as held-to-maturity</i>  Cost subject to impairment  Any premiums or discounts are amortised	Mandatory
			(iii) <i>Non-marketable securities</i>  Cost subject to impairment  Any premiums or discounts are amortised	Mandatory
			(iv) <i>Marketable equity instruments</i>  Market price	Mandatory
		(c) <i>Loans outside the euro area other than those under asset item 11.3 "Other financial assets"</i>	(c) <i>Loans outside the euro area</i>  Deposits at nominal value	Mandatory
		(d) <i>Securities other than those under asset item 11.3 "Other financial assets", issued by entities outside the euro area</i>  Securities issued by supranational or international organisations, e.g. the European Investment Bank, irrespective of their geographical location	(d) (i) <i>Marketable securities other than held-to-maturity</i>  Market price  Any premiums or discounts are amortised	Mandatory

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
			<p>(ii) <i>Marketable securities classified as held-to-maturity</i></p> <p>Cost subject to impairment</p> <p>Any premiums or discounts are amortised</p> <p>(iii) <i>Non-marketable securities</i></p> <p>Cost subject to impairment</p> <p>Any premiums or discounts are amortised</p>	Mandatory	
4.2	4.2	<b>Claims arising from the credit facility under ERM II</b>	Lending according to the ERM II conditions	Nominal value	Mandatory
5	5	<b>Lending to euro area credit institutions related to monetary policy operations denominated in euro</b>	Items 5.1 to 5.5: transactions according to the respective monetary policy instruments described in Annex I to Guideline ECB/2011/14 of 20 September 2011 on monetary policy instruments and procedures of the Eurosystem <sup>(3)</sup>		
5.1	5.1	<b>Main refinancing operations</b>	Regular liquidity-providing reverse transactions with a weekly frequency and normally a maturity of one week	Nominal value or repo cost	Mandatory
5.2	5.2	<b>Longer-term refinancing operations</b>	Regular liquidity-providing reverse transactions with a monthly frequency and normally a maturity of three months	Nominal value or repo cost	Mandatory
5.3	5.3	<b>Fine-tuning reverse operations</b>	Reverse transactions, executed as ad hoc transactions for fine-tuning purposes	Nominal value or repo cost	Mandatory
5.4	5.4	<b>Structural reverse operations</b>	Reverse transactions adjusting the structural position of the Eurosystem vis-à-vis the financial sector	Nominal value or repo cost	Mandatory
5.5	5.5	<b>Marginal lending facility</b>	Overnight liquidity facility at a pre-specified interest rate against eligible assets (standing facility)	Nominal value or repo cost	Mandatory
5.6	5.6	<b>Credits related to margin calls</b>	Additional credit to credit institutions, arising from value increases of underlying assets regarding other credit to these credit institutions	Nominal value or cost	Mandatory

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
6	6	<b>Other claims on euro area credit institutions denominated in euro</b>	Current accounts, fixed-term deposits, day-to-day money, reverse repo transactions in connection with the management of security portfolios under the asset item 7 'Securities of euro area residents denominated in euro', including transactions resulting from the transformation of former foreign currency reserves of the euro area and other claims. Correspondent accounts with non-domestic euro area credit institutions. Other claims and operations unrelated to monetary policy operations of the Eurosystem including Emergency Liquidity Assistance. Any claims stemming from monetary policy operations initiated by an NCB prior to joining the Eurosystem	Nominal value or cost	Mandatory
7	7	<b>Securities of euro area residents denominated in euro</b>			
7.1	7.1	<b>Securities held for monetary policy purposes</b>	Securities issued in the euro area held for monetary policy purposes. ECB debt certificates purchased for fine-tuning purposes	<p>(a) <i>Marketable securities other than held-to-maturity</i> Market price Any premiums or discounts are amortised</p> <p>(b) <i>Marketable securities classified as held-to-maturity</i> Cost subject to impairment (cost when the impairment is covered by a provision under liability item 13 (b) "Provisions") Any premiums or discounts are amortised</p> <p>(c) <i>Non-marketable securities</i> Cost subject to impairment Any premiums or discounts are amortised</p>	<p>Mandatory</p> <p>Mandatory</p> <p>Mandatory</p>
7.2	7.2	<b>Other securities</b>	Securities other than those under asset item 7.1 "Securities held for monetary policy purposes" and under asset item 11.3 "Other financial assets"; notes and bonds, bills, zero bonds, money market paper held outright, including government securities stemming from before EMU, denominated in euro. Equity instruments	<p>(a) <i>Marketable securities other than held-to-maturity</i> Market price Any premiums or discounts are amortised</p> <p>(b) <i>Marketable securities classified as held-to-maturity</i> Cost subject to impairment Any premiums or discounts are amortised</p>	<p>Mandatory</p> <p>Mandatory</p>

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
			(c) <i>Non-marketable securities</i> Cost subject to impairment Any premiums or discounts are amortised	Mandatory	
			(d) <i>Marketable equity instruments</i> Market price	Mandatory	
8	8	<b>General government debt denominated in euro</b>	Claims on government stemming from before EMU (non-marketable securities, loans)	Deposits/loans at nominal value, non-marketable securities at cost	Mandatory
—	9	<b>Intra-Eurosystem claims<sup>+</sup></b>			
—	9.1	<b>Participating interest in ECB<sup>+</sup></b>	Only an NCB balance sheet item The ECB capital share of each NCB in accordance with the Treaty and the respective capital key and contributions in accordance with Article 48.2 of the Statute of the ESCB	Cost	Mandatory
—	9.2	<b>Claims equivalent to the transfer of foreign reserves<sup>+</sup></b>	Only an NCB balance sheet item Euro-denominated claims on the ECB in respect of initial and additional transfers of foreign reserves under Article 30 of the Statute of the ESCB	Nominal value	Mandatory
—	9.3	<b>Claims related to the issuance of ECB debt certificates<sup>+</sup></b>	Only an ECB balance sheet item Intra-Eurosystem claims vis-à-vis NCBs, arising from the issuance of ECB debt certificates	Cost	Mandatory
—	9.4	<b>Net claims related to the allocation of euro banknotes within the Euro-system<sup>+</sup> (*)</b>	For the NCBs: net claim related to the application of the banknote allocation key i.e. including the ECB's banknote issue related intra-Eurosystem balances, the compensatory amount and its balancing accounting entry as defined by Decision ECB/2010/23 of 25 November 2010 on the allocation of monetary income of the national central banks of Member States whose currency is the euro <sup>(4)</sup> For the ECB: claims related to the ECB's banknote issue, in accordance with Decision ECB/2010/29	Nominal value	Mandatory
—	9.5	<b>Other claims within the Euro-system (net)<sup>+</sup></b>	Net position of the following sub-items:  (a) net claims arising from balances of TARGET2 accounts and correspondent accounts of NCBs, i.e. the net figure of claims and liabilities — see also liability item 10.4 "Other liabilities within the Eurosystem (net)"	(a) Nominal value	Mandatory

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
		(b) claim due to the difference between monetary income to be pooled and redistributed. Only relevant for the period between booking of monetary income as part of the year-end procedures, and its settlement on the last working day in January each year	(b) Nominal value	Mandatory	
		(c) other intra-Eurosystem claims denominated in euro that may arise, including the interim distribution of ECB income (*)	(c) Nominal value	Mandatory	
9	10	<b>Items in the course of settlement</b>	Settlement account balances (claims), including the float of cheques in collection	Nominal value	Mandatory
9	11	<b>Other assets</b>			
9	11.1	<b>Coins of euro area</b>	euro coins if an NCB is not the legal issuer	Nominal value	Mandatory
9	11.2	<b>Tangible and intangible fixed assets</b>	Land and buildings, furniture and equipment including computer equipment, software	Cost less depreciation Depreciation rates: — computers and related hardware/software and motor vehicles: 4 years — equipment, furniture and plant in building: 10 years — building and capitalised major refurbishment expenditure: 25 years Capitalisation of expenditure: limit based (below EUR 10 000 excluding VAT: no capitalisation)	Recommended
9	11.3	<b>Other financial assets</b>	— Participating interests and investments in subsidiaries; equities held for strategic/policy reasons  — Securities, including equities, and other financial instruments and balances (e.g. fixed-term deposits and current accounts), held as an earmarked portfolio  — Reverse repo transactions with credit institutions in connection with the management of securities portfolios under this item	(a) <i>Marketable equity instruments</i> Market price  (b) <i>Participating interests and illiquid equity shares, and any other equity instruments held as permanent investments</i> Cost subject to impairment  (c) <i>Investment in subsidiaries or significant interests</i> Net asset value  (d) <i>Marketable securities other than held-to-maturity</i> Market price Any premiums or discounts are amortised	Recommended  Recommended  Recommended  Recommended



Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
			<p>(e) <i>Marketable securities classified as held-to-maturity or held as a permanent investment</i></p> <p>Cost subject to impairment</p> <p>Any premiums or discounts are amortised</p> <p>(f) <i>Non-marketable securities</i></p> <p>Cost subject to impairment</p> <p>Any premiums or discounts are amortised</p> <p>(g) <i>Balances with banks and loans</i></p> <p>Nominal value, translated at the foreign exchange market rate if the balances or deposits are denominated in foreign currencies</p>	<p>Recommended</p> <p>Recommended</p> <p>Recommended</p>	
9	11.4	<b>Off-balance-sheet instruments revaluation differences</b>	Valuation results of foreign exchange forwards, foreign exchange swaps, interest rate swaps, forward rate agreements, forward transactions in securities, foreign exchange spot transactions from trade date to settlement date	Net position between forward and spot, at the foreign exchange market rate	Mandatory
9	11.5	<b>Accruals and prepaid expenditure</b>	Income not due in, but assignable to the reported period. Prepaid expenditure and accrued interest paid (i.e. accrued interest purchased with a security)	Nominal value, foreign exchange translated at market rate	Mandatory
9	11.6	<b>Sundry</b>	<p>Advances, loans and other minor items.</p> <p>Revaluation suspense accounts (only balance sheet item during the year: unrealised losses at revaluation dates during the year, which are not covered by the respective revaluation accounts under the liability item "Revaluation accounts"). Loans on a trust basis. Investments related to customer gold deposits. Coins denominated in national euro area currency units. Current expense (net accumulated loss), loss of the previous year before coverage. Net pension assets</p> <p>Outstanding claims arising from the default of Eurosystem counterparties in the context of Eurosystem credit operations</p> <p>Assets or claims (vis-à-vis third parties) appropriated and/or acquired in the context of the realisation of collateral submitted by Eurosystem counterparties in default</p>	<p>Nominal value or cost</p> <p><i>Revaluation suspense accounts</i></p> <p>Revaluation difference between average cost and market value, foreign exchange translated at market rate</p> <p><i>Investments related to customer gold deposits</i></p> <p>Market value</p> <p><i>Outstanding claims (from defaults)</i></p> <p>Nominal/recoverable value (before/after settlement of losses)</p> <p><i>Assets or claims (from defaults)</i></p> <p>Cost (converted at the foreign exchange market rate at the time of the acquisition if financial assets are denominated in foreign currencies)</p>	<p>Recommended</p> <p>Mandatory</p> <p>Mandatory</p> <p>Mandatory</p> <p>Mandatory</p>

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>
—	12	<b>Loss for the year</b>	Nominal value	Mandatory

(\*) Items to be harmonised. See recital 5 of this Guideline.

<sup>(1)</sup> The numbering in the first column relates to the balance sheet formats given in Annexes V, VI and VII (weekly financial statements and consolidated annual balance sheet of the Eurosystem). The numbering in the second column relates to the balance sheet format given in Annex VIII (annual balance sheet of a central bank). The items marked with a “\*” are consolidated in the Eurosystem’s weekly financial statements.

<sup>(2)</sup> The composition and valuation rules listed in this Annex are considered mandatory for the ECB’s accounts and for all material assets and liabilities in NCBS’ accounts for Eurosystem purposes, i.e. material to the Eurosystem’s operation.

<sup>(3)</sup> OJ L 331, 14.12.2011, p. 1.

<sup>(4)</sup> OJ L 35, 9.2.2011, p. 17.

#### LIABILITIES

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
1	1	<b>Banknotes in circulation</b> (*)	(a) Euro banknotes, plus/minus adjustments relating to the application of the banknote allocation key in accordance with Decision ECB/2010/23 and Decision ECB/2010/29	(a) Nominal value	Mandatory
			(b) Banknotes denominated in national euro area currency units during the cash changeover year	(b) Nominal value	Mandatory
2	2	<b>Liabilities to euro area credit institutions related to monetary policy operations denominated in euro</b>	Items 2.1, 2.2, 2.3 and 2.5: deposits in euro as described in Annex I to Guideline ECB/2011/14		
2.1	2.1	<b>Current accounts (covering the minimum reserve system)</b>	euro accounts of credit institutions that are included in the list of financial institutions subject to minimum reserves in accordance with the Statute of the ESCB. This item contains primarily accounts used in order to hold minimum reserves	Nominal value	Mandatory
2.2	2.2	<b>Deposit facility</b>	Overnight deposits at a pre-specified interest rate (standing facility)	Nominal value	Mandatory
2.3	2.3	<b>Fixed-term deposits</b>	Collection for liquidity absorption purposes owing to fine-tuning operations	Nominal value	Mandatory
2.4	2.4	<b>Fine-tuning reverse operations</b>	Monetary policy-related transactions with the aim of liquidity absorption	Nominal value or repo cost	Mandatory
2.5	2.5	<b>Deposits related to margin calls</b>	Deposits of credit institutions, arising from value decreases of underlying assets regarding credits to these credit institutions	Nominal value	Mandatory

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
3	3	<b>Other liabilities to euro area credit institutions denominated in euro</b>	Repo transactions in connection with simultaneous reverse repo transactions for the management of securities portfolios under asset item 7 "Securities of euro area residents denominated in euro". Other operations unrelated to Eurosystem monetary policy operations. No current accounts of credit institutions. Any liabilities/deposits stemming from monetary policy operations initiated by a central bank prior to joining the Eurosystem	Nominal value or repo cost	Mandatory
4	4	<b>Debt certificates issued</b>	Only an ECB balance sheet item — for the NCBS a transitional balance sheet item. Debt certificates as described in Annex I to Guideline ECB/2011/14. Discount paper, issued with the aim of liquidity absorption	Cost Any discounts are amortised	Mandatory
5	5	<b>Liabilities to other euro area residents denominated in euro</b>			
5.1	5.1	<b>General government</b>	Current accounts, fixed-term deposits, deposits repayable on demand	Nominal value	Mandatory
5.2	5.2	<b>Other liabilities</b>	Current accounts of staff, companies and clients including financial institutions listed as exempt from the obligation to hold minimum reserves (see liability item 2.1 "Current accounts"); fixed-term deposits, deposits repayable on demand	Nominal value	Mandatory
6	6	<b>Liabilities to non-euro area residents denominated in euro</b>	Current accounts, fixed-term deposits, deposits repayable on demand including accounts held for payment purposes and accounts held for reserve management purposes: of other banks, central banks, international/supranational institutions including the European Commission; current accounts of other depositors. Repo transactions in connection with simultaneous reverse repo transactions for the management of securities denominated in euro.  Balances of TARGET2 accounts of central banks of Member States whose currency is not the euro	Nominal value or repo cost	Mandatory
7	7	<b>Liabilities to euro area residents denominated in foreign currency</b>	Current accounts, liabilities under repo transactions; usually investment transactions using foreign currency assets or gold	Nominal value, translation at the foreign exchange market rate	Mandatory
8	8	<b>Liabilities to non-euro area residents denominated in foreign currency</b>			

Balance sheet item <sup>(1)</sup>		Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>	
8.1	8.1	<b>Deposits, balances and other liabilities</b>	Current accounts. Liabilities under repo transactions; usually investment transactions using foreign currency assets or gold	Nominal value, translation at the foreign exchange market rate	Mandatory
8.2	8.2	<b>Liabilities arising from the credit facility under ERM II</b>	Borrowing in accordance with the ERM II conditions	Nominal value, translation at the foreign exchange market rate	Mandatory
9	9	<b>Counterpart of special drawing rights allocated by the IMF</b>	SDR-denominated item which shows the amount of SDRs that were originally allocated to the respective country/NCB	Nominal value, translation at the market rate	Mandatory
—	10	<b>Intra-Eurosystem liabilities<sup>+</sup></b>			
—	10.1	<b>Liabilities equivalent to the transfer of foreign reserves<sup>+</sup></b>	Only an ECB balance sheet item denominated in euro	Nominal value	Mandatory
—	10.2	<b>Liabilities related to the issuance of ECB debt certificates<sup>+</sup></b>	Only an NCB balance sheet item Intra-Eurosystem liability vis-à-vis the ECB, arising from the issuance of ECB debt certificates	Cost	Mandatory
—	10.3	<b>Net liabilities related to allocation of euro banknotes within the Eurosystem<sup>+</sup> (*)</b>	Only an NCB balance sheet item. For the NCBs: net liability related to the application of the banknote allocation key, i.e. including the ECB's banknote issue related intra-Eurosystem balances, the compensatory amount and its balancing accounting entry as defined by Decision ECB/2010/23	Nominal value	Mandatory
—	10.4	<b>Other liabilities within the Eurosystem (net)<sup>+</sup></b>	Net position of the following sub-items:  (a) net liabilities arising from balances of TARGET2 accounts and correspondent accounts of NCBs, i.e. the net figure of claims and liabilities — see also asset item 9.5 "Other claims within the Eurosystem (net)"  (b) liability due to the difference between monetary income to be pooled and redistributed. Only relevant for the period between booking of monetary income as part of the year-end procedures, and its settlement at the last working day in January each year  (c) other intra-Eurosystem liabilities denominated in euro that may arise, including the interim distribution of ECB income (*)	(a) Nominal value  (b) Nominal value  (c) Nominal value	Mandatory  Mandatory  Mandatory
10	11	<b>Items in course of settlement</b>	Settlement account balances (liabilities), including the float of giro transfers	Nominal value	Mandatory



Balance sheet item <sup>(1)</sup>			Categorisation of contents of balance sheet items	Valuation principle	Scope of application <sup>(2)</sup>
11	14	<b>Revaluation accounts</b>	<p>Revaluation accounts related to price movements for gold, for every type of euro-denominated securities, for every type of foreign currency-denominated securities, for options; market valuation differences related to interest rate risk derivatives; revaluation accounts related to foreign exchange rate movements for every currency net position held, including foreign exchange swaps/forwards and SDRs</p> <p>The contributions from NCBs in accordance with Article 48.2 of the Statute of the ESCB to the ECB are consolidated with the respective amounts disclosed under asset item 9.1 "Participating interest in the ECB"<sup>†</sup>)</p>	Revaluation difference between average cost and market value, foreign exchange translated at market rate	Mandatory
12	15	<b>Capital and reserves</b>			
12	15.1	<b>Capital</b>	Paid-up capital — the ECB's capital is consolidated with the capital shares of the NCBs	Nominal value	Mandatory
12	15.2	<b>Reserves</b>	<p>Legal reserves and other reserves. Retained earnings</p> <p>The contributions from NCBs to the ECB in accordance with Article 48.2 of the Statute of the ESCB are consolidated with the respective amounts disclosed under asset item 9.1 "Participating interest in the ECB"<sup>†</sup>)</p>	Nominal value	Mandatory
10	16	<b>Profit for the year</b>		Nominal value	Mandatory

(\*) Items to be harmonised. See recital 5 of this Guideline.

<sup>(1)</sup> The numbering in the first column relates to the balance sheet formats given in Annexes V, VI and VII (weekly financial statements and consolidated annual balance sheet of the Eurosystem). The numbering in the second column relates to the balance sheet format given in Annex VIII (annual balance sheet of a central bank). The items marked with a "†" are consolidated in the Eurosystem's weekly financial statements.

<sup>(2)</sup> The composition and valuation rules listed in this Annex are considered mandatory for the ECB's accounts and for all material assets and liabilities in NCBs' accounts for Eurosystem purposes, i.e. material to the Eurosystem's operation.'

## ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

**DECISION No 2/2012 OF THE JOINT EUROPEAN UNION/SWITZERLAND AIR TRANSPORT  
COMMITTEE SET UP UNDER THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY  
AND THE SWISS CONFEDERATION ON AIR TRANSPORT**

**of 30 November 2012**

**replacing the Annex to the Agreement between the European Community and the Swiss  
Confederation on Air Transport**

(2012/834/EU)

THE EUROPEAN UNION/SWITZERLAND AIR TRANSPORT COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on Air Transport, hereinafter referred to as "the Agreement", and in particular Article 23(4) thereof,

HAS DECIDED AS FOLLOWS:

*Sole Article*

The Annex to this Decision replaces the Annex to the Agreement, as from 1 February 2013.

Done at Geneva, 30 November 2012.

*For the Joint Committee*

*The Head of the European Union Delegation*  
Matthew BALDWIN

*The Head of the Swiss Delegation*  
Peter MÜLLER

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## ANNEX

For the purposes of this Agreement:

- By virtue of the Treaty of Lisbon, entered into force on 1 December 2009, the European Union shall replace and succeed the European Community;
- Wherever acts specified in this Annex contain references to Member States of the European Community, as replaced by the European Union, or a requirement for a link with the latter, the references shall, for the purpose of the Agreement, be understood to apply equally to Switzerland or to the requirement of a link with Switzerland;
- The references to Council Regulations (EEC) No 2407/92 and (EEC) No 2408/92 made in the Articles 4, 15, 18, 27 and 35 of the Agreement, shall be understood as references to Regulation (EC) No 1008/2008 of the European Parliament and of the Council;
- Without prejudice to Article 15 of this Agreement, the term "Community air carrier" referred to in the following Community directives and regulations shall include an air carrier which is licensed and has its principal place of business and, if any, its registered office in Switzerland in accordance with the provisions of Regulation (EC) No 1008/2008. Any reference to Regulation (EEC) No 2407/92 shall be understood as reference to Regulation (EC) No 1008/2008;
- Any reference in the following texts to Articles 81 and 82 of the Treaty or to Articles 101 and 102 of the Treaty on the Functioning of the European Union shall be understood to mean Articles 8 and 9 of this Agreement.

#### 1. Aviation liberalisation and other civil aviation rules

*No 1008/2008*

Regulation of the European Parliament and of the Council of 24 September 2008 on common rules for the operation of air services in the Community

*No 2000/79*

Council Directive of 27 November 2000 concerning the implementation of the European Agreement on the Organisation of Working Time of Mobile Workers in Civil Aviation concluded by the Association of European Airlines (AEA), the European Transport Workers' Federation (ETF), the European Cockpit Association (ECA), the European Regions Airline Association (ERA) and the International Air Carrier Association (IACA)

*No 93/104*

Council Directive of 23 November 1993 concerning certain aspects of the organisation of working time, as amended by:

- Directive 2000/34/EC

*No 437/2003*

Regulation of the European Parliament and of the Council of 27 February 2003 on statistical returns in respect of the carriage of passengers, freight and mail by air

*No 1358/2003*

Commission Regulation of 31 July 2003 implementing Regulation (EC) No 437/2003 of the European Parliament and of the Council on statistical returns in respect of the carriage of passengers, freight and mail by air and amending Annexes I and II thereto

*No 785/2004*

Regulation of the European Parliament and of the Council of 21 April 2004 on insurance requirements for air carriers and aircraft operators, as amended by:

- Commission Regulation (EU) No 285/2010

*No 95/93*

Council Regulation of 18 January 1993 on common rules for the allocation of slots at Community airports (Articles 1-12), as amended by:

- Regulation (EC) No 793/2004



No 2009/12

Directive of the European Parliament and of the Council of 11 March 2009 on airport charges (to be applied by Switzerland as from 1 July 2011)

No 96/67

Council Directive of 15 October 1996 on access to the groundhandling market at Community airports

(Articles 1-9, 11-23, and 25)

No 80/2009

Regulation of the European Parliament and of the Council of 14 January 2009 on a Code of Conduct for computerised reservation systems and repealing Council Regulation (EEC) No 2299/89

## 2. Competition rules

No 3975/87

Council Regulation of 14 December 1987 laying down the procedures for the application of the rules on competition to undertakings in the air transport sector (Article 6(3)), as last amended by:

— Council Regulation (EC) No 1/2003 (Articles 1-13, 15-45)

No 1/2003

Council Regulation of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (Articles 1-13, 15-45)

(To the extent that this Regulation is relevant for the application of this agreement. The insertion of this Regulation does not affect the division of tasks according to this agreement)

Regulation No 17/62 has been repealed by Regulation No 1/2003 with the exception of Article 8(3) which continues to apply to decisions adopted pursuant to Article 81(3) of the Treaty prior to the date of application of this Regulation until the date of expiration of those decisions.

No 773/2004

Commission Regulation of 7 April 2004 relating to proceedings by the Commission pursuant to Articles 81 and 82 of the EC Treaty, as amended by:

— Commission Regulation (EC) No 1792/2006

— Commission Regulation (EC) No 622/2008

No 139/2004

Council Regulation of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation)

(Article 1-18, 19(1)-(2), and 20-23)

With respect to Article 4 (5) of the Merger Regulation the following shall apply between the European Community and Switzerland:

- (1) With regard to a concentration as defined in Article 3 of Regulation (EC) No 139/2004 which does not have a Community dimension within the meaning of Article 1 of that Regulation and which is capable of being reviewed under the national competition laws of at least three EC Member States and the Swiss Confederation, the persons or undertakings referred to in Article 4(2) of that Regulation may, before any notification to the competent authorities, inform the EC Commission by means of a reasoned submission that the concentration should be examined by the Commission.
- (2) The European Commission shall transmit all submissions pursuant to Article 4(5) of Regulation (EC) No 139/2004 and the previous paragraph to the Swiss Confederation without delay.
- (3) Where the Swiss Confederation has expressed its disagreement as regards the request to refer the case, the competent Swiss competition authority shall retain its competence, and the case shall not be referred from the Swiss Confederation pursuant to this paragraph.

With respect to time limits referred to in Articles 4(4) and (5), Articles 9(2) and (6), and Articles 22(2) of the Merger Regulation:

- (1) The European Commission shall transmit all the relevant documents pursuant to Articles 4(4) and (5), Articles 9(2) and (6) and Article 22(2) to the competent Swiss competition authority without delay.
- (2) The calculation of the time limits referred to in Articles 4(4) and (5), Articles 9(2) and (6), and Article 22(2) of Regulation (EC) No 139/2004 shall start, for the Swiss Confederation, upon receipt of the relevant documents by the competent Swiss competition authority.

*No 802/2004*

Commission Regulation of 7 April 2004 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (Articles 1-24), as amended by:

— Commission Regulation (EC) No 1792/2006

— Commission Regulation (EC) No 1033/2008

*No 2006/111*

Commission Directive of 16 November 2006 on the transparency of financial relations between Member States and public undertakings as well as on financial transparency within certain undertakings

*No 487/2009*

Council Regulation (EC) No 487/2009 of 25 May 2009 on the application of Article 81(3) of the Treaty to certain categories of agreements and concerted practices in the air transport sector.

### 3. Aviation safety

*No 216/2008*

Regulation of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC, as amended by:

— Commission Regulation (EC) No 690/2009,

— Regulation (EC) No 1108/2009

The Agency shall enjoy also in Switzerland the powers granted to it under the provisions of the Regulation.

The Commission shall enjoy also in Switzerland the powers granted to it for decisions pursuant to Article 11(2), Article 14(5) and (7), Article 24(5), Article 25(1), Article 38(3)(i), Article 39(1), Article 40(3), Article 41(3) and (5), Article 42(4), Article 54(1) and Article 61(3).

Notwithstanding the horizontal adaptation provided for in the second indent of the Annex to the Agreement between the European Community and the Swiss Confederation on Air Transport, the references to the "Member States" made in Article 65 of the Regulation or in the provisions of Decision 1999/468/EC mentioned in that provision shall not be understood to apply to Switzerland.

Nothing in this Regulation shall be construed so as to transfer to the EASA authority to act on behalf of Switzerland under international agreements for other purposes than to assist in the performance of its obligations pursuant to such agreements.

The text of the Regulation shall, for the purposes of this Agreement, be read with the following adaptations:

(a) Article 12 is amended as follows:

- (i) in paragraph 1, the words "or Switzerland" shall be inserted after the words "the Community";
- (ii) in paragraph 2(a), the words "or Switzerland" shall be inserted after the words "the Community";
- (iii) in paragraphs 2 points (b) and (c) are deleted;
- (iv) the following paragraph is added:

"3. Whenever the Community negotiates with a third country in order to conclude an agreement providing that a Member State or the Agency may issue certificates on the basis of certificates issued by the aeronautical authorities of that third country, it shall endeavour to obtain for Switzerland an offer of a similar agreement with the third country in question. Switzerland shall, in turn, endeavour to conclude with third countries agreements corresponding to those of the Community".

(b) In Article 29, the following paragraph shall be added:

"4. By way of derogation from Article 12(2)(a) of the Conditions of Employment of Other Servants of the European Communities, Swiss nationals enjoying their full rights as citizens may be engaged under contract by the Executive Director of the Agency."

(c) In Article 30, the following paragraph is added:

"Switzerland shall apply to the Agency the Protocol on the Privileges and Immunities of the European Union, which is set out as Annex A to the present Annex, in accordance with the Appendix to Annex A."

(d) In Article 37, the following paragraph is added:

"Switzerland shall participate fully in the Management Board and shall within it have the same rights and obligations as European Union Member States, except for the right to vote".

(e) In Article 59, the following paragraph shall be added:

"12. Switzerland shall participate in the financial contribution referred to in paragraph 1(b), according to the following formula:

$$S (0,2/100) + S [1 - (a + b) 0,2/100] c/C$$

where:

S = the part of the budget of the Agency not covered by the fees and charges mentioned in paragraph 1 (c) and (d)

a = the number of Associated States

b = the number of EU Member States

c = the contribution of Switzerland to the ICAO budget,

C = the total contribution of the EU Member States and of the Associated States to the ICAO budget."

(f) In Article 61, the following paragraph is added:

"The provisions relating to financial control by the Community in Switzerland concerning the participants in the activities of the Agency are set out in Annex B to the present Annex."

(g) Annex II to the Regulation shall be extended to include the following aircraft as products covered by Article 2(3)(a)(ii) of Commission Regulation (EC) No 1702/2003 of 24 September 2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations <sup>(1)</sup>:

A/c - [HB-ID]] – type CL600-2B19

A/c - [HB-IKR, HB-IMY, HB-IWY] – type Gulfstream G-IV

A/c - [HB-IM], HB-IVZ, HB-JES] – type Gulfstream G-V

A/c - [HB-XJF, HB-ZCW, HB-ZDF] – type MD900.

No 1108/2009

Regulation of the European Parliament and of the Council of 21 October 2009 amending Regulation (EC) No 216/2008 in the field of aerodromes, air traffic management and air navigation services and repealing Directive 2006/23/EC

No 805/2011

Commission Regulation of 10 August 2011 laying down detailed rules for air traffic controllers' licences and certain certificates pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council

No 1178/2011

Commission Regulation of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, as amended by:

— Commission Regulation (EU) No 290/2012

No 91/670

Council Directive of 16 December 1991 on mutual acceptance of personnel licences for the exercise of functions in civil aviation

(Articles 1-8)

<sup>(1)</sup> OJ L 243, 27.9.2003, p.6.

*No 3922/91*

Council Regulation of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation (Articles 1-3, 4(2), (5-11, and 13), as amended by:

- Regulation (EC) No 1899/2006,
- Regulation (EC) No 1900/2006,
- Commission Regulation (EC) No 8/2008,
- Commission Regulation (EC) No 859/2008

*No 996/2010*

Regulation of the European Parliament and of the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC

*No 2004/36*

Directive of the Parliament and of the Council of 21 April 2004 on the safety of third-country aircraft using Community airports (Articles 1-9, and 11-14), as last amended by:

- Commission Directive 2008/49/EC

*No 351/2008*

Commission Regulation of 16 April 2008 implementing Directive 2004/36/EC of the European Parliament and of the Council as regards the prioritisation of ramp inspections on aircraft using Community airports

*No 768/2006*

Commission Regulation of 19 May 2006 implementing Directive 2004/36/EC of the European Parliament and of the Council as regards the collection and exchange of information on the safety of aircraft using Community airports and the management of the information system

*No 2003/42*

Directive of the European Parliament and the Council of 13 June 2003 on occurrence reporting in civil aviation (Articles 1-12)

*No 1321/2007*

Commission Regulation of 12 November 2007 laying down implementing rules for the integration into a central repository of information on civil aviation occurrences exchanged in accordance with Directive 2003/42/EC of the European Parliament and of the Council

*No 1330/2007*

Commission Regulation of 24 September 2007 laying down implementing rules for the dissemination to interested parties of information on civil aviation occurrences referred to in Article 7(2) of Directive 2003/42/EC of the European Parliament and of the Council

*No 736/2006*

Commission Regulation of 16 May 2006 on working methods of the European Aviation Safety Agency for conducting standardisation inspections

*No 1702/2003*

Regulation of 24 September 2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations, as amended by:

- Commission Regulation (EC) No 335/2007,
- Commission Regulation (EC) No 381/2005,
- Commission Regulation (EC) No 375/2007,
- Commission Regulation (EC) No 706/2006,

- Commission Regulation (EC) No 287/2008,
- Commission Regulation (EC) No 1057/2008,
- Commission Regulation (EC) No 1194/2009,
- Commission Implementing Regulation (EU) No 90/2012

For the purposes of this Agreement, the provisions of the Regulation shall be read subject to the following adjustment:

Article 2 is amended as follows:

In paragraphs 3, 4, 6, 8, 10, 11, 13 and 14, the date "28 September 2003" shall be replaced by "the date of entry into force of the Decision of the Community/Switzerland Air Transport Committee which incorporates Regulation (EC) No 216/2008 into the Annex to the Regulation."

*No 2042/2003*

Commission Regulation of 20 November 2003 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks, as amended by:

- Commission Regulation (EC) No 707/2006,
- Commission Regulation (EC) No 376/2007,
- Commission Regulation (EC) No 1056/2008,
- Commission Regulation (EU) No 127/2010,
- Commission Regulation (EU) No 962/2010,
- Commission Regulation (EU) No 1149/2011,
- Commission Regulation (EU) No 593/2012

*No 104/2004*

Commission Regulation of 22 January 2004 laying down rules on the organisation and composition of the Board of Appeal of the European Aviation Safety Agency

*No 593/2007*

Commission Regulation of 31 May 2007 on the fees and charges levied by the European Aviation Safety Agency, as last amended by:

- Commission Regulation (EC) No 1356/2008,
- Commission Regulation (EU) No 494/2012

*No 2111/2005*

Regulation of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating air carrier, and repealing Article 9 of directive 2004/36/EC

*No 473/2006*

Commission Regulation of 22 March 2006 laying down implementing rules for the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council

*No 474/2006*

Commission Regulation of 22 March 2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council, as last amended by:

- Commission Implementing Regulation (EU) No 295/2012 <sup>(1)</sup>

*No 1332/2011*

Commission Regulation of 16 December 2011 laying down common airspace usage requirements and operating procedures for airborne collision avoidance

*No 646/2012*

Commission Implementing Regulation of 16 July 2012 laying down detailed rules on fines and periodic penalty payments pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council

<sup>(1)</sup> This Regulation shall apply in Switzerland as long as it is in force in the EU

No 748/2012

Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations

#### 4. Aviation Security

No 300/2008

Regulation of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002

No 272/2009

Commission Regulation of 2 April 2009 supplementing the common basic standards on civil aviation security laid down in the Annex to Regulation (EC) No 300/2008 of the European Parliament and of the Council, as amended by:

- Commission Regulation (EU) No 297/2010,
- Commission Regulation (EU) No 720/2011,
- Commission Regulation (EU) No 1141/2011

No 1254/2009

Commission Regulation (EU) of 18 December 2009 setting criteria to allow Member States to derogate from the common basic standards on civil aviation security and to adopt alternative security measures

No 18/2010

Commission Regulation (EU) of 8 January 2010 amending Regulation (EC) No 300/2008 of the European Parliament and of the Council as far as specifications for national quality control programmes in the field of civil aviation security are concerned

No 72/2010

Commission Regulation (EU) of 26 January 2010 laying down procedures for conducting Commission inspections in the field of aviation security

No 185/2010

Commission Regulation (EU) of 4 March 2010 laying down detailed measures for the implementation of the common basic standards on aviation security, as amended by:

- Commission Regulation (EU) No 357/2010,
- Commission Regulation (EU) No 358/2010,
- Commission Regulation (EU) No 573/2010,
- Commission Regulation (EU) No 983/2010,
- Commission Regulation (EU) No 334/2011,
- Commission Implementing Regulation (EU) No 859/2011,
- Commission Implementing Regulation (EU) No 1087/2011,
- Commission Implementing Regulation (EU) No 1147/2011,
- Commission Implementing Regulation (EU) No 173/2012,
- Commission Implementing Regulation (EU) No 711/2012,
- Commission Implementing Regulation (EU) No 1082/2012

No 2010/774

Commission Decision (EU) of 13 April 2010 laying down detailed measures for the implementation of the common basic standards on aviation security containing information as referred to in Point (a) of Article 18 of Regulation (EC) No 300/2008, as amended by:

- Commission Decision 2010/2604/EU,
- Commission Decision 2010/3572/EU,

- Commission Decision 2010/9139/EU,
- Commission Implementing Decision 2011/5862/EU,
- Commission Implementing Decision 2011/8042/EU,
- Commission Implementing Decision 2011/9407/EU,
- Commission Implementing Decision 2012/1228/EU,
- Commission Implementing Decision 2012/5672/EU,
- Commission Implementing Decision 2012/5880/EU.

#### 5. Air traffic management

*No 549/2004*

Regulation of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the Single European Sky (the Framework Regulation), as amended by:

- Regulation (EC) No 1070/2009

The Commission shall enjoy in Switzerland the powers granted to it pursuant to Articles 6, 8, 10, 11 and 12.

Article 10 shall be amended as follows:

In paragraph 2, the words "at Community level" should be replaced by words "at Community level, involving Switzerland".

Notwithstanding the horizontal adjustment referred to in the second indent of the Annex to the Agreement between the European Community and the Swiss Confederation on Air Transport, the references to the "Member States" made in Article 5 of Regulation (EC) No 549/2004 or in the provisions of Decision 1999/468/EC mentioned in that provision shall not be understood to apply to Switzerland.

*No 550/2004*

Regulation of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the Single European Sky (the Service Provision Regulation), as amended by:

- Regulation (EC) No 1070/2009

The Commission shall enjoy towards Switzerland the powers granted to it pursuant to Articles 9a, 9b, 15a, 16 and 17.

The provisions of the Regulation shall, for the purposes of this Agreement, be amended as follows:

- (a) Article 3 shall be amended as follows:

In paragraph 2, the words "and Switzerland" shall be inserted after the words "the Community".

- (b) Article 7 is amended as follows:

In paragraph 1 and paragraph 6, the words "and Switzerland" shall be inserted after the words "the Community".

- (c) Article 8 is amended as follows:

In paragraph 1, the words "and Switzerland" shall be inserted after the words "the Community".

- (d) Article 10 is amended as follows:

In paragraph 1, the words "and Switzerland" shall be inserted after the words "the Community".

- (e) Article 16(3) is replaced by the following:

"3. The Commission shall address its decision to the Member States and inform the service provider thereof, in so far as it is legally concerned."

*No 551/2004*

Regulation of the European Parliament and of the Council of 10 March 2004 on the organisation and use of the airspace in the Single European Sky (the Airspace Regulation), as amended by:

- Regulation (EC) No 1070/2009

The Commission shall enjoy in Switzerland the powers granted to it pursuant to Articles 3a, 6 and 10.

No 552/2004

Regulation of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the Interoperability Regulation), as amended by:

— Regulation (EC) No 1070/2009

The Commission shall enjoy in Switzerland the powers granted to it pursuant to Articles 4, 7 and 10(3).

The provisions of the Regulation shall, for the purposes of this Agreement, be amended as follows:

(a) Article 5 is amended as follows:

In paragraph 2, the words "or Switzerland" shall be inserted after the words "the Community".

(b) Article 7 is amended as follows:

In paragraph 4, the words "or Switzerland" shall be inserted after the words "the Community".

(c) Annex III shall be amended as follows:

In section 3, second and last indents, the words "or Switzerland" shall be inserted after the words "the Community".

No 2150/2005

Commission Regulation of 23 December 2005 laying down common rules for the flexible use of airspace

No 1033/2006

Commission Regulation of 4 July 2006 laying down the requirements on procedures for flight plans in the pre-flight phase for the Single European Sky, as last amended by:

— Commission Regulation (EU) No 929/2010

No 1032/2006

Commission Regulation of 6 July 2006 laying down requirements for automatic systems for the exchange of flight data for the purpose of notification, coordination and transfer of flights between air traffic control units, as last amended by:

— Commission Regulation (EC) No 30/2009

No 1794/2006

Commission Regulation of 6 December 2006 laying down a common charging scheme for air navigation services (to be applied by Switzerland as from the entry into force of the relevant Swiss legislation but at the latest as from 1 January 2012), as last amended by:

— Commission Regulation (EU) No 1191/2010

No 2006/23

Directive of the European Parliament and of the Council of 5 April 2006 on a Community air traffic controller licence

No 730/2006

Commission Regulation of 11 May 2006 on airspace classification and access of flights operated under visual flight rules above flight level 195

No 219/2007

Council Regulation of 27 February 2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR), as last amended by:

— Council Regulation (EC) No 1361/2008

No 633/2007

Commission Regulation of 7 June 2007 laying down requirements for the application of a flight message transfer protocol used for the purpose of notification, coordination and transfer of flights between air traffic control units, as amended by:

— Commission Regulation (EU) No 283/2011

No 1265/2007

Commission Regulation of 26 October 2007 laying down requirements on air-ground voice channel spacing for the Single European Sky



No 482/2008

Commission Regulation of 30 May 2008 establishing a software safety assurance system to be implemented by air navigation service providers and amending Annex II to Regulation (EC) N° 2096/2005

No 29/2009

Commission Regulation of 16 January 2009 laying down requirements on data link services for the Single European Sky

The text of the Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

"Switzerland UIR" is added in Annex I, part A.

No 262/2009

Commission Regulation of 30 March 2009 laying down requirements for the coordinated allocation and use of Mode S interrogator codes for the Single European Sky

No 73/2010

Commission Regulation of 26 January 2010 laying down requirements on the quality of aeronautical data and aeronautical information for the Single European Sky

No 255/2010

Commission Regulation of 25 March 2010 laying down common rules on air traffic flow management

No 691/2010

Commission Regulation of 29 July 2010 laying down a performance scheme for air navigation services and network functions and amending Regulation (EC) N° 2096/2005 laying down common requirements for the provision of air navigation services, as amended by:

— Commission Implementing Regulation (EU) No 1216/2011

Corrective measures adopted by the Commission under Article 14 paragraph 3 of the Regulation are mandatory for Switzerland after having been adopted by a decision of the Joint Committee

No 2010/5134

Commission Decision of 29 July 2010 on the designation of the Performance Review Body of the Single European Sky

No 2010/5110

Commission Decision of 12 August 2010 on the designation of a functional airspace blocks system coordinator in the context of the Single European Sky

No 176/2011

Commission Regulation of 24 February 2011 on the information to be provided before the establishment and modification of a functional airspace block

No 2011/121

Commission Decision of 21 February 2011 setting the European Union-wide performance targets and alert thresholds for the provision of air navigation services for the years 2012 to 2014

No 677/2011

Commission Regulation of 7 July 2011 laying down detailed rules for the implementation of air traffic management (ATM) network functions and amending Regulation (EU) No 691/2010

No 2011/4130

Commission Decision of 7 July 2011 on the nomination of the Network Manager for the air traffic management (ATM) network functions of the single European sky

No 1034/2011

Commission Implementing Regulation of 17 October 2011 on safety oversight in air traffic management and air navigation services and amending Regulation (EU) No 691/2010

No 1035/2011

Commission Implementing Regulation of 17 October 2011 laying down common requirements for the provision of air navigation services and amending Regulations (EC) No 482/2008 and (EU) No 691/2010

No 1206/2011

Commission Implementing Regulation of 22 November 2011 laying down requirements on aircraft identification for surveillance for the single European sky

The text of the Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

"Switzerland UIR" is added in Annex I.

No 1207/2011

Commission Implementing Regulation of 22 November 2011 laying down requirements for the performance and the interoperability of surveillance for the single European sky

## 6. Environment and noise

No 2002/30

Directive of the European Parliament and of the Council of 26 March 2002 on the establishment of rules and procedures with regard to the introduction of noise-related operating restrictions at Community airports (Articles 1-12, and 14-18)

(The amendments to Annex I, arising from Annex II, Chapter 8 (Transport policy), Section G (Air transport), point 2 of the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded, shall apply).

No 89/629

Council Directive of 4 December 1989 on the limitation of noise emissions from civil subsonic jet aeroplanes

(Articles 1-8)

No 2006/93/EC

Directive of the European Parliament and of the Council of 12 December 2006 on the regulation of the operation of aeroplanes covered by Part II, Chapter 3, Volume 1 of Annex 16 to the Convention on International Civil Aviation, second edition (1988).

## 7. Consumer protection

No 90/314

Council Directive of 13 June 1990 on package travel, package holidays and package tours.

(Articles 1-10)

No 93/13

Council Directive of 5 April 1993 on unfair terms in consumer contracts.

(Articles 1-11)

No 2027/97

Council Regulation of 9 October 1997 on air carrier liability in the event of accidents (Articles 1-8), as amended by:

— Regulation (EC) No 889/2002

No 261/2004

Regulation of the Parliament and of the Council of 11 February 2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights, and repealing Regulation (EEC) No 295/91

(Articles 1-18)

No 1107/2006

Regulation of the European Parliament and of the Council of 5 July 2006 concerning the right of disabled persons and persons with reduced mobility when travelling by air.

**8. Miscellaneous**

*No 2003/96*

Council Directive of 27 October 2003 restructuring the Community framework for the taxation of energy products and electricity

(Article 14(1)(b), and Article 14(2).

**9. Annexes**

A: Protocol on the Privileges and Immunities of the European Union

B: Provisions on financial control by the European Union as regards Swiss participants in activities of the EASA

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## ANNEX A

**PROTOCOL ON THE PRIVILEGES AND IMMUNITIES OF THE EUROPEAN UNION**

THE HIGH CONTRACTING PARTIES,

CONSIDERING that, in accordance with Article 343 of the Treaty on the Functioning of the European Union and Article 191 of the Treaty establishing the European Atomic Energy Community (EAEC), the European Union and the EAEC shall enjoy in the territories of the Member States such privileges and immunities as are necessary for the performance of their tasks,

HAVE AGREED upon the following provisions, which shall be annexed to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community:

## CHAPTER I

**PROPERTY, FUNDS, ASSETS AND OPERATIONS OF THE EUROPEAN UNION***Article 1*

The premises and buildings of the Union shall be inviolable. They shall be exempt from search, requisition, confiscation or expropriation. The property and assets of the Union shall not be the subject of any administrative or legal measure of constraint without the authorisation of the Court of Justice.

*Article 2*

The archives of the Union shall be inviolable.

*Article 3*

The Union, its assets, revenues and other property shall be exempt from all direct taxes.

The governments of the Member States shall, wherever possible, take the appropriate measures to remit or refund the amount of indirect taxes or sales taxes included in the price of movable or immovable property, where the Union makes, for its official use, substantial purchases the price of which includes taxes of this kind. These provisions shall not be applied, however, so as to have the effect of distorting competition within the Union.

No exemption shall be granted in respect of taxes and dues which amount merely to charges for public utility services.

*Article 4*

The Union shall be exempt from all customs duties, prohibitions and restrictions on imports and exports in respect of articles intended for its official use: articles so imported shall not be disposed of, whether or not in return for payment, in the territory of the country into which they have been imported, except under conditions approved by the government of that country.

The Union shall also be exempt from any customs duties and any prohibitions and restrictions on import and exports in respect of its publications.

## CHAPTER II

**COMMUNICATIONS AND LAISSEZ-PASSER***Article 5*

For their official communications and the transmission of all their documents, the institutions of the Union shall enjoy in the territory of each Member State the treatment accorded by that State to diplomatic missions.

Official correspondence and other official communications of the institutions of the Union shall not be subject to censorship.

*Article 6*

*Laissez-passer* in a form to be prescribed by the Council, acting by a simple majority, which shall be recognised as valid travel documents by the authorities of the Member States, may be issued to members and servants of the institutions of the Union by the Presidents of these institutions. These *laissez-passer* shall be issued to officials and other servants under conditions laid down in the Staff Regulations of officials and the Conditions of Employment of other servants of the Union.

The Commission may conclude agreements for these *laissez-passer* to be recognised as valid travel documents within the territory of third countries.

### CHAPTER III

#### MEMBERS OF THE EUROPEAN PARLIAMENT

##### Article 7

No administrative or other restriction shall be imposed on the free movement of Members of the European Parliament travelling to or from the place of meeting of the European Parliament.

Members of the European Parliament shall, in respect of customs and exchange control, be accorded:

- (a) by their own government, the same facilities as those accorded to senior officials travelling abroad on temporary official missions;
- (b) by the government of other Member States, the same facilities as those accorded to representatives of foreign governments on temporary official missions.

##### Article 8

Members of the European Parliament shall not be subject to any form of inquiry, detention or legal proceedings in respect of opinions expressed or votes cast by them in the performance of their duties.

##### Article 9

During the sessions of the European Parliament, its Members shall enjoy:

- (a) in the territory of their own State, the immunities accorded to members of their parliament;
- (b) in the territory of any other Member State, immunity from any measure of detention and from legal proceedings.

Immunity shall likewise apply to Members while they are travelling to and from the place of meeting of the European Parliament.

Immunity cannot be claimed when a Member is found in the act of committing an offence and shall not prevent the European Parliament from exercising its right to waive the immunity of one of its Members.

### CHAPTER IV

#### REPRESENTATIVES OF MEMBER STATES TAKING PART IN THE WORK OF THE INSTITUTIONS OF THE EUROPEAN UNION

##### Article 10

Representatives of Member States taking part in the work of the institutions of the Union, their advisers and technical experts shall, in the performance of their duties and during their travel to and from the place of meeting, enjoy the customary privileges, immunities and facilities.

This Article shall also apply to members of the advisory bodies of the Union.

### CHAPTER V

#### OFFICIALS AND OTHER SERVANTS OF THE EUROPEAN UNION

##### Article 11

In the territory of each Member State and whatever their nationality, officials and other servants of the Union shall:

- (a) subject to the provisions of the Treaties relating, on the one hand, to the rules on the liability of officials and other servants towards the Union and, on the other hand, to the jurisdiction of the Court of Justice of the European Union in disputes between the Union and its officials and other servants, be immune from legal proceedings in respect of acts performed by them in their official capacity, including their words spoken or written. They shall continue to enjoy this immunity after they have ceased to hold office;
- (b) together with their spouses and dependent members of their families, not be subject to immigration restrictions or to formalities for the registration of aliens;
- (c) in respect of currency or exchange regulations, be accorded the same facilities as are customarily accorded to officials of international organisations;

- (d) enjoy the right to import free of duty their furniture and effects at the time of first taking up their post in the country concerned, and the right to re-export free of duty their furniture and effects, on termination of their duties in that country, subject in either case to the conditions considered to be necessary by the government of the country in which this right is exercised;
- (e) have the right to import free of duty a motor car for their personal use, acquired either in the country of their last residence or in the country of which they are nationals on the terms ruling in the home market in that country, and to re-export it free of duty, subject in either case to the conditions considered to be necessary by the government of the country concerned.

#### *Article 12*

Officials and other servants of the Union shall be liable to a tax for the benefit of the Union on salaries, wages and emoluments paid to them by the Union, in accordance with the conditions and procedure laid down by the European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure and after consultation of the institutions concerned.

They shall be exempt from national taxes on salaries, wages and emoluments paid by the Union.

#### *Article 13*

In the application of income tax, wealth tax and death duties and in the application of conventions on the avoidance of double taxation concluded between Member States of the Union, officials and other servants of the Union who, solely by reason of the performance of their duties in the service of the Union, establish their residence in the territory of a Member State other than their country of domicile for tax purposes at the time of entering the service of the Union, shall be considered, both in the country of their actual residence and in the country of domicile for tax purposes, as having maintained their domicile in the latter country provided that it is a member of the Union. This provision shall also apply to a spouse, to the extent that the latter is not separately engaged in a gainful occupation, and to children dependent on and in the care of the persons referred to in this Article.

Movable property belonging to persons referred to in the preceding paragraph and situated in the territory of the country where they are staying shall be exempt from death duties in that country; such property shall, for the assessment of such duty, be considered as being in the country of domicile for tax purposes, subject to the rights of third countries and to the possible application of provisions of international conventions on double taxation.

Any domicile acquired solely by reason of the performance of duties in the service of other international organisations shall not be taken into consideration in applying the provisions of this Article.

#### *Article 14*

The European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure and after consultation of the institutions concerned, shall lay down the scheme of social security benefits for officials and other servants of the Union.

#### *Article 15*

The European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, and after consulting the other institutions concerned, shall determine the categories of officials and other servants of the Union to whom the provisions of Article 11, the second paragraph of Article 12, and Article 13 shall apply, in whole or in part.

The names, grades and addresses of officials and other servants included in such categories shall be communicated periodically to the governments of the Member States.

### CHAPTER VI

#### **PRIVILEGES AND IMMUNITIES OF MISSIONS OF THIRD COUNTRIES ACCREDITED TO THE EUROPEAN UNION**

#### *Article 16*

The Member State in whose territory the Union has its seat shall accord the customary diplomatic immunities and privileges to missions of third countries accredited to the Union.

## CHAPTER VII

**GENERAL PROVISIONS***Article 17*

Privileges, immunities and facilities shall be accorded to officials and other servants of the Union solely in the interests of the Union.

Each institution of the Union shall be required to waive the immunity accorded to an official or other servant wherever that institution considers that the waiver of such immunity is not contrary to the interests of the Union.

*Article 18*

The institutions of the Union shall, for the purpose of applying this Protocol, cooperate with the responsible authorities of the Member States concerned.

*Article 19*

Articles 11 to 14 and Article 17 shall apply to Members of the Commission.

*Article 20*

Articles 11 to 14 and Article 17 shall apply to the Judges, the Advocates-General, the Registrars and the Assistant Rapporteurs of the Court of Justice of the European Union, without prejudice to the provisions of Article 3 of the Protocol on the Statute of the Court of Justice of the European Union relating to immunity from legal proceedings of Judges and Advocates-General.

*Article 21*

This Protocol shall also apply to the European Investment Bank, to the members of its organs, to its staff and to the representatives of the Member States taking part in its activities, without prejudice to the provisions of the Protocol on the Statute of the Bank.

The European Investment Bank shall in addition be exempt from any form of taxation or imposition of a like nature on the occasion of any increase in its capital and from the various formalities which may be connected therewith in the State where the Bank has its seat. Similarly, its dissolution or liquidation shall not give rise to any imposition. Finally, the activities of the Bank and of its organs carried on in accordance with its Statute shall not be subject to any turnover tax.

*Article 22*

This Protocol shall also apply to the European Central Bank, to the members of its organs and to its staff, without prejudice to the provisions of the Protocol on the Statute of the European System of Central Banks and the European Central Bank.

The European Central Bank shall, in addition, be exempt from any form of taxation or imposition of a like nature on the occasion of any increase in its capital and from the various formalities which may be connected therewith in the State where the bank has its seat. The activities of the Bank and of its organs carried on in accordance with the Statute of the European System of Central Banks and of the European Central Bank shall not be subject to any turnover tax.

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*Appendix***PROCEDURES FOR THE APPLICATION IN SWITZERLAND OF THE PROTOCOL ON PRIVILEGES AND IMMUNITIES OF THE EUROPEAN UNION**

## 1. Extension of application to Switzerland

Wherever the Protocol on the privileges and immunities of the European Union (hereinafter called "the Protocol") contains references to Member States, the references are to be understood to apply equally to Switzerland, unless the following provisions determine otherwise.

## 2. Exemption of the Agency from indirect taxation (including VAT)

Goods and services exported from Switzerland are not to be subject to Swiss value added tax (VAT). In the case of goods and services provided to the Agency in Switzerland for its official use, in accordance with the second paragraph of Article 3 of the Protocol, exemption from VAT is by way of refund. Exemption from VAT shall be granted if the actual purchase price of the goods and services mentioned in the invoice or equivalent document totals at least 100 Swiss francs (inclusive of tax).

The VAT refund is to be granted on presentation to the Federal Tax Administration's VAT Main Division of the Swiss forms provided for the purpose. As a rule, refund applications must be processed within the three months following the date on which they were lodged together with the necessary supporting documents.

## 3. Procedures for the application of the rules relating to the Agency's staff

As regards the second paragraph of Article 12 of the Protocol, Switzerland shall exempt, according to the principles of its national law, officials and other servants of the Agency within the meaning of Article 2 of Regulation (Euratom, ECSC, EEC) No 549/69 <sup>(1)</sup> from federal, cantonal and communal taxes on salaries, wages and emoluments paid to them by the European Union and subject to an internal tax for its own benefit.

Switzerland shall not be considered as a Member State within the meaning of point 1 above for the application of Article 13 of the Protocol.

Officials and other servants of the Agency and members of their families who are members of the social insurance system applicable to officials and other servants of the European Union are not obliged to be members of the Swiss social security system.

The Court of Justice of the European Union shall have exclusive jurisdiction in any matters concerning relations between the Agency or the Commission and its staff with regard to the application of Council Regulation (EEC, Euratom, ECSC) No 259/68 <sup>(2)</sup> and the other provisions of the European Union law laying down working conditions.

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<sup>(1)</sup> Regulation (Euratom, ECSC, EEC) No 549/69 of the Council of 25 March 1969 determining the categories of officials and other servants of the European Communities to whom the provisions of Article 12, the second paragraph of Article 13 and Article 14 of the Protocol on the Privileges and Immunities of the Communities apply (OJ L 74, 27.3.1969, p. 1). Regulation last amended by Commission Regulation (EC) No 1749/2002 (OJ L 264, 2.10.2002, p. 13.)

<sup>(2)</sup> Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities and instituting special measures temporarily applicable to officials of the Commission (Conditions of Employment of Other Servants) (OJ L 56, 4.3.1968, p. 1). Regulation last amended by Commission Regulation (EC) No 2104/2005 (OJ L 337, 22.12.2005, p. 7.)



## ANNEX B

**FINANCIAL CONTROL AS REGARDS SWISS PARTICIPANTS IN ACTIVITIES OF THE EUROPEAN AVIATION AGREEMENT***Article 1***Direct communication**

The Agency and the Commission shall communicate directly with all persons or entities established in Switzerland and participating in activities of the Agency, as contractors, participants in Agency programmes, recipients of payments from the Agency or the Community budget, or subcontractors. Such persons may send directly to the Commission and to the Agency all relevant information and documentation which they are required to submit on the basis of the instruments referred to in this Decision and of contracts or agreements concluded and any decisions taken pursuant to them.

*Article 2***Checks**

1. In accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>(1)</sup> and the Financial Regulation adopted by the Management Board of the Agency on 26 March 2003, with Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>(2)</sup> and with the other instruments referred to in this Decision, contracts or agreements concluded and decisions taken with beneficiaries established in Switzerland may provide for scientific, financial, technological or other audits to be conducted at any time on the premises of the beneficiaries and of their subcontractors by Agency and Commission officials or by other persons mandated by the Agency and the Commission.

2. Agency and Commission officials and other persons mandated by the Agency and the Commission shall have appropriate access to sites, works and documents and to all the information required in order to carry out such audits, including in electronic form. This right of access shall be stated explicitly in the contracts or agreements concluded to implement the instruments referred to in this Decision.

3. The European Court of Auditors is to have the same rights as the Commission.

4. The audits may take place until five years after the expiry of this Decision or under the terms of the contracts or agreements concluded and the decisions taken.

5. The Swiss Federal Audit Office is to be informed in advance of audits conducted on Swiss territory. This information will not be a legal condition for carrying out such audits.

*Article 3***On-the-spot checks**

1. Under this Agreement, the Commission (OLAF) is authorised to carry out on-the-spot checks and inspections on Swiss territory, under the terms and conditions set out in Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities<sup>(3)</sup>.

2. On-the-spot checks and inspections shall be prepared and conducted by the Commission in close cooperation with the Swiss Federal Audit Office or with other competent Swiss authorities appointed by the Swiss Federal Audit Office, which shall be notified in good time of the object, purpose and legal basis of the checks and inspections, so that they can provide all the requisite help. To that end, the officials of the competent Swiss authorities may participate in the on-the-spot checks and inspections.

3. If the Swiss competent authorities concerned so wish, the on-the-spot checks and inspections may be carried out jointly by the Commission and the Swiss competent authorities.

<sup>(1)</sup> OJ L 248, 16.9.2002, p. 1.

<sup>(2)</sup> OJ L 357, 31.12.2002, p. 72.

<sup>(3)</sup> OJ L 292, 15.11.1996, p. 2.

4. Where the participants in the programme resist an on-the-spot check or inspection, the Swiss authorities, acting in accordance with national rules, shall give the Commission inspectors such assistance as they need to allow them to discharge their duty in carrying out an on-the-spot check or inspection.

5. The Commission shall report as soon as possible to the Swiss Federal Audit Office any fact or suspicion relating to an irregularity which has come to its notice in the course of the on-the-spot check or inspection. In any event the Commission is required to inform the aforementioned authority of the result of such checks and inspections.

#### Article 4

##### **Information and consultation**

1. For the purposes of proper implementation of this Annex, the competent Swiss and Community authorities shall exchange information regularly and, at the request of one of the Parties, shall conduct consultations.

2. The competent Swiss authorities shall inform the Agency and the Commission without delay of any fact or suspicion which has come to their notice relating to an irregularity in connection with the conclusion and implementation of the contracts or agreements concluded in application of the instruments referred to in this Decision.

#### Article 5

##### **Confidentiality**

Information communicated or acquired in any form whatsoever pursuant to this Annex will be covered by professional confidentiality and protected in the same way as similar information is protected by the national legislation of Switzerland and by the corresponding provisions applicable to the Community institutions. Such information shall not be communicated to persons other than those within the Community institutions, in the Member States, or in Switzerland whose functions require them to know it, nor may it be used for purposes other than to ensure effective protection of the financial interests of the Contracting Parties.

#### Article 6

##### **Administrative measures and penalties**

Without prejudice to application of Swiss criminal law, administrative measures and penalties may be imposed by the Agency or the Commission in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 and Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 and with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests<sup>(1)</sup>.

#### Article 7

##### **Recovery and enforcement**

Decisions taken by the Agency or the Commission within the scope of this Decision which impose a pecuniary obligation on persons other than States shall be enforceable in Switzerland.

The enforcement order must be issued, without any further control than verification of the authenticity of the act, by the authority designated by the Swiss government, which must inform the Agency or the Commission thereof. Enforcement must take place in accordance with the Swiss rules of procedure. The legality of the enforcement decision is subject to control by the Court of Justice of the European Union.

Judgments given by the Court of Justice of the European Union pursuant to an arbitration clause are enforceable on the same terms.

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<sup>(1)</sup> OJ L 312, 23.12.1995, p. 1.

GUIDELINES

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