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EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

DECISIONS

EN

[1] Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 18 July 2011

on the conclusion of the Agreement between the European Union and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia

(2012/837/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, certificates and markings between the European Community and Australia [1] entered into force on 1 January 1999 [2].

(2) In accordance with Council Decision 2011/456/EU [3], the Agreement between the European Union and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia ('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 Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia ('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 [4].

Article 3

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

Done at Brussels, 18 July 2011.

For the Council
The President
M. DOWGIELEWICZ

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[1] OJ L 229, 17.8.1998, p. 3.
[2] OJ L 5, 9.1.1999, p. 74.
[3] OJ L 194, 26.7.2011, p. 1.

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

AGREEMENT

between the European Union and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia

THE EUROPEAN UNION

and

AUSTRALIA,

hereinafter 'the Parties',

HAVING concluded the Agreement on mutual recognition in relation to conformity assessment, certificates and markings [1] signed in Canberra on 24 June 1998 (hereinafter 'the Agreement on Mutual Recognition');

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

NOTING the need to clarify the status of the Sectoral Annexes 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;

WHEREAS Article 4 of the Agreement on Mutual Recognition restricts the application of the Agreement to industrial 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;

RECOGNISING that the Parties may need to undertake certain domestic procedures before amendments to the Sectoral Annexes or the adoption of new Sectoral Annexes take effect;

[1] OJ L 229, 17.8.1998, p. 3.

CONSIDERING that in order to simplify the operation of the Agreement on Mutual Recognition, the need for the Joint Committee to take action 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 afterwards suspended or withdrawn should be clarified,

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 the conformity assessment of 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 the suspension of, 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 competence or compliance is challenged 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 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 eliminate an immediate risk posed by a product covered by a Sectoral Annex, it shall notify the other Party of the measures and the reasons for their imposition immediately, or as otherwise specified in the Sectoral Annex.'.

7. Article 12 is amended as follows:

(a) paragraphs 3 to 7 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 for both Parties on the date on which the Joint Committee receives notification from each Party confirming completion of their respective procedures for the amendments or new Sectoral Annex to take effect, unless otherwise mutually determined in writing by the Parties.

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 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 the procedures of 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 suspension 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 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.';

(b) the following paragraph is added:

'9. The Joint Committee shall keep the Sectoral Annexes up-to-date and shall provide these to the Parties upon the amendments taking effect.'.

8. Article 15 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The Annex to this Agreement forms an integral part thereof. The Sectoral Annexes form the administrative arrangements for the implementation of this Agreement and have less than treaty status.';

(b) 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.';

(c) 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 and come into effect in accordance with Article 12(5).'.

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. 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-AUSTRALIA AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

1. The Parties mutually establish that the provisions of this Sectoral Annex will cover all medicinal products which are industrially manufactured in Australia 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 Australia 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 feedingstuffs, and, where appropriate, vitamins, minerals, herbal remedies and homeopathic 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 mutually 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 may be 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 in conformity with GMP. The batch certificate will be signed by the person authorised to release the batch for sale or supply, i.e. in the European Union the "qualified person" as referred to in relevant European Union legislation; in Australia, the persons responsible for manufacturing quality control as specified in the relevant Australian 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 listed in the Appendix.

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.

SECTION II

OFFICIAL INSPECTION SERVICES

The lists of official inspection services related to this Sectoral Annex have been mutually established 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 that 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 case 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**

The Parties mutually acknowledge that 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 Australia 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 will 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 procedures for medicinal products for human use are published by the European Directorate for the Quality of Medicines & HealthCare. For Australia, 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 agreed between 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 mutually 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, inspectors training sessions, technical requirements, will be:

FOR AUSTRALIA:

For medicinal products for human use:

The Head of Office
Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
Australia

Tel. 61-6-232-8622
Fax 61-6-232-8426

For medicinal products for use in animals:

The Manager, Manufacturing Quality and Licensing Section
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Australia

Tel. 61-6210-4803
Fax 61-6210-4741

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 mutually 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.

In accordance with this Agreement, the Australian veterinary medicinal product manufacturers will be inspected by the Therapeutic Goods Administration (TGA) on behalf of the Australian Pesticides and Veterinary Medicines Authority (APVMA), according to the current Australian code of GMP and the European Union GMP Guide for veterinary medicinal products. The European Union will recognise the conclusions of inspections carried out by the TGA and Australian manufacturers' certifications of batch conformity. Should APVMA begin to carry out inspections itself, inspection reports will also be routinely transmitted to the importing Party until there has been a satisfactory verification of the APVMA GMP inspection programme.

Appendix

LIST OF APPLICABLE LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

For the European Union:

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;

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;

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;

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;

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;

Guide to Good Distribution Practice (94/C 63/03);

Volume 4 — Guidelines for good manufacturing practices for medicinal products for human and veterinary use.

For Australia:

For products for human use:

Therapeutic Goods Act 1989, and Regulations, Orders and Determinations thereunder, including Orders setting standards such as labelling, the Determination establishing Manufacturing Principles and Australian Codes of Good Manufacturing Practice.

For products for veterinary use:

Legislation — Commonwealth:

— Agricultural and Veterinary Chemicals (Administration) Act, 1992

— Agricultural and Veterinary Chemicals Act, 1994

— Agricultural and Veterinary Chemicals Code Act, 1994

— Agricultural and Veterinary Chemicals (Administration) Regulations, 1995

— Agricultural and Veterinary Chemicals Instrument No 1 (Manufacturing Principles), 2007

— Agricultural and Veterinary Chemicals Code Regulations, 1995

Legislation — New South Wales:

— Stock Foods Act, 1940

— Stock Medicines Act, 1989

— Public Health Act, 1991

— Poisons and Therapeutic Goods Act, 1966

— Pesticides Act, 1979

— Agricultural and Veterinary Chemicals (NSW) Act, 1994

including any regulations, orders or instruments made under the above legislation

Legislation — Victoria:

— Animal Preparations Act, 1987

— Health Act, 1958

— Drugs, Poisons and Controlled Substances Act, 1981

— Agricultural and Veterinary Chemicals (Victoria) Act, 1994

including any regulations, orders or instruments made under the above legislation

Legislation — Queensland:

— Agricultural Standards Act, 1994

— Stock Act, 1915

— Health Act, 1937

— Agricultural and Veterinary Chemicals (Queensland) Act, 1994

including any regulations, orders or instruments made under the above legislation

Legislation — South Australia:

— Stock Medicines Act, 1939-1978

— Stock Foods Act, 1941

— Dangerous Substances Act, 1986

— Controlled Substances Act, 1984

— Stock Diseases Act, 1934

— Agricultural and Veterinary Chemicals (SA) Act, 1994

including any regulations, orders or instruments made under the above legislation

Legislation — Western Australia:

— Veterinary Preparations and Animal Feeding Stuffs Act, 1976–1982

— Poisons Act, 1964-1981

— Health Act, 1911

— Agricultural and Veterinary Chemicals (WA) Act, 1995

— Health (Pesticides) Regulations, 1956

including any regulations, orders or instruments made under the above legislation

Legislation — Tasmania:

— Veterinary Medicines Act, 1987

— Poisons Act, 1971

— Public Health Act, 1997

— Agricultural and Veterinary Chemicals (Tasmania) Act, 1994

— Pesticides Act, 1968

including any regulations, orders or instruments made under the above legislation

Legislation — Northern Territory:

— Poisons and Dangerous Drugs Act, 1983

— Therapeutic Goods and Cosmetics Act, 1986

— Stock Diseases Act, 1954

— Agricultural and Veterinary Chemicals (NT) Act, 1994

including any regulations, orders or instruments made under the above legislation

Legislation — Australian Capital Territory

— Environment Protection Act, 1997

including any regulations, orders or instruments made under the above legislation.'.

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

'SECTORAL ANNEX ON MEDICAL DEVICES TO THE EUROPEAN COMMUNITY-AUSTRALIA AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The Parties mutually establish that the provisions of this Sectoral Annex will apply to the following products:

Products for export to the European Union	Products for export to Australia
(1) All medical devices: (a) manufactured in Australia; and (b) subject to third party conformity assessment procedures, both product- and quality systems-related; and (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 (d) provided for in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended.	(1) All medical devices: (a) manufactured in the European Union; and (b) subject to conformity assessment procedures, both product- and quality systems-related, under the Australian Therapeutic Goods Act 1989 and Therapeutic Goods Regulations, as amended.
(2) For the purposes of paragraph 1: (a) medical devices provided for in the Appendix are excluded; and (b) unless otherwise provided for or by mutual arrangement by the Parties, "manufacture" of a medical device does not include:	(2) For the purposes of paragraph 1: (a) medical devices provided for in the Appendix are excluded; and (b) unless otherwise provided for or by mutual arrangement by the Parties, "manufacture" of a medical device does not include:

Products for export to the European Union	Products for export to Australia
(i) restoration or renovation processes such as repairing, re-conditioning, overhauling or refurbishing; or	(i) restoration or renovation processes such as repairing, re-conditioning, overhauling or refurbishing; or
(ii) operations such as pressing, labelling, ticketing, packaging and preparation for sale, conducted alone or in combination with each other; or	(ii) operations such as pressing, labelling, ticketing, packaging and preparation for sale, conducted alone or in combination with each other; or
(iii) quality control inspections alone; or	(iii) quality control inspections alone; or
(iv) sterilisation alone.	(iv) sterilisation alone.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

Legislative, regulatory and administrative requirements of the European Union with which Australian-designated conformity assessment bodies will assess compliance	Legislative, regulatory and administrative requirements of Australia with which European Union-designated conformity assessment bodies will assess compliance
— 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 — Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended — and any legislation adopted on the basis of these Directives	— Therapeutic Goods Act 1989, as amended — Therapeutic Goods Regulations 1990, as amended — Therapeutic Goods (Medical Devices) Regulations 2002, as amended — and any subordinate legislation referred to in the above Acts or Regulations, as amended [1]

[1] General reference to Australia's subordinate legislation referred to in the Therapeutic Goods Act and Regulations and to anticipate any legislative changes.

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

Conformity assessment bodies designated by Australia to assess products against the European Union's legislative, regulatory and administrative requirements	Conformity assessment bodies designated by the European Union to assess products against Australia's legislative, regulatory and administrative requirements
The lists of designated conformity assessment bodies have been mutually established by the Parties and will be maintained by them.	The lists of designated conformity assessment bodies have been mutually established by the Parties and will be maintained by them.

SECTION III

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES FOR THE PURPOSES OF THIS AGREEMENT

For the conformity assessment bodies designated by Australia	For the conformity assessment bodies designated by the Member States of the European Union
— Department of Health and Ageing for the Therapeutic Goods Administration	— *Belgium* Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie

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

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

For the conformity assessment bodies designated by Australia	For the conformity assessment bodies designated by the Member States of the European Union
	— *Sweden* Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Medicines and Healthcare products Regulatory Agency

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

Procedures to be followed by Australia in designating conformity assessment bodies to assess products against the European Union's requirements	Procedures to be followed by the European Union in designating conformity assessment bodies to assess products against Australia's requirements
The Therapeutic Goods Administration of the Department of Health and Ageing will meet the requirements of the Directives listed in Section I, taking into account 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, insofar as it refers to the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, and be designated for specific categories or classes of devices and conformity assessment procedures. For products covered by Section V, designation will occur on the basis of a confidence-building programme as referred to in point 1.2 of Section V. ([1])	Conformity assessment bodies will meet the requirements mentioned in the Directives listed in Section I, taking into account 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, insofar as it refers to the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, and be designated for specific categories or classes of devices and conformity assessment procedures. For products covered by Section V, designation will occur on the basis of a confidence-building programme as referred to in point 1.2 of Section V. ([2])

([1]) Presumption of competence is following successful completion of confidence-building for Section V devices.
([2]) Presumption of competence is following successful completion of confidence-building for Section V devices.

SECTION V

ADDITIONAL PROVISIONS

1. **Confidence-building with respect to high-risk devices**

1.1. 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.

1.2. The Parties will establish a detailed programme to this effect involving the Therapeutic Goods Administration and the European Union's competent authorities.

1.3. The confidence-building period will be reviewed after two years commencing from the date this Sectoral Annex, as amended, becomes effective.

1.4. Additional specific requirements for regulatory progress:

1.4.1. 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.

1.4.2. These specific requirements may include training, observed conformity assessment body audits, visits and information and document exchange, including audit reports.

1.4.3. These requirements may likewise be applicable in relation to the designation of a conformity assessment body in accordance with this Agreement.

2. **Registration, listing and inclusion procedures for the Australian Register of Therapeutic Goods (ARTG)**

2.1. The Parties recognise that Australian procedures under the Therapeutic Goods Act 1989 for the registration, listing or inclusion of products for market surveillance purposes, and corresponding European Union procedures, are unaffected by this Agreement.

2.2. Within the framework of this Agreement, the Australian Regulatory Authority will without delay enter a product from the European Union on the ARTG without further assessment of the product. This is contingent upon receipt of a product application accompanied by the prescribed fee and the conformity assessment body's certification to Australia's requirements.

2.3. Any fees attached to registration by either Party will be related only to the costs of the medical device registration, enforcement and post-market surveillance activities of the Parties in this sector.

3. **Exchange of information**

The Parties agree to inform each other of:

— certificates withdrawn, suspended, restricted or revoked;

— adverse events in the context of the GHTF medical device vigilance procedure;

— matters concerning product safety; and

— any legislation or amendment to existing legislation adopted on the basis of the legal texts listed in Section I.

The Parties will establish contact points for each of these purposes.

The Parties will consider the consequences of the establishment of European Database on Medical Devices (Eudamed).

In addition, the Therapeutic Goods Administration will advise of any certificates issued.

4. **New legislation**

The Parties jointly note that Australia is to introduce new legislation concerning *in vitro* diagnostics (IVDs), and that any new arrangements will respect the principles on which this Agreement is based.

The Parties mutually declare their plan to extend the scope of this Agreement to IVDs as soon as the Australian legislation on IVDs is in place.

5. **Measures to protect public health and safety**

Implementation of this Sectoral Annex will not constrain a Party from taking measures necessary to protect public health and safety, in accordance with the legislation referred to in Section I. Each Party will duly inform the other Party of such measures.

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. 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 other medical devices, except for sterilisers using dry heat, moist heat or ethylene oxide.

Both Parties may decide by mutual 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 duplicate 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 Австралия
Por Australia
Za Austrálii
For Australien
Für Australien
Austraalia nimel
Για την Αυστραλία
For Australia
Pour l'Australie
Per l'Australia
Austrālijas vārdā –
Australijos vardu
Ausztrália nevében
Għall-Awstralja
Voor Australië
W imieniu Australii
Pela Austrália
Pentru Australia
Za Austráliu
V imenu Avstralije
Australian puolesta
För Australien

REGULATIONS

COUNCIL REGULATION (EU) No 1272/2012

of 20 December 2012

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

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 74 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) Council Regulation (EC) No 1104/2008 of 24 October 2008 on migration from the Schengen Information System (SIS 1+) to the second generation Schengen Information System (SIS II) [2] and Council Decision 2008/839/JHA of 24 October 2008 on migration from the Schengen Information System (SIS 1+) to the second generation Schengen Information System (SIS II) [3] have been substantially amended. Since further amendments are to be made, they should be recast in the interest of clarity.

(2) The Schengen Information System (SIS) set up pursuant to the provisions of Title IV of the Convention of 19 June 1990 implementing the Schengen Agreement of 14 June 1985 between the Governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders [4] (the 'Schengen Convention'), and the further development, thereof, SIS 1+, constitute essential tools for the application of the provisions of the Schengen *acquis* as integrated into the framework of the European Union.

(3) The development of the second generation Schengen Information System (SIS II) was entrusted by the Council to the Commission pursuant to Regulation (EC) No 2424/2001 [5] and Decision 2001/886/JH [6]. Those acts expired on 31 December 2008 prior to the completion of the SIS II developments. They therefore needed to be supplemented firstly by Regulation (EC) No 1104/2008 and by Decision 2008/839/JHA and subsequently by this Regulation and Council Regulation (EU) No 1273/2012 of 20 December 2012 on migration from the Schengen Information System (SIS 1+) to the second generation Schengen Information System (SIS II) [7] at the latest until the termination of the migration from SIS 1+ to SIS II or until a date to be fixed by the Council, acting in accordance with Regulation (EC) No 1987/2006 of the European Parliament and of the Council of 20 December 2006 on the establishment, operation and use of the second generation Schengen Information System (SIS II) [8] and Council Decision 2007/533/JHA of 12 June 2007 on the establishment, operation and use of the second generation Schengen Information System (SIS II) [9].

(4) SIS II was established by Regulation (EC) No 1987/2006 and by Decision 2007/533/JHA. This Regulation should be without prejudice to the provisions of those acts.

(5) Certain tests of SIS II are provided for in Council Regulation (EC) No 189/2008 [10] and in Council Decision 2008/173/JHA [11].

(6) The development of SIS II should be continued and should be finalised in the framework of the SIS II global schedule endorsed by the Council on 6 June 2008 and subsequently amended in October 2009 in the light of orientations given by the Council of 4 June 2009 (Justice and Home Affairs). The new version of the SIS II global schedule was presented by the Commission to the European Parliament and the Council in October 2010.

(7) A comprehensive test of SIS II should be conducted in full cooperation between the Member States and the Commission, in accordance with the provisions of this Regulation. As soon as possible after its completion, that test should be validated as provided for by Regulation (EC) No 1987/2006 and Decision 2007/533/JHA. Only test data should be used for the purpose of the comprehensive test.

[1] Opinion of 21 November 2012 (not yet published in the Official Journal).
[2] OJ L 299, 8.11.2008, p. 1.
[3] OJ L 299, 8.11.2008, p. 43.
[4] OJ L 239, 22.9.2000, p. 19.
[5] OJ L 328, 13.12.2001, p. 4.
[6] OJ L 328, 13.12.2001, p. 1.
[7] See page 32 of this Official Journal.
[8] OJ L 381, 28.12.2006, p. 4.
[9] OJ L 205, 7.8.2007, p. 63.
[10] OJ L 57, 1.3.2008, p. 1.
[11] OJ L 57, 1.3.2008, p. 14.

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

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

(10) In order to better manage the potential difficulties brought about by the migration from SIS 1+ to SIS II, an interim migration architecture for SIS should be established and tested. The interim migration architecture should have no impact on the operational availability of SIS 1+. A converter should be provided by the Commission.

(11) The Member State issuing an alert should be responsible for ensuring that the data entered into SIS is accurate, up to date and lawful.

(12) The Commission should remain responsible for Central SIS II and its communication infrastructure. This responsibility includes the maintenance and continuation of the development of SIS II and its communication infrastructure, including at all times the correction of errors. The Commission should provide coordination and support for the joint activities. The Commission should provide, in particular, the necessary technical and operational support to the Member States at Central SIS II level including the availability of a helpdesk.

(13) The Member States are and should remain responsible for the development and maintenance of their national systems (N.SIS II).

(14) France should remain responsible for the technical support function of SIS 1+, as expressly provided for in the Schengen Convention.

(15) Representatives of the Member States participating in SIS 1+ should coordinate their actions within the framework of the Council. It is necessary to set out a framework for that organisational action.

(16) In order to support Member States in opting for the most favourable technical and financial solution, the Commission should initiate without delay the process of adapting this Regulation by proposing a legal framework for the migration from SIS 1+ to SIS II which better reflects the technical migration approach outlined in the Migration Plan for the SIS Project (the 'Migration Plan') adopted by the Commission after a positive vote by the SIS-VIS Committee on 23 February 2011.

(17) The Migration Plan envisages that within the switchover period all Member States, consecutively, will perform their individual switchover of the national application from SIS 1+ into SIS II. It is desirable from a technical point of view that Member States that have switched over be able to use the full scope of SIS II from the time of the switchover and not have to wait until other Member States have also switched over. Therefore, it is necessary to apply Regulation (EC) No 1987/2006 and Decision 2007/533/JHA from the time of the initiation of the switchover by the first Member State. For reasons of legal certainty, the period of switchover should be kept as short as possible, and should not exceed 12 hours. The application of Regulation (EC) No 1987/2006 and Decision 2007/533/JHA should not prevent Member States, which have not switched over yet or which have had to fall back for technical reasons, from using SIS II limited to SIS 1+ functionalities during the intensive monitoring period. In order to apply the same standards and conditions to alerts, data processing and data protection in all Member States, it is necessary to apply the SIS II legal framework to the SIS operational activities of the Member States which did not yet switch over.

(18) It is necessary to maintain the application of certain provisions of Title IV of the Schengen Convention on a temporary basis by incorporating those provisions into this Regulation as they provide the legal framework for the converter and the interim migration architecture during the migration. The interim migration architecture for the operations of SIS 1+ allows SIS 1+ and certain technical parts of the SIS II architecture to operate in parallel during a limited transitional period which is needed to make possible an incremental migration from SIS 1+ to SIS II.

(19) Regulation (EC) No 1987/2006 and Decision 2007/533/JHA provide that the best available technology, subject to a cost-benefit analysis, should be used for Central SIS II. The Annex to the Council Conclusions on the further direction of SIS II of 4-5 June 2009 laid down milestones which should be met in order to continue with the current SIS II project. In parallel, a study has been conducted concerning the elaboration of an alternative technical scenario for developing SIS II based on SIS 1+ evolution (SIS 1+ RE) as the contingency plan, in case the tests demonstrate non-compliance with the milestone requirements. Based on these parameters, the Council may decide to invite the Commission to switch to the alternative technical scenario.

(20) The description of the technical components of the interim migration architecture should therefore be adapted to allow for another technical solution, and in particular the SIS 1+ RE regarding the development of Central SIS II. SIS 1+ RE is a possible technical solution to develop Central SIS II and to achieve the objectives of the SIS II laid down in Regulation (EC) No 1987/2006 and Decision 2007/533/JHA.

(21) The SIS 1+ RE is characterised by uniqueness of means between SIS II development and SIS 1+. The references in this Regulation to the technical architecture of SIS II and to the migration process should therefore, in case of implementation of an alternative technical scenario, be read as the references to SIS II based on another technical solution, as applied mutatis mutandis to the technical specificities of that solution, in keeping with the objective to develop Central SIS II.

(22) In any technical scenario, the result of migration at central level should be availability of the SIS 1+ database and new SIS II functionalities, including additional data categories, in the Central SIS II. In order to facilitate data loading it should be specified that deleted data as referred to in Article 113(2) of the Schengen Convention will not be migrated from SIS 1+ to SIS II.

(23) The Commission should be empowered to contract out to third parties, including national public bodies, tasks conferred upon it by this Regulation and tasks relating to the implementation of the budget, in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [1] (the 'Financial Regulation').

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

(24) As regards the financing of the development of the Central SIS II based on an alternative technical solution, it should be covered by the general budget of the Union while respecting the principle of sound financial management. In accordance with the Financial Regulation the Commission may delegate budget implementation tasks to national public sector bodies. Following the political orientation and subject to the conditions laid down in the Financial Regulation, the Commission would be invited, in case of switchover to the alternative solution, to delegate the budget implementation tasks related to the development of the SIS II based on SIS 1+ RE to France.

(25) Regulation (EC) No 1987/2006 and Decision 2007/533/JHA, as well as Decision No 574/2007/EC of the European Parliament and of the Council of 23 May 2007 establishing the External Borders Fund for the period 2007 to 2013 as part of the General Programme Solidarity and Management of Migration Flows [2], included SIS II national developments among the eligible actions to be co-financed under the External Borders Fund (EBF). Commission Decision 2007/599/EC of 27 August 2007 implementing Decision No 574/2007/EC of the European Parliament and of the Council as regards the adoption of strategic guidelines for 2007 to 2013 [3] further identified SIS II as one of the five strategic priorities under the EBF, recognising the importance of supporting the coherent and timely development of the national projects alongside the central SIS II.

Since the adoption of those legal acts, the SIS II project received a significant reorientation in the course of 2010, after the completion of an important test campaign, the 'Milestone 1'. Furthermore, the evolutions in the use of the SIS by the Member States led to a need to update the SIS II technical requirements concerning performance and storage capacity which affected the costs of the SIS II project both at central and national level.

(26) With regard to the migration process from SIS 1+ to SIS II, the evolution in requirements and the advances made in the completion of the SIS II project led to a redefinition of the migration architecture, of the migration calendar and of the testing requirements. An important part of the activities that would now be required at Member State level for the migration to SIS II were not anticipated at the time when Regulation (EC) No 1104/2008 and Decision 2008/839/JHA were adopted or at the time when the financial package and the multiannual programmes under the EBF were drawn up. It is, therefore, necessary to partly realign the cost distribution principles for the migration from SIS 1+ to SIS II. Certain national activities related to that migration, in particular in connection with the participation of Member States in migration-related testing activities could be co-financed from the SIS II budget line of the general budget of the Union. That possibility should cover specific and well-defined activities beyond, and not to coincide with, other SIS II related actions which would continue to be supported under the EBF. The financial assistance thus provided under this Regulation should be complementary to that provided by the EBF.

(27) In relation to the co-financing provided under this Regulation, appropriate measures should be taken to prevent irregularities and fraud and the necessary steps should be taken to recover funds lost, wrongly paid or incorrectly used, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests [4], 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 [5], and Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) [6].

[1] OJ L 248, 16.9.2002, p. 1.
[2] OJ L 144, 6.6.2007, p. 22.
[3] OJ L 233, 5.9.2007, p. 3.
[4] OJ L 312, 23.12.1995, p. 1.
[5] OJ L 292, 15.11.1996, p. 2.
[6] OJ L 136, 31.5.1999, p. 1.

(28) In order to ensure uniform conditions for the implementation of this Regulation, taking into consideration the financial impacts of the decision upon Member States, which should remain fully involved when the Commission exercises its implementing powers, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([1]).

(29) The Commission and the Member States should continue to cooperate closely during all steps of the development of the SIS II and the migration from SIS 1+ to SIS II in order to complete the process. In the Council conclusions on SIS II of 26-27 February 2009 and 4-5 June 2009, an informal body consisting of the experts of the Member States and designated as the Global Programme Management Board, was established to enhance the cooperation and to provide direct Member States support to the central SIS II project. The positive result of the work of that group of experts and the necessity of further enhancing the cooperation and the transparency of the central SIS II project justify the formal integration of the group of experts into the SIS II management structure. A group of experts, called the Global Programme Management Board, should therefore be formally established to complement the current SIS II organisational structure. In order to ensure efficiency as well as cost effectiveness the number of experts should be limited. The activities of the Global Programme Management Board should be without prejudice to the responsibilities of the Commission and of the Member States.

(30) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ([2]) applies to the processing of personal data by the Commission.

(31) The European Data Protection Supervisor is responsible for monitoring and ensuring the application of Regulation (EC) No 45/2001 and is competent to monitor the activities of the Union institutions and bodies in relation to the processing of personal data. The Joint Supervisory Authority is responsible for supervising the technical support function of the current SIS 1+ until the entry into force of the SIS II legal framework. National Supervisory Authorities are responsible for supervising the processing of SIS 1+ personal data on the territory of their respective Member States and remain responsible for monitoring the lawfulness of the processing of SIS II personal data on the territory of their respective Member States. This Regulation should be without prejudice to the specific provisions of the Schengen Convention as well as of Regulation (EC) No 1987/2006 and of Decision 2007/533/JHA on the protection and security of personal data. That SIS II legal framework provides that the National Supervisory Authorities and the European Data Protection Supervisor ensure the coordinated supervision of SIS II.

(32) The migration from SIS 1+ to SIS II is a complex process which, despite extensive preparation by all stakeholders, entails significant technical risks. It is desirable for the legal framework to provide for the necessary flexibility to respond to unexpected difficulties which the central system or one or several national systems could face during the migration process. Therefore, while for reasons of legal certainty the switchover phase and the intensive monitoring period during which the interim migration architecture continues to exist should be as short as possible, the Council should, in case of technical difficulties, be enabled to fix the final date for the termination of migration in accordance with Article 55(2) of Regulation (EC) No 1987/2006 and Article 71(2) of Decision 2007/533/JHA.

(33) Since the objectives of this Regulation, namely setting up the interim migration architecture and migrating the data from SIS 1+ to SIS II, cannot be sufficiently achieved by the Member States and can, therefore, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve those objectives.

(34) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.

(35) In order to give effect in 2012 to the financial facility which could be provided to Member States from the general budget of the Union in accordance with this Regulation, this Regulation should enter into force on the day following its publication.

([1]) OJ L 55, 28.2.2011, p. 13.
([2]) OJ L 8, 12.1.2001, p. 1.

(36) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latters' association with the implementation, application and development of the Schengen *acquis* ([1]) which fall within the area referred to in Article 1, point G, of Council Decision 1999/437/EC ([2]) on certain arrangements for the application of that Agreement.

(37) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ([3]) which fall within the area referred to in Article 1, point G, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC ([4]).

(38) As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ([5]) which fall within the area referred to in Article 1, point G, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU ([6]).

(39) In accordance with Articles 1 and 2 of Protocol (No 22) on the position of Denmark, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen *acquis*, Denmark shall, in accordance with Article 4 of that Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it in its national law.

(40) The United Kingdom is taking part in this Regulation, in accordance with Article 5(1) of the Protocol (No 19) on the Schengen *acquis* integrated into the framework of the European Union, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, and Article 8(2) of Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen *acquis* ([7]).

(41) Ireland is taking part in this Regulation, in accordance with Article 5(1) of the Protocol (No 19) on the Schengen *acquis* integrated into the framework of the European Union, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, and Article 6(2) of Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* ([8]).

(42) This Regulation is without prejudice to the arrangements for the partial participation of Ireland and the United Kingdom in the Schengen *acquis* as determined by Decisions 2000/365/EC and 2002/192/EC respectively.

(43) As regards Cyprus, this Regulation constitutes an act building upon, or otherwise related to, the Schengen *acquis* within the meaning of Article 3(2) of the 2003 Act of Accession.

(44) The European Data Protection Supervisor was consulted and delivered an opinion on 9 July 2012 ([9]),

HAS ADOPTED THIS REGULATION:

Article 1

General purpose

1. The Schengen Information System (SIS), set up pursuant to the provisions of Title IV of the Schengen Convention (SIS 1+), shall be replaced by a new system, the Schengen Information System II (SIS II), the establishment, operation and use of which is regulated by Decision 2007/533/JHA.

2. In accordance with the procedures and the division of tasks set out in this Regulation, SIS II shall be developed by the Commission and the Member States as a single integrated system and shall be prepared for operations.

3. The development of SIS II may be achieved by implementing an alternative technical scenario characterised by its own technical specifications.

Article 2

Definitions

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

(a) 'Central SIS II' means the technical support function of SIS II containing a database, the 'SIS II database', and a uniform national interface (NI-SIS);

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

(c) 'N.SIS' means the national system of SIS 1+, consisting of the national data systems which communicate with C.SIS;

([1]) OJ L 176, 10.7.1999, p. 36.
([2]) OJ L 176, 10.7.1999, p. 31.
([3]) OJ L 53, 27.2.2008, p. 52.
([4]) OJ L 53, 27.2.2008, p. 1.
([5]) OJ L 160, 18.6.2011, p. 21.
([6]) OJ L 160, 18.6.2011, p. 19.
([7]) OJ L 131, 1.6.2000, p. 43.
([8]) OJ L 64, 7.3.2002, p. 20.
([9]) OJ C 336, 6.11.2012, p. 10.

(d) 'N.SIS II' means the national system of SIS II, consisting of the national data systems which communicate with Central SIS II;

(e) 'converter' means a technical tool to allow consistent and reliable communication between C.SIS and Central SIS II, ensuring the functionalities provided for in Article 10(3) and allowing the conversion and synchronisation of data between C.SIS and Central SIS II;

(f) 'comprehensive test' means the test referred to in Article 71(3)(c) of Decision 2007/533/JHA;

(g) 'test on supplementary information' means functional tests between the SIRENE Bureaux.

Article 3

Subject matter and scope

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

(a) the maintenance and continuation of the development of SIS II;

(b) a comprehensive test of SIS II;

(c) a test on supplementary information;

(d) the continuation of the development and testing of a converter;

(e) the establishment and testing of an interim migration architecture;

(f) the migration from SIS 1+ to SIS II.

Article 4

Technical components of the interim migration architecture

In order to ensure the migration from SIS 1+ to SIS II, the following components shall be made available to the extent necessary:

(a) the C.SIS and the connection to the converter;

(b) the communication infrastructure for SIS 1+ allowing the C.SIS to communicate with the N.SIS;

(c) the N.SIS;

(d) Central SIS II, NI-SIS and the communication infrastructure for SIS II allowing the Central SIS II to communicate with N.SIS II and the converter;

(e) the N.SIS II;

(f) the converter.

Article 5

Main responsibilities in the development of SIS II

1. The Commission shall continue to develop the Central SIS II, the communication infrastructure and the converter.

2. France shall make available and operate C.SIS in accordance with the provisions of the Schengen Convention.

3. The Member States shall continue to develop N.SIS II.

4. The Member States participating in SIS 1+ shall maintain N.SIS in accordance with the provisions of the Schengen Convention.

5. The Member States participating in SIS 1+ shall make available and operate the communication infrastructure for SIS 1+.

6. The Commission shall coordinate the activities and provide the necessary support for the implementation of the tasks and responsibilities referred to in paragraphs 1 to 3.

Article 6

Continuing development

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

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

Article 7

Main activities

1. The Commission together with Member States participating in SIS 1+ shall conduct a comprehensive test.

2. An interim migration architecture shall be set up and a test of that architecture shall be performed by the Commission together with France and the other Member States participating in SIS 1+.

3. The Commission and the Member States participating in SIS 1+ shall perform the migration from SIS 1+ to SIS II.

4. The Member States participating in SIS 1+ shall perform a test on the exchange of supplementary information.

5. The Commission shall provide the necessary support at Central SIS II level for the activities referred to in paragraphs 1 to 4.

6. The activities referred to in paragraphs 1 to 3 shall be coordinated by the Commission and the Member States participating in SIS 1+ acting within the Council.

Article 8

Comprehensive test

1. The comprehensive test shall not start before the Commission has declared that it considers that the level of success of the tests referred to in Article 1 of Decision 2008/173/JHA is sufficient to begin such a test.

2. A comprehensive test aiming at confirming, in particular, the completion by the Commission and the Member States participating in SIS 1+ of the necessary technical arrangements to process SIS II data and the demonstration that the level of performance of SIS II is at least equivalent to that achieved with SIS 1+ shall be performed.

3. The comprehensive test shall be executed by the Member States participating in SIS 1+ for the N.SIS II and by the Commission for the Central SIS II.

4. The comprehensive test shall follow a detailed schedule defined by the Member States participating in SIS 1+ acting within the Council in cooperation with the Commission.

5. The comprehensive test shall be based on the technical specifications defined by the Member States participating in SIS 1+ acting within the Council in cooperation with the Commission.

6. The Commission and the Member States participating in SIS 1+ acting within the Council shall define the criteria for determining whether the necessary technical arrangements to process SIS II data are completed and the level of performance of SIS II is at least equivalent to that achieved with SIS 1+.

7. The test results shall be analysed using the criteria referred to in paragraph 6 of this Article, by the Commission and the Member States participating in SIS 1+ acting within the Council. The test results shall be validated in accordance with Article 71(3)(c) of Decision 2007/533/JHA.

8. Member States not participating in SIS 1+ may participate in the comprehensive test. Their results shall not affect the overall validation of that test.

Article 9

Test on supplementary information

1. The Member States participating in SIS 1+ shall conduct functional SIRENE tests.

2. The Commission shall make available Central SIS II and its communication infrastructure during the execution of the test on supplementary information.

3. The test on supplementary information shall follow a detailed schedule defined by the Member States participating in SIS 1+ acting within the Council.

4. The test on supplementary information shall be based on the technical specifications defined by the Member States participating in SIS 1+ acting within the Council.

5. The test results shall be analysed by the Member States participating in SIS 1+ acting within the Council. The Member States participating in SIS 1+ shall ensure that the global test result is transmitted to the European Parliament.

6. Member States not participating in SIS 1+ may participate in the test on supplementary information. Their results shall not affect the overall validation of that test.

Article 10

Interim migration architecture

1. An interim migration architecture shall be set up, consisting of the components as set out in points (a) to (f) of Article 4. The converter connects Central SIS II and C.SIS for a transitional period. The N.SIS are connected to C.SIS, the N.SIS II to Central SIS II.

2. The Commission shall provide a converter, the Central SIS II and its communication infrastructure as part of the interim migration architecture.

3. To the extent necessary, the converter shall convert data in two directions between the C.SIS and Central SIS II and keep C.SIS and Central SIS II synchronised.

4. The Commission shall test the communication between Central SIS II and the converter.

5. France shall test the communication between C.SIS and the converter.

6. The Commission and France shall test the communication between Central SIS II and C.SIS via the converter.

7. France, together with the Commission, shall connect C.SIS via the converter to Central SIS II.

8. The Commission, together with France and the other Member States participating in SIS 1+, shall test the interim migration architecture as a whole in accordance with a test plan provided by the Commission.

9. France shall make available data for test purpose, if necessary.

Article 11

Migration from SIS 1+ to SIS II

1. For the migration from C.SIS to Central SIS II, France shall make available the SIS 1+ database and the Commission shall introduce the SIS 1+ database into Central SIS II. Data of SIS 1+ database referred to in Article 113(2) of the Schengen Convention shall not be introduced into Central SIS II.

2. The Member States participating in SIS 1+ shall migrate from N.SIS to N.SIS II using the interim migration architecture, with the support of France and of the Commission.

3. The migration of the national system from SIS 1+ to SIS II shall start with the data loading of N.SIS II, when that N.SIS II is to contain a data file, the national copy, containing a complete or partial copy of the SIS II database.

The data loading as described in the first subparagraph shall be followed by a switchover from N.SIS to N.SIS II for each Member State. The switchover shall start on the date to be fixed by the Council, acting in accordance with Article 71(2) of Decision 2007/533/JHA, after the conditions of Article 71(3) of that Decision are met. The switchover from N.SIS to N.SIS II for all Member States shall be completed within no more than 12 hours. The national applications for the exchange of supplementary information shall migrate to s-TESTA network in parallel with the switchover.

The migration shall be terminated following an intensive monitoring period. That intensive monitoring period shall be limited in time, and shall not exceed 30 days from the date of the switchover of the first Member State.

The migration shall follow a detailed schedule provided by the Commission and the Member States participating in SIS 1+ acting within the Council.

4. The Commission shall assist in coordination and support of the common activities during the migration.

Article 12

Substantive legal framework

For the data loading phase of the migration referred to in the first subparagraph of Article 11(3), the provisions of Title IV of the Schengen Convention shall continue to apply to the SIS 1+.

As from the switchover of the first Member State from N.SIS to N.SIS II, as referred to in the second subparagraph of Article 11(3) of this Regulation, Decision 2007/533/JHA shall apply.

This Regulation shall continue to apply to the interim migration architecture during the entire migration as referred to in Article 11(3).

Article 13

Cooperation

1. The Member States and the Commission shall cooperate for the execution of all the activities covered by this Regulation in accordance with their respective responsibilities.

2. The Commission shall in particular provide the necessary support at Central SIS II level for the testing of and migration to N.SIS II.

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

Article 14

Replacement of the national sections by N.SIS II

1. The N.SIS II may replace the national section referred to in Article 92 of the Schengen Convention, in which case the Member States need not hold a national data file.

2. If any of the Member States replace their national section by N.SIS II, the compulsory functions of the technical support function towards that national section as referred to in Article 92(2) and (3) of the Schengen Convention shall become compulsory functions towards Central SIS II, without prejudice to the obligations referred to in Article 5(1) and Article 10(1), (2) and (3) of this Regulation.

Article 15

Processing of data and keeping of records in Central SIS II

1. The Central SIS II database shall be available for the purpose of carrying out automated searches in the territory of each Member State.

2. Central SIS II shall provide the services necessary for the entry and processing of SIS 1+ data, the online update of N.SIS II national copies, the synchronisation of and consistency between N.SIS II national copies and the Central SIS II database and provide operations for initialisation and restoration of N.SIS II national copies.

3. Without prejudice to the relevant provisions of Title IV of the Schengen Convention, the Commission shall ensure that every access to and all exchanges of personal data within Central SIS II are recorded for the purposes of checking whether or not the search is lawful, monitoring the lawfulness of data processing and ensuring the proper functioning of Central SIS II and of national systems, data integrity and security.

4. The records shall show, in particular, the date and time of the data transmitted, the data used to perform searches, the reference to the data transmitted and the name of the competent authority responsible for processing the data.

5. The records may only be used for the purposes referred to in paragraph 3 and shall be deleted at the earliest one year, and at the latest three years after their creation.

6. Records may be kept longer if they are required for monitoring procedures that are already under way.

7. The competent authorities referred to in Article 60(1) and Article 61(1) of Decision 2007/533/JHA in charge of checking whether or not a search is lawful, monitoring the lawfulness of data processing, self-monitoring and ensuring the proper functioning of Central SIS II, data integrity and security, shall, in accordance with the provisions of Decision 2007/533/JHA, have access, within the limits of their competence and at their request, to those records for the purpose of fulfilling their tasks.

Article 16

Costs

1. The costs arising from migration, the comprehensive test, the test on supplementary information, maintenance and development measures at Central SIS II level or concerning the communication infrastructure shall be borne by the general budget of the Union.

2. The costs arising from installation, migration, testing, maintenance and development of the national systems as well as from the tasks to be performed by the national systems under this Regulation shall be borne by each Member State concerned as it is provided for by Article 119(2) of the Schengen Convention.

3. Complementing the financial assistance provided by the External Borders Fund, the Union may provide a financial contribution to the expenditures of the Member States for their migration and migration related testing activities performed under Articles 8, 9, 10(8) and 11 of this Regulation to cover specific and well-defined activities.

The Union contribution related to the activities referred to in the first subparagraph shall take the form of grants as provided for by Title VI of the Financial Regulation. That contribution shall not exceed 75 % of the eligible expenditures of each Member State and it shall not exceed EUR 750 000 per Member State. The Commission shall appraise, decide and administer the co-financing operation in accordance with the budgetary and other procedures, in particularly those laid down in the Financial Regulation.

Each Member State requesting such a financial contribution shall prepare a financial forecast indicating a breakdown of the operational as well as administrative costs of the activities related to the testing and migration. Where Member States use Union funds for their expenditures, those expenditures shall be reasonable and comply with the principles of sound financial management, in particular, value for money and cost-effectiveness. Member States shall present a report to the Commission on their use of the Union contributionby not later than six months following the date of switchover fixed by the Council, acting in accordance with Article 71(2) of Decision 2007/533/JHA.

Where the Union contribution is not implemented or is implemented inadequately, partially or late, the Union may reduce, withhold or terminate its financial contribution. Where the Member States do not contribute or contribute only partially or late to the financing of activities referred to in the first subparagraph, the Union may reduce its financial contribution.

4. The Court of Auditors shall be entitled to carry out the appropriate audits in liaison with national audit bodies or with the competent national departments. The Commission shall be empowered to carry out all the checks and inspections necessary to ensure the proper management of the Union funds and to protect the Union's financial interest against any fraud or irregularity. To this end, the Member States shall make available all the relevant documents and records to the Commission and the Court of Auditors.

5. The costs of installing and operating the technical support function referred to in Article 92(3) of the Schengen Convention, including the cost of lines connecting the national sections of SIS 1+ to the technical support function, and of activities performed in conjunction with tasks conferred upon France for the purpose of this Regulation shall be borne jointly by the Member States as it is provided for by Article 119(1) of the Schengen Convention.

Article 17

Committee procedure

1. The Commission shall be assisted by the Committee established by Article 67 of Decision 2007/533/JHA (the 'Committee'). The Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 applies.

3. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 18

Global Programme Management Board

1. Without prejudice to the respective responsibilities and activities of the Commission, the Committee, France and the Member States participating in SIS 1+, a group of technical experts, called the Global Programme Management Board (the 'Board'), is hereby set up. The Board shall be an advisory body for assistance to the central SIS II project and shall facilitate consistency between central and national SIS II projects. The Board shall have no decision-making power nor any mandate to represent the Commission or Member States.

2. The Board shall be composed of a maximum of 10 members, meeting on a regular basis. A maximum of 8 experts and an equal number of alternates shall be designated

by the Member States participating in SIS 1+ acting within the Council. A maximum of two experts and two alternates shall be designated by the Director-General of the responsible Directorate-General of the Commission from among the Commission officials.

The meetings of the Board may be attended by other experts of Member States and Commission officials directly involved in the development of the SIS II projects, at the expense of their respective administration or institution.

The Board may invite other experts to participate in the Board's meetings as defined in the terms of reference referred to in paragraph 5, at the expense of their respective administration, institution or company.

3. Experts designated by the Member States acting as Presidency and incoming Presidency shall always be invited to participate in the Board's meetings.

4. The Board's secretariat shall be ensured by the Commission.

5. The Board shall draw up its own terms of reference which shall include in particular procedures on:

— alternative chairmanship between the Commission and the Presidency,

— meeting venues,

— preparation of meetings,

— admission of other experts,

— communication plan ensuring full information to non-participating Member States.

The terms of reference shall take effect after a favourable opinion has been given by the Director-General of the responsible Directorate-General of the Commission and by Member States participating in SIS 1+ meeting within the framework of the Committee.

6. The Board shall regularly submit written reports about the progress of the project including advice which has been given, and its justification, to the Committee or, as appropriate, to the relevant Council preparatory bodies.

7. Without prejudice to Article 16(2), the administrative costs and travel expenses arising from the activities of the Board shall be borne by the general budget of the Union, to the extent that they are not reimbursed from other sources. As regards travel expenses of the members in the Board designated by the Member States participating in SIS 1+ acting within the Council and experts invited pursuant to paragraph 3 of this Article which arise in connection with the work of the Board, the Commission's 'Rules on the reimbursement of expenses incurred by people from outside the Commission invited to attend meetings in an expert capacity' shall apply.

Article 19

Reporting

The Commission shall submit by the end of every six month period, and for the first time by the end of the first six month period of 2009, a progress report to the European Parliament and the Council concerning the development of SIS II and the migration from SIS 1+ to SIS II. The Commission shall inform the European Parliament of the results of the tests referred to in Articles 8 and 10.

Article 20

Repeal

Decision 2008/839/JHA is repealed.

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

Article 21

Entry into force and applicability

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

It shall expire upon the termination of the migration as referred to in the third subparagraph of Article 11(3). If that date cannot be complied with due to outstanding technical difficulties related to the migration process, it shall expire on a date to be fixed by the Council, acting in accordance with Article 71(2) of Decision 2007/533/JHA.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 20 December 2012.

For the Council
The President
E. FLOURENTZOU

ANNEX I

REPEALED DECISION WITH ITS SUCCESSIVE AMENDMENTS

Council Decision 2008/839/JHA
(OJ L 299, 8.11.2008, p. 43).
Council Decision 542/2010/JHA
(OJ L 155, 22.6.2010, p. 23).

ANNEX II

CORRELATION TABLE

Decision 2008/839/JHA	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 9	Article 9
Article 10	Article 10
Article 11	Article 11
Article 12	Article 12
Article 13	Article 13
—	Article 14
Article 14	Article 15
Article 15	Article 16
Article 16	—
Article 17	Article 17
Article 17a	Article 18
Article 18	Article 19
—	Article 20
Article 19	Article 21
—	Annex I
—	Annex II

COUNCIL REGULATION (EU) No 1273/2012

of 20 December 2012

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

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 74 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) Council Regulation (EC) No 1104/2008 of 24 October 2008 on migration from the Schengen Information System (SIS 1+) to the second generation Schengen Information System (SIS II) [2] and Council Decision 2008/839/JHA of 24 October 2008 on migration from the Schengen Information System (SIS 1+) to the second generation Schengen Information System (SIS II) [3] have been substantially amended. Since further amendments are to be made, they should be recast in the interest of clarity.

(2) The Schengen Information System (SIS) set up pursuant to the provisions of Title IV of the Convention of 19 June 1990 implementing the Schengen Agreement of 14 June 1985 between the Governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders [4] (the 'Schengen Convention'), and the further development, thereof, SIS 1+, constitute essential tools for the application of the provisions of the Schengen *acquis* as integrated into the framework of the European Union.

(3) The development of the second generation Schengen Information System (SIS II) was entrusted by the Council to the Commission pursuant to Regulation (EC) No 2424/2001 [5] and Decision 2001/886/JHA [6]. Those acts expired on 31 December 2008 prior to the completion of the SIS II developments. They therefore needed to be supplemented firstly by Regulation (EC) No 1104/2008 and by Decision 2008/839/JHA and subsequently by this Regulation and Council Regulation (EU) No 1272/2012 of 20 December 2012 on migration from the Schengen Information System (SIS 1+) to the second generation Schengen Information System (SIS II) [7] at the latest until the termination of the migration from SIS 1+ to SIS II or until a date to be fixed by the Council, acting in accordance with Regulation (EC) No 1987/2006 of the European Parliament and of the Council of 20 December 2006 on the establishment, operation and use of the second generation Schengen Information System (SIS II) [8] and Council Decision 2007/533/JHA of 12 June 2007 on the establishment, operation and use of the second generation Schengen Information System (SIS II) [9].

(4) SIS II was established by Regulation (EC) No 1987/2006 and by Decision 2007/533/JHA. This Regulation should be without prejudice to the provisions of those acts.

(5) Certain tests of SIS II are provided for in Council Regulation (EC) No 189/2008 [10] and in Council Decision 2008/173/JHA [11].

(6) The development of SIS II should be continued and should be finalised in the framework of the SIS II global schedule endorsed by the Council on 6 June 2008 and subsequently amended in October 2009 in the light of orientations given by the Council of 4 June 2009 (Justice and Home Affairs). The new version of the SIS II global schedule was presented by the Commission to the European Parliament and the Council in October 2010.

(7) A comprehensive test of SIS II should be conducted in full cooperation between the Member States and the Commission, in accordance with the provisions of this Regulation. As soon as possible after its completion, that test should be validated as provided for by Regulation (EC) No 1987/2006 and Decision 2007/533/JHA. Only test data should be used for the purpose of the comprehensive test.

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

[1] Opinion of 21 November 2012 (not yet published in the Official Journal).
[2] OJ L 299, 8.11.2008, p. 1.
[3] OJ L 299, 8.11.2008, p. 43.
[4] OJ L 239, 22.9.2000, p. 19.
[5] OJ L 328, 13.12.2001, p. 4.
[6] OJ L 328, 13.12.2001, p. 1.
[7] See page 21 of this Official Journal.
[8] OJ L 381, 28.12.2006, p. 4.
[9] OJ L 205, 7.8.2007, p. 63.
[10] OJ L 57, 1.3.2008, p. 1.
[11] OJ L 57, 1.3.2008, p. 14.

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

(10) In order to better manage the potential difficulties brought about by the migration from SIS 1+ to SIS II, an interim migration architecture for SIS should be established and tested. The interim migration architecture should have no impact on the operational availability of SIS 1+. A converter should be provided by the Commission.

(11) The Member State issuing an alert should be responsible for ensuring that the data entered into SIS is accurate, up to date and lawful.

(12) The Commission should remain responsible for Central SIS II and its communication infrastructure. This responsibility includes the maintenance and continuation of the development of SIS II and its communication infrastructure, including at all times the correction of errors. The Commission should provide coordination and support for the joint activities. The Commission should provide, in particular, the necessary technical and operational support to the Member States at Central SIS II level including the availability of a helpdesk.

(13) The Member States are and should remain responsible for the development and maintenance of their national systems (N.SIS II).

(14) France should remain responsible for the technical support function of SIS 1+, as expressly provided for in the Schengen Convention.

(15) Representatives of the Member States participating in SIS 1+ should coordinate their actions within the framework of the Council. It is necessary to set out a framework for that organisational action.

(16) In order to support Member States in opting for the most favourable technical and financial solution, the Commission should initiate without delay the process of adapting this Regulation by proposing a legal framework for the migration from SIS 1+ to SIS II which better reflects the technical migration approach outlined in the Migration Plan for the SIS Project (the 'Migration Plan') adopted by the Commission after a positive vote by the SIS-VIS Committee on 23 February 2011.

(17) The Migration Plan envisages that within the switchover period all Member States, consecutively, will perform their individual switchover of the national application from SIS 1+ into SIS II. It is desirable from a technical point of view that Member States that have switched over be able to use the full scope of SIS II from the time of the switchover and not have to wait until other Member States have also switched over. Therefore, it is necessary to apply Regulation (EC) No 1987/2006 and Decision 2007/533/JHA from the time of the initiation of the switchover by the first Member State. For reasons of legal certainty, the period of switchover should be kept as short as possible, and should not exceed 12 hours. The application of Regulation (EC) No 1987/2006 and Decision 2007/533/JHA should not prevent Member States, which have not switched over yet or which have had to fall back for technical reasons, from using SIS II limited to SIS 1+ functionalities during the intensive monitoring period. In order to apply the same standards and conditions to alerts, data processing and data protection in all Member States, it is necessary to apply the SIS II legal framework to the SIS operational activities of the Member States which did not yet switch over.

(18) It is necessary to maintain the application of certain provisions of Title IV of the Schengen Convention on a temporary basis by incorporating those provisions into this Regulation as they provide the legal framework for the converter and the interim migration architecture during the migration. The interim migration architecture for the operations of SIS 1+ allows SIS 1+ and certain technical parts of the SIS II architecture to operate in parallel during a limited transitional period which is needed to make possible an incremental migration from SIS 1+ to SIS II.

(19) Regulation (EC) No 1987/2006 and Decision 2007/533/JHA provide that the best available technology, subject to a cost-benefit analysis, should be used for Central SIS II. The Annex to the Council Conclusions on the further direction of SIS II of 4-5 June 2009 laid down milestones which should be met in order to continue with the current SIS II project. In parallel, a study has been conducted concerning the elaboration of an alternative technical scenario for developing SIS II based on SIS 1+ evolution (SIS 1+ RE) as the contingency plan, in case the tests demonstrate non-compliance with the milestone requirements. Based on these parameters, the Council may decide to invite the Commission to switch to the alternative technical scenario.

(20) The description of the technical components of the interim migration architecture should therefore be adapted to allow for another technical solution, and in particular the SIS 1+ RE regarding the development of Central SIS II. SIS 1+ RE is a possible technical solution to develop Central SIS II and to achieve the objectives of the SIS II laid down in Regulation (EC) No 1987/2006 and Decision 2007/533/JHA.

(21) The SIS 1+ RE is characterised by uniqueness of means between SIS II development and SIS 1+. The references in this Regulation to the technical architecture of SIS II and to the migration process should therefore, in case of implementation of an alternative technical scenario, be read as the references to SIS II based on another technical solution, as applied mutatis mutandis to the technical specificities of that solution, in keeping with the objective to develop Central SIS II.

(22) In any technical scenario, the result of migration at central level should be availability of the SIS 1+ database and new SIS II functionalities, including additional data categories, in the Central SIS II. In order to facilitate data loading it should be specified that deleted data as referred to in Article 113(2) of the Schengen Convention will not be migrated from SIS 1+ to SIS II.

(23) The Commission should be empowered to contract out to third parties, including national public bodies, tasks conferred upon it by this Regulation and tasks relating to the implementation of the budget, in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [1] (the 'Financial Regulation').

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

(24) As regards the financing of the development of the Central SIS II based on an alternative technical solution, it should be covered by the general budget of the Union while respecting the principle of sound financial management. In accordance with the Financial Regulation the Commission may delegate budget implementation tasks to national public sector bodies. Following the political orientation and subject to the conditions laid down in the Financial Regulation, the Commission would be invited, in case of switchover to the alternative solution, to delegate the budget implementation tasks related to the development of the SIS II based on SIS 1+ RE to France.

(25) Regulation (EC) No 1987/2006 and Decision 2007/533/JHA, as well as Decision No 574/2007/EC of the European Parliament and of the Council of 23 May 2007 establishing the External Borders Fund for the period 2007 to 2013 as part of the General Programme Solidarity and Management of Migration Flows [2], included SIS II national developments among the eligible actions to be co-financed under the External Borders Fund (EBF). Commission Decision 2007/599/EC of 27 August 2007 implementing Decision No 574/2007/EC of the European Parliament and of the Council as regards the adoption of strategic guidelines for 2007 to 2013 [3] further identified SIS II as one of the five strategic priorities under the EBF, recognising the importance of supporting the coherent and timely development of the national projects alongside the central SIS II.

Since the adoption of those legal acts, the SIS II project received a significant reorientation in the course of 2010, after the completion of an important test campaign, the 'Milestone 1'. Furthermore, the evolutions in the use of the SIS by the Member States led to a need to update the SIS II technical requirements concerning performance and storage capacity which affected the costs of the SIS II project both at central and national level.

(26) With regard to the migration process from SIS 1+ to SIS II, the evolution in requirements and the advances made in the completion of the SIS II project led to a redefinition of the migration architecture, of the migration calendar and of the testing requirements. An important part of the activities that would now be required at Member State level for the migration to SIS II were not anticipated at the time when Regulation (EC) No 1104/2008 and Decision 2008/839/JHA were adopted or at the time when the financial package and the multiannual programmes under the EBF were drawn up. It is, therefore, necessary to partly realign the cost distribution principles for the migration from SIS 1+ to SIS II. Certain national activities related to that migration, in particular in connection with the participation of Member States in migration-related testing activities could be co-financed from the SIS II budget line of the general budget of the Union. That possibility should cover specific and well-defined activities beyond, and not to coincide with, other SIS II related actions which would continue to be supported under the EBF. The financial assistance thus provided under this Regulation should be complementary to that provided by the EBF.

(27) In relation to the co-financing provided under this Regulation, appropriate measures should be taken to prevent irregularities and fraud and the necessary steps should be taken to recover funds lost, wrongly paid or incorrectly used, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests [4], 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

[1] OJ L 248, 16.9.2002, p. 1.

[2] OJ L 144, 6.6.2007, p. 22.

[3] OJ L 233, 5.9.2007, p. 3.

[4] OJ L 312, 23.12.1995, p. 1.

protect the European Communities' financial interests against fraud and other irregularities [1], and Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) [2].

(28) In order to ensure uniform conditions for the implementation of this Regulation, taking into consideration the financial impacts of the decision upon Member States, which should remain fully involved when the Commission exercises its implementing powers, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [3].

(29) The Commission and the Member States should continue to cooperate closely during all steps of the development of the SIS II and the migration from SIS 1+ to SIS II in order to complete the process. In the Council conclusions on SIS II of 26-27 February 2009 and 4-5 June 2009, an informal body consisting of the experts of the Member States and designated as the 'Global Programme Management Board', was established to enhance the cooperation and to provide direct Member States support to the central SIS II project. The positive result of the work of that group of experts and the necessity of further enhancing the cooperation and the transparency of the central SIS II project justify the formal integration of the group of experts into the SIS II management structure. A group of experts, called the Global Programme Management Board, should therefore be formally established to complement the current SIS II organisational structure. In order to ensure efficiency as well as cost effectiveness the number of experts should be limited. The activities of the Global Programme Management Board should be without prejudice to the responsibilities of the Commission and of the Member States.

(30) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data [4] applies to the processing of personal data by the Commission.

(31) The European Data Protection Supervisor is responsible for monitoring and ensuring the application of Regulation (EC) No 45/2001 and is competent to monitor the activities of the Union institutions and bodies in relation to the processing of personal data. The Joint Supervisory Authority is responsible for supervising the technical support function of the current SIS 1+ until the entry into force of the SIS II legal framework. National Supervisory Authorities are responsible for the supervision of the processing of SIS 1+ personal data on the territory of their respective Member States and remain responsible for monitoring the lawfulness of the processing of SIS II personal data on the territory of their respective Member States. This Regulation should be without prejudice to the specific provisions of the Schengen Convention as well as of Regulation (EC) No 1987/2006 and of Decision 2007/533/JHA on the protection and security of personal data. That SIS II legal framework provides that the National Supervisory Authorities and the European Data Protection Supervisor ensure the coordinated supervision of SIS II.

(32) The migration from SIS 1+ to SIS II is a complex process which, despite extensive preparation by all stakeholders, entails significant technical risks. It is desirable for the legal framework to provide for the necessary flexibility to respond to unexpected difficulties which the central system or one or several national systems could face during the migration process. Therefore, while for reasons of legal certainty the switchover phase and the intensive monitoring period during which the interim migration architecture continues to exist should be as short as possible, the Council should, in case of technical difficulties, be enabled to fix the final date for the termination of migration in accordance with Article 55(2) of Regulation (EC) No 1987/2006 and Article 71(2) of Decision 2007/533/JHA.

(33) Since the objectives of this Regulation, namely setting up the interim migration architecture and migrating the data from SIS 1+ to SIS II, cannot be sufficiently achieved by the Member States and can, therefore, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve those objectives.

(34) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.

(35) In order to give effect in 2012 to the financial facility which could be provided to Member States from the general budget of the Union in accordance with this Regulation, this Regulation should enter into force on the day following its publication.

[1] OJ L 292, 15.11.1996, p. 2.
[2] OJ L 136, 31.5.1999, p. 1.
[3] OJ L 55, 28.2.2011, p. 13.
[4] OJ L 8, 12.1.2001, p. 1.

(36) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latters' association with the implementation, application and development of the Schengen acquis [1] which fall within the area referred to in Article 1, point G, of Council Decision 1999/437/EC [2] on certain arrangements for the application of that Agreement.

(37) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis [3] which fall within the area referred to in Article 1, point G, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC [4].

(38) As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* [5] which fall within the area referred to in Article 1, point G, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU [6].

(39) In accordance with Articles 1 and 2 of Protocol (No 22) on the position of Denmark, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen *acquis*, Denmark shall, in accordance with Article 4 of that Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it in its national law.

(40) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which the United Kingdom does not take part, in accordance with Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen acquis [7]; the United Kingdom is therefore not taking part in its adoption and is not bound by it or subject to its application.

(41) This Regulation constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part, in accordance with Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* [8]; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application.

(42) This Regulation is without prejudice to the arrangements for the partial participation of Ireland and the United Kingdom in the Schengen *acquis* as determined by Decisions 2000/365/EC and 2002/192/EC respectively.

(43) As regards Cyprus, this Regulation constitutes an act building upon, or otherwise related to, the Schengen *acquis* within the meaning of Article 3(2) of the 2003 Act of Accession.

(44) The European Data Protection Supervisor was consulted and delivered an opinion on 9 July 2012 [9],

HAS ADOPTED THIS REGULATION:

Article 1

General purpose

1. The Schengen Information System (SIS), set up pursuant to the provisions of Title IV of the Schengen Convention (SIS 1+), shall be replaced by a new system, the Schengen Information System II (SIS II), the establishment, operation and use of which is regulated by Regulation (EC) No 1987/2006.

2. In accordance with the procedures and the division of tasks set out in this Regulation, SIS II shall be developed by the Commission and the Member States as a single integrated system and shall be prepared for operations.

3. The development of SIS II may be achieved by implementing an alternative technical scenario characterised by its own technical specifications.

Article 2

Definitions

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

(a) 'Central SIS II' means the technical support function of SIS II containing a database, the 'SIS II database', and a uniform national interface (NI-SIS);

[1] OJ L 176, 10.7.1999, p. 36.
[2] OJ L 176, 10.7.1999, p. 31.
[3] OJ L 53, 27.2.2008, p. 52.
[4] OJ L 53, 27.2.2008, p. 1.
[5] OJ L 160, 18.6.2011, p. 21.
[6] OJ L 160, 18.6.2011, p. 19.
[7] OJ L 131, 1.6.2000, p. 43.
[8] OJ L 64, 7.3.2002, p. 20.
[9] OJ C 336, 6.11.2012, p. 10.

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

(c) 'N.SIS' means the national system of SIS 1+, consisting of the national data systems which communicate with C.SIS;

(d) 'N.SIS II' means the national system of SIS II, consisting of the national data systems which communicate with Central SIS II;

(e) 'converter' means a technical tool to allow consistent and reliable communication between C.SIS and Central SIS II, ensuring the functionalities provided for in Article 10(3) and allowing the conversion and synchronisation of data between C.SIS and Central SIS II;

(f) 'comprehensive test' means the test referred to in Article 55(3)(c) of Regulation (EC) No 1987/2006;

(g) 'test on supplementary information' means functional tests between the SIRENE Bureaux.

Article 3

Subject matter and scope

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

(a) the maintenance and continuation of the development of SIS II;

(b) a comprehensive test of SIS II;

(c) a test on supplementary information;

(d) the continuation of the development and testing of a converter;

(e) the establishment and testing of an interim migration architecture;

(f) the migration from SIS 1+ to SIS II.

Article 4

Technical components of the interim migration architecture

In order to ensure the migration from SIS 1+ to SIS II, the following components shall be made available to the extent necessary:

(a) the C.SIS and the connection to the converter;

(b) the communication infrastructure for SIS 1+ allowing the C.SIS to communicate with the N.SIS;

(c) the N.SIS;

(d) Central SIS II, NI-SIS and the communication infrastructure for SIS II allowing the Central SIS II to communicate with N.SIS II and the converter;

(e) the N.SIS II;

(f) the converter.

Article 5

Main responsibilities in the development of SIS II

1. The Commission shall continue to develop the Central SIS II, the communication infrastructure and the converter.

2. France shall make available and operate C.SIS in accordance with the provisions of the Schengen Convention.

3. The Member States shall continue to develop N.SIS II.

4. The Member States participating in SIS 1+ shall maintain N.SIS in accordance with the provisions of the Schengen Convention.

5. The Member States participating in SIS 1+ shall make available and operate the communication infrastructure for SIS 1+.

6. The Commission shall coordinate the activities and provide the necessary support for the implementation of the tasks and responsibilities referred to in paragraphs 1 to 3.

Article 6

Continuing development

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

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

Article 7

Main activities

1. The Commission together with Member States participating in SIS 1+ shall conduct a comprehensive test.

2. An interim migration architecture shall be set up and a test of that architecture shall be performed by the Commission together with France and the other Member States participating in SIS 1+.

3. The Commission and the Member States participating in SIS 1+ shall perform the migration from SIS 1+ to SIS II.

4. The Member States participating in SIS 1+ shall perform a test on the exchange of supplementary information.

5. The Commission shall provide the necessary support at Central SIS II level for the activities referred to in paragraphs 1 to 4.

6. The activities referred to in paragraphs 1 to 3 shall be coordinated by the Commission and the Member States participating in SIS 1+ acting within the Council.

Article 8

Comprehensive test

1. The comprehensive test shall not start before the Commission has declared that it considers that the level of success of the tests referred to in Article 1 of Regulation (EC) No 189/2008 is sufficient to begin such a test.

2. A comprehensive test aiming at confirming, in particular, the completion by the Commission and the Member States participating in SIS 1+ of the necessary technical arrangements to process SIS II data and the demonstration that the level of performance of SIS II is at least equivalent to that achieved with SIS 1+ shall be performed.

3. The comprehensive test shall be executed by the Member States participating in SIS 1+ for the N.SIS II and by the Commission for the Central SIS II.

4. The comprehensive test shall follow a detailed schedule defined by the Member States participating in SIS 1+ acting within the Council in cooperation with the Commission.

5. The comprehensive test shall be based on the technical specifications defined by the Member States participating in SIS 1+ acting within the Council in cooperation with the Commission.

6. The Commission and the Member States participating in SIS 1+ acting within the Council shall define the criteria for determining whether the necessary technical arrangements to process SIS II data are completed and the level of performance of SIS II is at least equivalent to that achieved with SIS 1+.

7. The test results shall be analysed using the criteria referred to in paragraph 6 of this Article, by the Commission and the Member States participating in SIS 1+ acting within the Council. The test results shall be validated in accordance with Article 55(3)(c) of Regulation (EC) No 1987/2006.

8. Member States not participating in SIS 1+ may participate in the comprehensive test. Their results shall not affect the overall validation of that test.

Article 9

Test on supplementary information

1. The Member States participating in SIS 1+ shall conduct functional SIRENE tests.

2. The Commission shall make available Central SIS II and its communication infrastructure during the execution of the test on supplementary information.

3. The test on supplementary information shall follow a detailed schedule defined by the Member States participating in SIS 1+ acting within the Council.

4. The test on supplementary information shall be based on the technical specifications defined by the Member States participating in SIS 1+ acting within the Council.

5. The test results shall be analysed by the Member States participating in SIS 1+ acting within the Council. The Member States participating in SIS 1+ shall ensure that the global test result is transmitted to the European Parliament.

6. Member States not participating in SIS 1+ may participate in the test on supplementary information. Their results shall not affect the overall validation of that test.

Article 10

Interim migration architecture

1. An interim migration architecture shall be set up, consisting of the components as set out in points (a) to (f) of Article 4. The converter connects Central SIS II and C.SIS for a transitional period. The N.SIS are connected to C.SIS, the N.SIS II to Central SIS II.

2. The Commission shall provide a converter, the Central SIS II and its communication infrastructure as part of the interim migration architecture.

3. To the extent necessary, the converter shall convert data in two directions between the C.SIS and Central SIS II and keep C.SIS and Central SIS II synchronised.

4. The Commission shall test the communication between Central SIS II and the converter.

5. France shall test the communication between C.SIS and the converter.

6. The Commission and France shall test the communication between Central SIS II and C.SIS via the converter.

7. France, together with the Commission, shall connect C.SIS via the converter to Central SIS II.

8. The Commission, together with France and the other Member States participating in SIS 1+, shall test the interim migration architecture as a whole in accordance with a test plan provided by the Commission.

9. France shall make available data for test purpose, if necessary.

Article 11

Migration from SIS 1+ to SIS II

1. For the migration from C.SIS to Central SIS II, France shall make available the SIS 1+ database and the Commission shall introduce the SIS 1+ database into Central SIS II. Data of SIS 1+ database referred to in Article 113(2) of the Schengen Convention shall not be introduced into Central SIS II.

2. The Member States participating in SIS 1+ shall migrate from N.SIS to N.SIS II using the interim migration architecture, with the support of France and of the Commission.

3. The migration of the national system from SIS 1+ to SIS II shall start with the data loading of N.SIS II, when that N.SIS II is to contain a data file, the national copy, containing a complete or partial copy of the SIS II database.

The data loading as described in the first subparagraph shall be followed by a switchover from N.SIS to N.SIS II for each Member State. The switchover shall start on the date to be fixed by the Council, acting in accordance with Article 55(2) of Regulation (EC) No 1987/2006, after the conditions of Article 55(3) of that Regulation are met. The switchover from N.SIS to N.SIS II for all Member States shall be completed within no more than 12 hours. The national applications for the exchange of supplementary information shall migrate to s-TESTA network in parallel with the switchover.

The migration shall be terminated following an intensive monitoring period. That intensive monitoring period shall be limited in time, and shall not exceed 30 days from the date of the switchover of the first Member State.

The migration shall follow a detailed schedule provided by the Commission and the Member States participating in SIS 1+ acting within the Council.

4. The Commission shall assist in coordination and support of the common activities during the migration.

Article 12

Substantive legal framework

For the data loading phase of the migration referred to in the first subparagraph of Article 11(3), the provisions of Title IV of the Schengen Convention shall continue to apply to the SIS 1+.

As from the switchover of the first Member State from N.SIS to N.SIS II, as referred to in the second subparagraph of Article 11(3) of this Regulation, Regulation (EC) No 1987/2006 shall apply.

This Regulation shall continue to apply to the interim migration architecture during the entire migration as referred to in Article 11(3).

Article 13

Cooperation

1. The Member States and the Commission shall cooperate for the execution of all the activities covered by this Regulation in accordance with their respective responsibilities.

2. The Commission shall in particular provide the necessary support at Central SIS II level for the testing of and migration to N.SIS II.

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

Article 14

Replacement of the national sections by N.SIS II

1. The N.SIS II may replace the national section referred to in Article 92 of the Schengen Convention, in which case the Member States need not hold a national data file.

2. If any of the Member States replace their national section by N.SIS II, the compulsory functions of the technical support function towards that national section as referred to in Article 92(2) and (3) of the Schengen Convention shall become compulsory functions towards Central SIS II, without prejudice to the obligations referred to in Article 5(1) and Article 10(1), (2) and (3) of this Regulation.

Article 15

Processing of data and keeping of records in Central SIS II

1. The Central SIS II database shall be available for the purpose of carrying out automated searches in the territory of each Member State.

2. Central SIS II shall provide the services necessary for the entry and processing of SIS 1+ data, the online update of N.SIS II national copies, the synchronisation of and consistency between N.SIS II national copies and the Central SIS II database and provide operations for initialisation and restoration of N.SIS II national copies.

3. Without prejudice to the relevant provisions of Title IV of the Schengen Convention, the Commission shall ensure that every access to and all exchanges of personal data within Central SIS II are recorded for the purposes of checking whether or not the search is lawful, monitoring the lawfulness of data processing and ensuring the proper functioning of Central SIS II and of national systems, data integrity and security.

4. The records shall show, in particular, the date and time of the data transmitted, the data used to perform searches, the reference to the data transmitted and the name of the competent authority responsible for processing the data.

5. The records may only be used for the purposes referred to in paragraph 3 and shall be deleted at the earliest one year, and at the latest three years after their creation.

6. Records may be kept longer if they are required for monitoring procedures that are already under way.

7. The competent authorities referred to in Article 60(1) and Article 61(1) of Decision 2007/533/JHA in charge of checking whether or not a search is lawful, monitoring the lawfulness of data processing, self-monitoring and ensuring the proper functioning of Central SIS II, data integrity and security, shall, in accordance with the provisions of Decision 2007/533/JHA, have access, within the limits of their competence and at their request, to those records for the purpose of fulfilling their tasks.

Article 16

Costs

1. The costs arising from migration, the comprehensive test, the test on supplementary information, maintenance and development measures at Central SIS II level or concerning the communication infrastructure shall be borne by the general budget of the Union.

2. The costs arising from installation, migration, testing, maintenance and development of the national systems as well as from the tasks to be performed by the national systems under this Regulation shall be borne by each Member State concerned as it is provided for by Article 119(2) of the Schengen Convention.

3. Complementing the financial assistance provided by the External Borders Fund, the Union may provide a financial contribution to the expenditures of the Member States for their migration and migration related testing activities performed under Articles 8, 9, Article 10(8) and Article 11 of this Regulation to cover specific and well-defined activities.

The Union contribution related to the activities referred to in the first subparagraph shall take the form of grants as provided for by Title VI of the Financial Regulation. That contribution shall not exceed 75 % of the eligible expenditures of each Member State and it shall not exceed EUR 750 000 per Member State. The Commission shall appraise, decide and administer the co-financing operation in accordance with the budgetary and other procedures, in particularly those laid down in the Financial Regulation.

Each Member State requesting such a financial contribution shall prepare a financial forecast indicating a breakdown of the operational as well as administrative costs of the activities related to the testing and migration. Where Member States use Union funds for their expenditures, those expenditures shall be reasonable and comply with the principles of sound financial management, in particular, value for money and cost-effectiveness. Member States shall present a report to the Commission on their use of the Union contribution by not later than six months following the date of switchover fixed by the Council, acting in accordance with Article 55(2) of Regulation (EC) No 1987/2006.

Where the Union contribution is not implemented or is implemented inadequately, partially or late, the Union may reduce, withhold or terminate its financial contribution. Where the Member States do not contribute or contribute only partially or late to the financing of activities referred to in the first subparagraph, the Union may reduce its financial contribution.

4. The Court of Auditors shall be entitled to carry out the appropriate audits in liaison with national audit bodies or with the competent national departments. The Commission shall be empowered to carry out all the checks and inspections necessary to ensure the proper management of the Union funds and to protect the Union's financial interest against any fraud or irregularity. To this end, the Member States shall make available all the relevant documents and records to the Commission and the Court of Auditors.

5. The costs of installing and operating the technical support function referred to in Article 92(3) of the Schengen Convention, including the cost of lines connecting the national sections of SIS 1+ to the technical support function, and of activities performed in conjunction with tasks conferred upon France for the purpose of this Regulation shall be borne jointly by the Member States as it is provided for by Article 119(1) of the Schengen Convention.

Article 17

Committee procedure

1. The Commission shall be assisted by the Committee established by Article 51 of Regulation (EC) No 1987/2006 (the 'Committee'). The Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 applies.

3. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 18

Global Programme Management Board

1. Without prejudice to the respective responsibilities and activities of the Commission, the Committee, France and the Member States participating in SIS 1+, a group of technical experts, called the Global Programme Management Board (the 'Board'), is hereby set up. The Board shall be an advisory body for assistance to the central SIS II project and shall facilitate consistency between central and national SIS II projects. The Board shall have no decision-making power nor any mandate to represent the Commission or Member States.

2. The Board shall be composed of a maximum of 10 members, meeting on a regular basis. A maximum of eight experts and an equal number of alternates shall be designated by the Member States participating in SIS 1+ acting within the Council. A maximum of two experts and two alternates shall be designated by the Director-General of the responsible Directorate-General of the Commission from among the Commission officials.

The meetings of the Board may be attended by other experts of Member States and Commission officials directly involved in the development of the SIS II projects, at the expense of their respective administration or institution.

The Board may invite other experts to participate in the Board's meetings as defined in the terms of reference referred to in paragraph 5, at the expense of their respective administration, institution or company.

3. Experts designated by the Member States acting as Presidency and incoming Presidency shall always be invited to participate in the Board's meetings.

4. The Board's secretariat shall be ensured by the Commission.

5. The Board shall draw up its own terms of reference which shall include in particular procedures on:

— alternative chairmanship between the Commission and the Presidency,

— meeting venues,

— preparation of meetings,

— admission of other experts,

— communication plan ensuring full information to non-participating Member States.

The terms of reference shall take effect after a favourable opinion has been given by the Director-General of the responsible Directorate-General of the Commission and by Member States participating in SIS 1+ meeting within the framework of the Committee.

6. The Board shall regularly submit written reports about the progress of the project including advice which has been given, and its justification, to the Committee or, as appropriate, to the relevant Council preparatory bodies.

7. Without prejudice to Article 16(2), the administrative costs and travel expenses arising from the activities of the Board shall be borne by the general budget of the Union, to the extent that they are not reimbursed from other sources. As regards travel expenses of the members in the Board designated by the Member States participating in SIS 1+ acting within the Council and experts invited pursuant to paragraph 3 of this Article which arise in connection with the work of the Board, the Commission's 'Rules on the reimbursement of expenses incurred by people from outside the Commission invited to attend meetings in an expert capacity' shall apply.

Article 19

Reporting

The Commission shall submit by the end of every six month period, and for the first time by the end of the first six month period of 2009, a progress report to the European Parliament and the Council concerning the development of SIS II and the migration from SIS 1+ to SIS II. The Commission shall inform the European Parliament of the results of the tests referred to in Articles 8 and 10.

Article 20

Repeal

Regulation (EC) No 1104/2008 is repealed.

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

Article 21

Entry into force and applicability

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

It shall expire upon the termination of the migration as referred to in the third subparagraph of Article 11(3). If that date cannot be complied with due to outstanding technical difficulties related to the migration process, it shall expire on a date to be fixed by the Council, acting in accordance with Article 55(2) of Regulation (EC) No 1987/2006.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 20 December 2012.

For the Council
The President
E. FLOURENTZOU

ANNEX I

REPEALED REGULATION WITH ITS SUCCESSIVE AMENDMENTS

Council Regulation (EC) No 1104/2008

(OJ L 299, 8.11.2008, p. 1).

Council Regulation (EU) No 541/2010

(OJ L 155, 22.6.2010, p. 19).

ANNEX II

CORRELATION TABLE

Regulation (EC) No 1104/2008	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 9	Article 9
Article 10	Article 10
Article 11	Article 11
Article 12	Article 12
Article 13	Article 13
—	Article 14
Article 14	Article 15
—	—
Article 15	Article 16
Article 16	—
Article 17	Article 17
Article 17a	Article 18
Article 18	Article 19
—	Article 20
Article 19	Article 21
—	Annex I
—	Annex II

DECISIONS

COMMISSION DECISION

of 18 December 2012

on the adoption of the Rules to ensure consistent verification of the existence and legal status of participants, as well as their operational and financial capacities, in indirect actions supported through the form of a grant under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities and under the Seventh Framework Programme of the European Atomic Energy Community for nuclear research and training activities

(Text with EEA relevance)

(2012/838/EU, Euratom)

THE EUROPEAN COMMISSION,

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

Having regard to the Treaty establishing the European Atomic Energy Community,

Having regard to Regulation (EC) No 1906/2006 of the European Parliament and of the Council of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013) [1], and in particular Article 16(4),

Having regard to Council Regulation (Euratom) No 1908/2006 of 19 December 2006 laying down the rules for the participation of undertakings, research centres and universities in action under the Seventh Framework Programme of the European Atomic Energy Community and for the dissemination of research results (2007 to 2011) [2], and in particular Article 15(4),

Whereas:

(1) By Decision C(2007) 2466 of 13 June 2007 on the adoption of the Rules to ensure consistent verification of the existence and legal status of participants, as well as their operational and financial capacities, in indirect actions supported through the form of a grant under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and under the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007-2011), the Commission has drawn up the rules ensuring consistent verification of the existence and legal status of participants, as well as their operational and financial capacities, in indirect actions supported through the form of a grant under Decision No 1982/2006/EC of the European Parliament and the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) [3] and Council Decision 2006/970/Euratom of 18 December 2006 concerning the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007 to 2011) [4] (hereinafter 'the Rules').

(2) Those Rules were designed to establish a clear and transparent framework to be implemented in a homogeneous manner by all services involved in the management of grants awarded under Decision No 1982/2006/EC and Decision 2006/970/Euratom. Those Rules aimed to ensure a coherent approach across the Programmes established by those Decisions, and for the duration of those Programmes, while allowing a measure of flexibility where necessary.

(3) Those Rules should be modified in order to specify some elements and codify the practice up to date, such as definitions of legal statuses/categories and provisions on requested documents and the effective date, cases of incomplete, contradictory or false declarations and/or supporting documents, the Legal Entity Appointed Representative, the modification and the review of validations and the Validation Panel.

(4) It is necessary that those Rules are changed to guarantee a uniform implementation and interpretation by introducing specific cases. In addition, the section on protection measures needs to be reinforced.

[1] OJ L 391, 30.12.2006, p. 1.
[2] OJ L 400, 30.12.2006, p. 1.
[3] OJ L 412, 30.12.2006, p. 1.
[4] OJ L 400, 30.12.2006, p. 60.

(5) At the same time, those Rules should be brought in line with the Treaty on the Functioning of the European Union.

(6) For reasons of clarity and legal security, Decision C(2007) 2466 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

The rules to ensure consistent verification of the existence and legal status of participants, as well as their operational and financial capacities, in indirect actions supported through the form of a grant under Decision No 1982/2006/EC, Decision 2006/970/Euratom and Council Decision 2012/93/Euratom [1] are set out in the Annex to this Decision.

Article 2

Decision C(2007) 2466 is repealed. References to the repealed Decision shall be construed as references to this Decision.

Article 3

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

Done at Brussels, 18 December 2012.

For the Commission

The President

José Manuel BARROSO

[1] OJ L 47, 18.2.2012, p. 25.

ANNEX

TABLE OF CONTENTS

FOREWORD

The Rules for Participation for FP7 [1] (FP7 RP) stipulate that *'the Commission shall adopt and publish rules to ensure consistent verification of the existence and legal status of participants in indirect actions as well as their financial capacity. The Commission shall refrain from renewing such verification unless the situation of the participant concerned has changed'* [2].

This document defines these rules. It is based on the regulatory requirements provided by the FP7 RP and the Financial Regulation [3] (FR) and its associated Implementing Rules [4] (IR). It has been adopted by the Commission on the 13th of June 2007 and it is applicable from the 1st of January 2007 for any relevant FP7 indirect actions.

These rules concern all FP7 indirect actions taking the form of an EC or EURATOM grant agreement and will be applied by services implementing FP7 indirect actions ('Research Directorates-General' and bodies to which these tasks have been delegated) up to the date of entry into force of a subsequent version of this document.

For any subsequent versions, a change history and a comparison to the previous version(s) will be provided in order to identify the modifications/updates and ease the understanding.

The following substantial modifications have been made in the rules in order to clarify a number of points based on experience to date:

— Part 1 on the 'Verification of the legal existence and legal status/category' has been updated with:

  — definitions of legal statuses/categories,

  — provisions regarding requested documents and the effective date,

  — provisions regarding cases of incomplete, contradictory or false declarations and/or supporting documents,

  — provisions regarding the Legal Entity Appointed Representative (LEAR),

  — provisions regarding the modification and the review of validations,

  — provisions regarding the Validation Panel.

— Part 3 and 4 regarding the 'Verification of the financial capacity' have been modified as follows:

  — Section 3.4 on the 'Requested data and documents' is complemented with specific cases.

  — The relevant sections on the financial viability ratios (sections 3.5.3 and 4.2.1) are complemented with the definition of exceptional cases.

  — Section 4.2.2 on the 'Protection measures' is modified.

In addition, the following editorial modifications have been introduced:

— Section 1 and 3 have been updated with a reference to the validation services [5] carrying out the verification of the legal existence and legal status/category, verifying the accuracy of the participant's financial data and carrying out the concise financial analysis.

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[1] **EC FP7 RP** – Regulation (EC) No 1906/2006.
EURATOM FP7 RP – Regulation (Euratom) No 1908/2006 and Council Regulation (Euratom) No 139/2012 of 19 December 2011 laying down the rules for the participation of undertakings, research centres and universities in actions under the Framework Programme of the European Atomic Energy Community and for the dissemination of research results (2012-2013), (OJ L 47, 18.2.2012, p. 1).
The **EC FP7 RP** and the **EURATOM FP7 RP** together are hereinafter referred to as **FP7 RP** (in particular when reference is made to articles which bear the same number in both regulations).

[2] Article 16(4) of the **EC FP7 RP** and Article 15(4) of the EURATOM FP7 RP.

[3] **FR** – Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (OJ L 248, 16.9.2002, p. 1).

[4] **IR** – Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities (OJ L 357, 31.12.2002, p. 1).

[5] The validation services are set up by the Commission in order to support the services responsible for the evaluation of proposals, for the negotiation of grants or for the management of grant agreements, e.g. by verifying the legal existence and legal status/category of applicants, recording the indirect cost method declared by the applicant, and verifying the financial data provided by the applicant.

— The references to the Unique Registration Facility are replaced by references to the Research Participant Portal.

— Further editorial modifications were made necessary in order to take into account the autonomy of the executive agencies and other bodies implementing FP7 (references to the Commission services are replaced by references to 'services implementing FP7' as far as tasks are performed by services of the Commission as well as other bodies to which implementing tasks have been delegated).

— The text is brought in line with the Treaty on the Functioning of the European Union.

GENERAL PURPOSE

This document addresses the rules to ensure a consistent verification of:

— the legal existence;

— the FP7 status;

— the operational capacity; and

— the financial capacity

of an FP7 participant in order to ensure the implementation of an indirect action (achievement of the expected objectives and results) and the protection of the financial interests of the Union.

The following guiding principles, developed over successive meetings of a working group involving all Research Directorates-General and based on a strong will of simplification and rationalisation, underlie the approach adopted by the Commission:

— Only information that is strictly required by the FP7 RP and/or the FR and/or its IR or for the provision of essential statistics (Commission Annual Activity Report – cf Article 190 TFEU) will be requested from the applicants/participants.

— The Research Participant Portal (http://ec.europa.eu/research/participants/portal) facilitates the participation of legal entities in subsequent FP7 proposals. Through the Research Participant Portal legal entities have to provide their basic data and official documents only once. However, they will be obliged to inform the validation services, also via the Participant Portal, of any modifications.

— Each validated legal entity must appoint one person, a Legal Entity Appointed Representative (LEAR), who is authorised to manage online the legal and financial information of the legal entity via the Research Participant Portal.

— Information requested at proposal stage will not be asked again during negotiations or that information that e.g. needs to be verified at grant agreement stage is not requested at proposal stage, unless it is obvious that the information provided is no longer up to date at the time of verification [1].

— The verification will as much as possible rely on the self-declaration and auto-verification by applicants/participants. For this to happen the Commission will ensure that they have access to clear information/instructions and any tools they need (e.g. to assess themselves their financial viability). The results delivered by such tools provide non-binding indications; they do not pre-empt the results of a formal financial viability check by the services implementing FP7. Irregularities and/or false declarations may lead to the application of financial penalties or administrative penalties in the form of exclusion of the applicants/participants for future participation.

[1] More specification on the role and responsibility of the LEAR is provided in section 1.2.4.

— While the legal and operational verification has to be performed for each entity, not all entities are subject to financial capacity verification. Section 3.3 which includes a 'Decision Tree on Financial Capacity Verification' gives detailed information on the conditions that lead to a verification of the financial capacity of an entity.

— Due to the introduction of a Participants' Guarantee Fund (PGF), no additional financial guarantee or security will be requested from participants or imposed on them, such as reduction of pre-financing for a particular participant, trust accounts, blocked accounts, financial guarantees, etc. The services implementing FP7 will however strengthen ex-post controls to ensure the good implementation of FP7 indirect actions and protect the financial interests of the participants and of the Union.

1. VERIFICATION OF THE LEGAL EXISTENCE AND LEGAL STATUS/CATEGORY

1.1. **Principles**

1.1.1. *Confidentiality and protection of data*

All data and documents related to the legal and financial verification communicated to the validation services shall be treated as confidential and subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data [1]. All data shall be processed in accordance with the principles of transparency, proportionality, impartiality and legality.

1.1.2. *Legal Existence*

In compliance with Article 4 of the FP7 RP, a grant can only be awarded to an existing legal entity who:

— has submitted an eligible proposal using the procedure defined by the Commission; and

— is not in one of the situations mentioned in Articles 93(1), 94 and 96(2)(a) of the FR.

In accordance with Article 2(1) of the FP7 RP, a legal entity is any natural person, or any legal person created under the national law of its place of establishment, or under Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.

1.1.3. *Legal status according to the Rules for Participation for FP7 (Categories of legal entities)*

The FP7 RP (as well as, in certain cases, the Work Programme and the call for proposals) refer to different categories of legal entities. These differences are mainly based on the legal status and/or characteristics of the legal entity.

According to the category(ies) of legal entities to which it belongs, a legal entity may have different rights and obligations [2], in particular with respect to:

— rights in terms of the EU financial contribution to a participant (including its maximum level of funding);

— whether or not a financial capacity check of a legal entity will be mandatory;

— whether or not a competent public officer is allowed to certify the financial statement(s) [3];

— the financial responsibility in the implementation of the indirect action (cf implementation modalities of the Participants' Guarantee Fund).

[1] OJ L 8, 12.1.2001, p. 1.

[2] The categorization of legal entities participating in an FP7 indirect action must be carried out in due time (initially during the negotiation stage; subsequently during the implementation stage, before any payment if a change occurs during a reporting period of the project) in order to protect the interests of the participants and of the Union, and to avoid delays of implementation or duplications at the different stages of the procedure(s).

[3] The services implementing FP7 may require the audit methodology used by the competent public officer for the calculation of eligible costs.

The main categories of legal entities that shall be identified are the following [1]:

<table>
<tr><td colspan="3">Natural person [1]</td></tr>
<tr><td rowspan="6">Legal person</td><td colspan="2">Public body</td></tr>
<tr><td rowspan="2">Profit</td><td>Non-profit public body</td></tr>
<tr><td>Profit public body</td></tr>
<tr><td rowspan="2">International Organisation</td><td>Of European Interest</td></tr>
<tr><td>Other</td></tr>
<tr><td colspan="2">Secondary and Higher education Establishment</td></tr>
<tr><td colspan="2">Research Organisation</td></tr>
<tr><td rowspan="2">Enterprise</td><td>SME</td></tr>
<tr><td>Non-SME</td></tr>
</table>

[1] A natural person can qualify as an enterprise in the meaning of the Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36), e.g. if self-employed with a VAT number.

The verification of the eligibility criteria that are introduced in specific funding schemes and/or in specific calls for proposals will also be part of the categorization exercise [2].

As a general rule, if a legal entity may be categorized in different categories the validation services shall consider the most favourable one for this legal entity in terms of rights and/or obligations [3].

Even if the participant loses its status/category of non-profit public body, secondary and higher education establishment, research organisation or SME, he/she will retain the advantages of this status for the signed grant agreements for the whole duration (unless it can be shown that the status/category granted was based on false declarations or manipulated intentionally with the sole purpose of obtaining the FP7 grant). However, participants must inform the validation services whenever such change occurs. If the participant signs another grant agreement after having lost the respective status it will not qualify to have the status.

1.1.3.1. Definitions

1. 'Public body' means according to Article 2(13) of the EC FP7 RP and Article 2(12) of the EURATOM FP7 RP any legal entity established as such by national law, and international organisations. 'Established as public body by national law' means

   (1) incorporated as a public body in the formal act of creation or recognised as public body by the national law and

   (2) governed by public law.

   However, public bodies may act and be subject to private law for some or most of their activities. A legal entity established under private law with a public service mission is not considered as a public body according the FP7 RP.

[1] As defined in Article 2 of the **EC FP7 RP** and in Article 2 of the **EURATOM FP7 RP** and referred to in Art 32(5) and Art 33(1) of the EC FP7 RP and of the EURATOM FP7 RP.

[2] Even if an applicant is not eligible to participate in an indirect action, this does not automatically lead to the non-eligibility of the proposal: in such a case (non-eligibility of one or several applicant(s)), the proposal is non-eligible only if the eligibility criteria in the Rules for Participation, Work programme and the call are not met. As examples: ERA-NET Coordination and Support Actions will limit the participation to certain types of legal entities (National authorities like Ministries or regions, Executive agencies of these national authorities, etc…); a call for proposals of collaborative projects may restrict the participation to a certain type of legal entities, e.g. SMEs or Civil Society Organisations.

[3] Legal entities belonging to several categories will be registered as such, in particular for statistical purposes.

2. 'Non-profit public body' (Article 32(5) and Article 33(1) of the FP7 RP) means any legal entity which cumulatively meets the conditions of being a 'public body' and of being a 'non-profit organisation'.

3. 'Non-profit organisation' means a legal entity which by its legal form is non-profit-making and/or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members. The decisions of the managing board, associates, stakeholders, members or representatives of the organisation on the distribution of profits are not considered as sufficient elements to prove the non-profit nature of an entity.

4. 'Research organisation' means according to Article 2(7) of the EC FP7 RP and Article 2(7) of the EURATOM FP7 RP a legal entity established as a non-profit organisation which carries out research or technological development as one of its main objectives. The definition of 'non-profit organisation' set forth in point 3 above shall apply. The mere financing of research activities carried out by other entities, the dissemination of knowledge and the promotion or coordination of research activities are not considered as research activities within the sense of this definition.

5. 'Secondary and higher education establishment' means a legal entity which is recognised as such by its national education system, being either a public or a private body.

6. 'SMEs' mean according to Article 2(14) of the EC FP7 RP and Article 2(13) of the EURATOM FP7 RP micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC [1].

   (a) According to Article 1 of the Annex of Recommendation 2003/361/EC an enterprise is considered to be any entity engaged in an economic activity, irrespective of its legal form. This includes, in particular, self-employed persons and family businesses engaged in craft or other activities, and partnerships or associations regularly engaged in an economic activity.

   (b) According to Article 2(1) of the Annex of Recommendation 2003/361/EC the category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons (expressed in annual working units as defined in Article 5 of the Recommendation) and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.

   (c) The following definitions shall apply in addition to those set out in Recommendation 2003/361/EC:

      (i) A legal entity is considered to be engaged in an economic activity, if it proves to be involved in any form of trade or activity done for remuneration or pecuniary interest in a given market. In general, any activity consisting in offering goods or services on a given market is an economic activity.

      (ii) The following shall not be considered economic activities

         (1) Activities which do not entail some sort of pecuniary offset; or

         (2) Activities for which there is no given/direct market; or

         (3) Activities for which the income generated is not distinct from the personal income of its members or shareholders.

   (d) For non-autonomous SMEs (partner enterprises and linked enterprises as set forth in Article 3(2) and (3) of the Annex of Recommendation 2003/361/EC), that is SMEs owned or controlled by other enterprises ('upstream enterprises') or which own or control others ('downstream enterprises') the data of upstream and downstream enterprises shall be used according to Article 6(2) to (4) of Recommendation 2003/361/EC to determine whether the enterprise meets the criteria to qualify as an SME.

   (e) According to Article 4(2) of the Annex of Recommendation 2003/361/EC, SME status is only lost after exceeding the ceilings stated in Article 2 of the Recommendation over two consecutive accounting periods. This rule is not applicable if an SME is merged or acquired by a larger group, in which case the SME shall lose its status immediately from the date of the transaction.

[1] See also http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index_en.htm.

Therefore, applicants who had their validation as SME refused on grounds of having exceeded the ceilings stated in Article 2 of Recommendation 2003/361/EC during the last accounting period shall get the validation reversed if they prove that those ceilings were not reached in the second-last accounting period. This does not apply if an SME has exceeded the thresholds as a result of a merger or acquisition.

1.1.4. *Requested data and documents*

Applicants, depending on their legal type, shall provide in the framework of the validation process supporting documents (except if previously provided and no changes have since taken place), which shall prove:

(1) Their legal name;

(2) Their legal form when they are legal persons;

(3) Their legal address; this shall be, by default, the address of the head office for legal persons or the address of the habitual residence for natural persons.

Documents are accepted in all the official EU languages. To facilitate the work of the validation services applicants may be requested to submit a free translation of these documents. Documents submitted in a non-EU official language ([1]) may be refused if not accompanied by a certified/official/legal translation by an accredited body or translator. The supporting documents must not be over 6 months old.

Legal entities shall provide in particular the supporting documents listed in the following. An electronic version of these documents is accepted.

(a) A signed legal entity identification form ([2]).

(b) For natural persons:

(i) A legible photocopy of the valid identity card or passport;

(ii) If applicable, an official VAT document.

(c) For public bodies:

(iii) A copy of the resolution, law, decree or decision establishing the legal entity in question as a public body; or, in the absence of this, any other official document attesting the establishment of the entity as a public body;

(iv) If applicable, an official VAT document. If a legal entity is not registered for VAT, the proof of the VAT exemption may be requested by the validation services.

(d) For other legal entities:

(v) A copy of any official document (e.g. official gazette, register of companies, etc.) showing the applicant's legal name and address and the registration number given to it by the national authorities or, depending on the country of registration, a copy of any other acceptable legal document;

(vi) A copy of the VAT registration document, if any, and only if the VAT number does not appear on the official document referred to above. If an entity is not registered for VAT, the proof of the VAT exemption shall be requested.

(e) For SMEs:

(vii) An annual balance sheet and profit and loss accounts for the last accounting period;

(viii) The annexes to these accounts with the indication of downstream and upstream enterprises when this is not shown in the balance sheet;

([1]) Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385/58).
([2]) EN: http://ec.europa.eu/budget/info_contract/legal_entities_en.htm.

(ix) A declaration on the staff headcount expressed in Annual Working Units as defined in Article 5 of Recommendation 2003/361/EC;

(x) The balance sheet and the profit and loss accounts, and their annexes, for the latest approved accounting period, as well as the staff headcount of upstream and downstream enterprises as defined in Article 6 of Recommendation 2003/361/EC.

(xi) As laid down in Article 4(3) of Recommendation 2003/361/EC in the case of newly established enterprises whose accounts have not yet been approved, a declaration including a bona fide estimate made in the course of the financial year shall be accepted.

(xii) A declaration shall be accepted as means of evidence to demonstrate that, in spite of lack of turnover, the enterprise is engaged in an economic activity, namely by the investments made and the likely expected return.

(xiii) The supporting documents above can be replaced by an official certificate issued by an official authority or competent body in the Member State in which the legal entity has its legal address or habitual residence and which certifies that the enterprise is an SME in the sense of Recommendation 2003/361/EC. However, sworn or solemn statements made by the applicant before a judicial or administrative authority, a notary or a public officer in the country of origin or provenance shall not be accepted as replacement of the required supporting documents.

1.1.5. *Effective date of the legal existence and the legal status/category*

1. The date on which the legal existence and the legal status/category of a legal entity are taken into account as being effective by the Commission (effective date) is the date upon which the legal act establishing the constitution or incorporation of a legal entity becomes valid. That date shall be, in order of precedence:

(1) The date of registration in the country's official registry (e.g. commercial registry);

(2) The date of publication on the national official journal;

(3) The date of the legal deposit of the act in the court registry;

(4) The date of signature of the parties.

2. When there is no act of constitution or incorporation, the legal entity shall be deemed to exist since a default date.

3. The effective date of SME status shall be the account closure date of the accounting period on which the assessment of the SME status is based in accordance with Article 4(2) of the Annex of Recommendation 2003/361/EC (see section 1.1.3.1, point (6)(e) above). For newly established enterprises whose accounts have not yet been closed, the effective date is the date of their creation.

1.2. **Implementation of the verification of legal existence and legal status/category**

Any legal entity shall register its basic administrative and legal data (such as organisation's legal name, legal address, etc.) in the web interface of the Participant Portal. Registration is necessary only once. In order to avoid double registrations, the 'Participant Identification Code' (PIC) issued at the first registration shall be used in any subsequent participation of the legal entity ([1]).

Entities without an independent legal personality shall participate using the same 'Participant Identification Code' (PIC) as the legal entity from which they depend. However, the following entities may be validated as separate entities and be attributed a separate PIC:

(1) Ministries or other executive services part of the central public administration of the – central or federated – State, directly linked to the government in accordance with the officially published organisation of the State,

([1]) The temporary PIC issued at the first registration will become final once the entity is validated. Basic legal and financial data of FP7 participants are accessible via the Research Participant Portal (http://ec.europa.eu/research/participants/portal).

(2) Specialised agencies set up by international organisations, including (but not limited to), the ones referred to in Article 43(2) of the IR.

(3) The Joint Research Centre and its delegations.

At the stage of proposal submission no supporting documents will be requested and no verification of the data by the services implementing FP7 will be carried out.

Entities need to have a PIC, registered and validated in the Commission's database, before a grant agreement can be signed. To this end, the legal existence and legal status/category of the entity have to be verified by the validation services on the basis of the data and supporting documents provided by the entity if this has not been done before [1]. The verification of legal existence and the attribution of a legal status/category shall be carried out once the entity has self-registered. It shall only be carried out if the basic legal data (legal name, legal form and legal address) of the entity are clearly indicated and supported by the required supporting documents, provided none of these are manifestly erroneous, incorrect or illegible.

The same procedure will be used and the same documents will be requested for legal entities joining an indirect action or for any changes of the legal personality of a participant during the implementation of this indirect action, which lead to a new validation of the entity starting with its self-registration at the Participant Portal.

The supporting documents for proving the legal existence and legal status/category shall be submitted to the validation services via the web interface of the Participant Portal or by e-mail [2] within the deadline specified by the services implementing FP7 in the invitation or/and in the framework for negotiation.

In case of non-solicited self-registrations, the validation services, when requesting clarifications and supporting documents, will specify the timeframe within which the applicant must reply. If the applicant does not submit, clarify or complete the supporting documents within the indicated timeframe, taking into account any special and justified circumstances, the validation services reserve the right to discard self-registrations.

While the validation services verify the legal existence of the applicant, they also verify if the entity is already registered in the Research Participant Portal or in another central European Commission database containing the same relevant information and take this information into consideration [3].

Once the legal existence of the applicant is determined, the validation services shall verify on the basis of the supporting documents the FP7 legal status and identify the category to which each legal entity participating in an FP7 indirect action belongs.

After having verified the legal existence and legal status/category of an entity the validation services shall verify and record the indirect cost method declared by the applicant.

1.2.1. *Provisions regarding cases of incomplete, contradictory or false declarations and/or supporting documents*

1. All evidence is presumed to be truthful and provided in good faith. The validation services may resort to all publicly available information for clarification purposes.

(a) If the findings do not corroborate the applicant's declaration,

(b) If the evidence provided by the applicant is illegible, incomplete or ambiguous,

(c) If indications point at incomplete or false declarations or other irregularities,

[1] The sequence of these verification procedures is referred to as 'validation'.
[2] To the functional mailbox: REA-URF-Validation@ec.europa.eu.
[3] If the legal entity is subject to exclusion in application of points a, b, c, d, e of Article 93(1), Article 94 or Article 96, the entity will be automatically excluded from the participation. Further reference: Commission Decision 2008/969/EC, Euratom of 16 December 2008 on the Early Warning System for the use of authorising officers of the Commission and the executive agencies (OJ L 344, 20.12.2008, p. 125) and Commission Regulation (EC, Euratom) No 1302/2008 of 17 December 2008 on the central exclusion database (OJ L 344, 20.12.2008, p. 12).

the validation services shall inform the applicant and request to provide further clarification or to complete the documents submitted within a reasonable deadline.

2. In the following cases, namely

(a) If the applicant fails to supply the requested information,

(b) If he commits a misrepresentation in supplying the information required,

(c) If the supporting documents are invalid or outdated,

(d) If there remains a manifest contradiction between the applicant's declaration and the supporting documents,

the validation services shall:

(i) Where it concerns the proof of legal existence, refuse the validation of the concerned legal entity;

(ii) Where it concerns the attribution of legal status/category, validate the legal entity in accordance with the documents submitted and not of the applicant's declaration.

3. In case of refusal of validation or of refusal of the attribution of the self-declared legal status/category the validation services shall inform the applicant of the grounds and of the legal consequences.

4. In case of irregularities and/or false declarations the validation services shall inform the concerned Authorising officer and, if necessary, the European Anti-Fraud Office (OLAF).

Irregularities and/or false declarations may lead to the application of financial penalties or administrative penalties in the form of exclusion of the applicants/participants for future participation, as laid down in Article 96 of the Financial Regulation

1.2.2. *Information on the outcome of the validation and the validated 'Participant Identification Code' (PIC)*

The validation services shall duly inform the applicants, of the outcome of the verification of the legal existence and the attributed legal status/category.

Each validated entity receives a unique validated 9-digit registration number, the 'Participant Identification Code' (PIC) which shall be used in any participation of the entity in subsequent FP7 proposals.

1.2.3. *Declaration on the correctness of the basic data in the Grant Preparation Form*

During negotiations the basic administrative and legal data registered by the legal entity in the Participant Portal will be automatically uploaded into the Grant agreement Preparation Forms (GPF).

The legal representative of the organisation is the person authorised to commit the organisation and to sign the grant agreement. He/she must:

(a) Verify that the basic administrative and legal data provided in the GPF for his/her organisation are correct; and, if not, ask for their modification via the Participant Portal.

(b) Declare on his/her honour that all the information provided in the GPF regarding his/her organisation is complete, accurate and correct, declare that it is not in one of the situations mentioned in Articles 93(1), 94 and 96(2)(a) of the FR and provide a signature certifying the above in the GPF. Supporting documents regarding the legal representatives of the legal persons mentioned in this section can be requested by the services implementing FP7.

1.2.4. *Legal Entity Appointed Representative (LEAR)*

After the validation of the legal entity, the legal representative shall appoint a Legal Entity Appointed Representative (LEAR) who will be the official contact person recognised by the validation services and authorised to request changes to validation data, on the basis of relevant supporting documents. To this end, the legal representative will send the Lear Appointment Form – by regular mail or by e-mail - duly signed and stamped, to the validation services. The nomination of a LEAR is mandatory. Being appointed as LEAR is an administrative function which may but need not be distinct from being a legal representative of the entity.

As soon as registered in the central database the LEAR becomes the official contact person to the validation services on all issues related to the legal and financial data and the FP7 status/category of the entity. The LEAR has access to a dedicated online tool on the Research Participant Portal and has to maintain the validated information of the entity up to date. He/she shall inform the validation services of any change in the legal data or legal status/category of the entity immediately following the change. Upon request, he/she provides also financial data of the entity.

In case of such changes of legal data or legal status/category, the LEAR shall request a modification of a previous validation on the basis of the legal and/or financial supporting documents.

1.2.5. *Modification of validations*

Requests for modification of a previous validation shall only be accepted if submitted by the LEAR. If a LEAR has not been nominated yet, this nomination process must be achieved for the treatment of the modification request to begin.

1.2.5.1. Modifications of validations due to an error of the initial validation

Such modifications are registered retroactively with an effective date as from the date of the initial validation.

However, in such cases and if considered necessary, other protection measures, i.e. listed in point 4.2.2, can be implemented. When the modification concerns an error attributable to the validation services, the retroactive effect may be waived by the authorising officer of the competent service implementing FP7, when duly justified and complying with the principles of sound financial management and proportionality.

1.2.5.2. Modifications of validations due to a change of the legal existence and legal status/category

The validation services shall encode the effective date of the modification of the legal existence or legal status/category of a legal entity which is determined by the date on which the act establishing the change becomes valid, unless the terms of this act stipulate another date. For SMEs the effective date of the modification of status shall be the closure date of the accounting period on which the change of status is based and which is determined according to the rules laid down in section 1.1.3.1, paragraph (6)(e) above.

1.2.5.3. Changes of the indirect cost method (ICM)

The validation services shall reflect changes of the indirect cost method declared by the participant in accordance with the rules laid down in Article II.15 of the Model Grant Agreement.

Indirect costs are those eligible indirect costs which cannot be identified by the participant as being directly attributed to the project but which can be identified and justified by its accounting system as being incurred in direct relationship with the eligible direct costs attributed to the project. They may be identified according to the methods specified in Article II.15(2) of the Model Grant Agreement ([1]).

The following situations of changes of the ICM can be distinguished ([2]):

Any requests for change of the ICM shall be duly justified either by an evolution of the legal status or of the accounting system of the participant; or by a mistake made during the negotiation of the first project where the legal entity participates.

([1]) The detailed conditions of the use of the methods of calculation of indirect costs and of the distinction between direct and indirect costs, are specified in Annex II, Part B, Section 1of the relevant Model Grant Agreement, in particular Article II.15 (the general Seventh Framework Programme Model Grant Agreement,, the ERC Model Grant Agreement and the REA Model Grant Agreement are available under the following link: http://cordis.europa.eu/fp7/calls-grant-agreement_en.html#standard_ga and in the Guide to Financial Issues relating to FP7 Indirect Actions ftp://ftp.cordis.europa.eu/pub/fp7/docs/financialguide_en.pdf.

([2]) For more detailed information see Amendments Guide for FP7 Grant Agreements, ftp://ftp.cordis.europa.eu/pub/fp7/docs/financialguide_en.pdf.

By requesting an ICM change, the participant declares to have read and accepted the rules regarding the choice of the ICM (Article II.15 of the Model Grant Agreement).

(1) Changes of the legal status of the participant

If a change of the legal status of the participant results in the acquisition of the status/category of non-profit public body, secondary and higher education establishment, research organisation or SME, the participant may ask for the application of the 60 % flat rate for future projects if it fulfils the other conditions set in the Model Grant Agreement for the use of this specific rate [1].

The effective date of the change of the ICM shall be the same as that of the change of legal status/category laid down in section 1.2.5.2.

The effective date of the change of the ICM is only applicable for the future and shall therefore not affect on-going projects.

(2) Changes in the accounting system of the participant:

(a) In cases of changes of the accounting system, the LEAR shall inform the validation services, in its request for change of the ICM via the Participant Portal, on the date to which the change shall take effect. The effective date registered by the validation services is the date stated by the LEAR if it is accepted as such by the services implementing FP7.

(b) If the participant had originally opted for a flat rate and decided afterward to opt for the actual indirect cost method for subsequent participation the change does not need to be proved.

(c) The effective date of the change of the ICM is only applicable for the future and shall therefore not affect on-going projects. However, if due to changes in their accounting system participants are no longer able to identify the actual indirect costs, the effective date of the change of the ICM is applicable for on-going projects.

(3) If a mistake regarding the ICM has been made during the negotiation of the first project where the legal entity participates and if the correction of such a mistake has been accepted by the services implementing FP7, the effective date of the modification of the ICM is the same date as that of the initial validation of the entity and is applicable for on-going projects.

1.2.6. *Administrative review of validations*

1. Prior to any request for review, the applicant shall ask for the confirmation of the outcome of the validation.

2. Requests for review [2] of validations may be addressed in writing with no other formalities being required directly to the competent validation service by the nominated LEAR of the concerned legal entity.

Requests for review submitted by a party not concerned by the validation shall be rejected.

3. The validation services shall acknowledge the receipt of the request for review. They shall duly inform the concerned party of the decision thereon. In case of rejection, the grounds shall be given.

A request for review of a validation does not suspend the validation, which shall remain in force until it is overturned. This administrative review process is without prejudice to the applicant's rights of appeal before the European Ombudsman or the Court of Justice of the European Union.

[1] See the relevant section regarding Article II.15 MGA in the Guide to Financial Issues relating to FP7 Indirect Actions ftp://ftp.cordis.europa.eu/pub/fp7/docs/financialguide_en.pdf.

[2] Acts of an executive agency can be referred to the Commission for a review of its legality under Article 22 of Council Regulation EC No 58/2003.

1.2.7. *The Validation Panel*

The DGs and the Executive Agencies of the European Commission implementing FP7 shall set up an inter-service panel for coordination purposes (referred to as the validation panel) and shall delegate their representative to this panel. The validation services shall participate in the validation panel without voting rights and assure the secretariat of the validation panel under the supervision of the Chair of the validation panel. The Commission shall establish the rules of procedure for the coordination processes including a register of common practices.

In case a request for review is submitted by an applicant to the competent validation services in accordance with 1.2.7 above, these services shall refer the request to the validation panel. The validation panel shall review and decide on the referred cases of legal entity validation. The validation panel does not have the mandate to deal with cases related to the verification of the financial capacity.

2. VERIFICATION OF THE OPERATIONAL CAPACITY

2.1. **Principles**

As mentioned in Article 115 of the FR and Article 176 of its IR, the operational and financial capacity of an applicant must be assessed in order to ensure the applicant's ability to complete the proposed action or work programme.

The operational capacity is to be distinguished from the financial capacity for which a specific verification will be carried out (see infra).

The term 'operational capacity' relates to the professional (technical, scientific, technological, managerial, administrative … [1]) skills, qualifications, tools and/or knowledge necessary to achieve the objectives and expected results.

Since most of the FP7 indirect actions are implemented by a consortium of several legal entities, two levels of operational capacity are distinguished:

— The consortium's operational capacity;

— Each applicant's operational capacity.

The purpose of the verification is therefore to assess whether the applicants (collectively and individually) have or will have in due time the professional competencies and qualifications required to complete the indirect action.

In case a natural person performs the specific role of coordinator, particular attention has to be given to the assessment of his/her operational capacity.

2.2. **Implementation**

2.2.1. *At proposal stage*

The operational capacity of the consortium will be addressed at the Evaluation Stage [2] by the independent external evaluators when assessing the evaluation criterion 'Implementation'.

In order to allow the independent external evaluators to perform this task, the applicants will be required to provide inter alia within their proposal: at applicant level, a brief description of the organisation and a short profile of staff members who will undertake the work (See Guide for Applicants); at consortium level, the applicants will describe how they collectively constitute a consortium capable of achieving the project objectives (See Guide for Applicants).

An above-threshold score will indicate a positive assessment by the independent external evaluators.

[1] For example, the coordinator of an indirect action has to demonstrate its professional skills and qualifications in terms of administrative, financial, legal and team management.

[2] The evaluation takes place after the proposal submission and before the negotiation of the award of FP7 grants.

The independent external evaluators will provide comments to the services implementing FP7 (cf Evaluation Summary Report) for any legal entity for which they consider that the necessary operational capacity to perform its foreseen tasks is obviously insufficient or not enough demonstrated.

2.2.2. *At negotiation stage*

As a general rule, the services implementing FP7 will follow the recommendations of the independent external evaluators regarding the operational capacity – including the possibility to refuse the participation of an applicant from a positively evaluated proposal because of its operational incapacity. If the services implementing FP7 are aware of any additional information that may impinge on the judgement of the independent external evaluators, the services implementing FP7 may decide not to select a legal entity and/or a proposal for EU financial contribution, on the basis of a strong and well-supported argumentation. Such additional information may come from different sources such as the findings of previous audits, management of previous (or on-going) projects, the consultation of external databases, etc.

Each applicant shall provide to the services implementing FP7 a declaration on its honour that it has, or will have in the time required, the necessary resources for the implementation of their work in the relating FP7 indirect action. This declaration is part of the GPF and will be signed by a person authorised to sign the grant agreement and to legally commit the organisation. When an applicant does not have the own operational resources for the implementation of the work, the applicant should describe how he/she intends to fulfil his/her obligations. If any task is to be subcontracted or other third parties are involved in the project, it will have to be discussed and agreed during negotiations, and clearly described in Annex I to the Grant Agreement.

In the particular case of a legal entity joining the consortium during the negotiation or during the implementation of the indirect action, the assessment of its operational capacity will be based on the same principles.

3. VERIFICATION OF THE FINANCIAL CAPACITY: RULES OF IMPLEMENTATION

3.1. **Principles**

The verification of the financial capacity to carry out the proposed action is an integral part of the negotiation stage and needs to be completed before the signature of the grant agreement.

The following rules specify the minimum requirements for financial checks that authorising officers must conduct in accordance with Article 16(4) of the FP7 RP and with Articles 173 and 176 of the IR of the FR.

The verification of the financial capacity of an applicant to carry out the action essentially proceeds in four steps:

— As a first step, legal entities subject to a mandatory verification of their financial capacity are identified in accordance with FP7 RP, the FR and its IR (see section 3.3);

— In a second step, these legal entities provide – if not already available – their financial information and relevant supporting documents covering the last closed financial year (see section 3.4); the information is then verified by the validation services.

— In a third step, on the basis of the above, the validation services will proceed with a concise financial analysis on the last closed financial year. This concise financial analysis will consist of:

  — a financial viability check (see section 3.5);

  — in addition the Equity flag will be checked (see section 3.5);

  — a co-financing capacity's check and financial exposure flag (if relevant) (see section 3.6).

— Finally, as a fourth step, on the basis of the above, the authorising officer will take the appropriate measures, including, if necessary, a more in-depth financial analysis. (See Section 4).

The same procedure and documents, as described hereafter, will be used/requested for legal entities joining an indirect action during the negotiation or the implementation of this indirect action.

3.2. **Reasons for a concise financial analysis as a general rule**

Given the important number of applicants whose financial capacity has to be analysed and in order to avoid unreasonable delays, a concise financial viability check is carried out. However, if the result of the concise financial viability check [1] of a legal entity is 'weak', a more in-depth financial analysis [2] shall be carried out [3].

3.3. **Categories of legal entities subject to (or exempted from) a verification of their financial capacity**

In compliance with the FR and its IR (article 176(4)), the following categories of legal entities are not subject to a verification of their financial capacity:

— natural persons in receipt of scholarships;

— public bodies;

— international organisations referred to in Article 43(2) of the IR:

  — international public-sector organisations set up by intergovernmental agreements, and specialised agencies set up by such organisations;

  — the International Committee of the Red Cross (ICRC);

  — the International Federation of National Red Cross and Red Crescent Societies;

  — the European Investment Bank and the European Investment Fund.

Moreover, due to the introduction in the FP7 RP of a Participants' Guarantee Fund:

— in compliance with article 38 of the FP7 RP (paragraphs 5 and 6), the following categories of legal entities are not subject to a verification of their financial capacity:

  — legal entities whose participation in the indirect action is guaranteed by a Member State or an Associated country;

  — higher and secondary education establishments.

— In addition, in compliance with paragraph 6 of article 38 of the FP7 RP, any other category of legal entities applying for an EU financial contribution in an FP7 indirect action inferior or equal to EUR 500 000, are also not subject to a verification of their financial capacity, except if:

  — the legal entity is the coordinator of the indirect action and it does not belong to one of the above-mentioned categories; and/or

  — in exceptional circumstances, according to information already available to the services implementing FP7, there are justified grounds to doubt the financial capacity of an applicant (eg.: if there are findings of serious administrative errors or fraud involving the entity; or if the entity is subject to pending legal procedures or judicial proceedings for serious administrative errors or fraud; or if the entity is subject to an attachment order or significant recovery order for an outstanding amount issued by the Commission on which the payment is significantly overdue); or

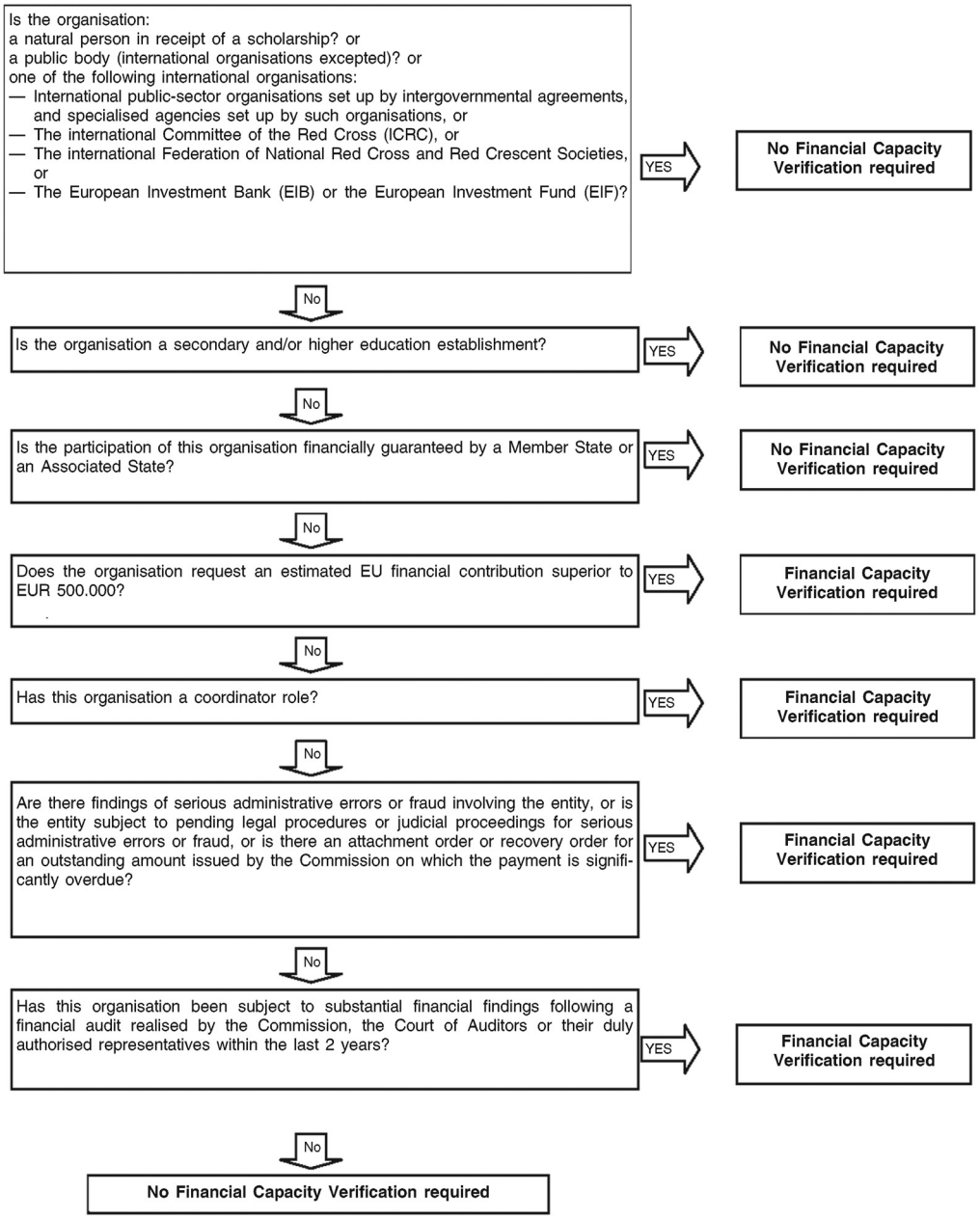
  — it has been subject to substantial financial findings relating to its financial capacity following a financial audit carried out by the Commission, the Court of Auditors or their duly authorised representatives within the last 2 years).

[1] See section 3.5.
[2] See section 4.2.1.
[3] The electronic tools automatically display all financial ratios on the basis of the Simplified Balance Sheet's data.

For any other legal entity participating in an FP7 indirect action, a verification of its financial capacity is mandatory.

A decision tree to identify categories of legal entities subject to a verification of their financial capacity is provided in the next page.

Decision tree on financial capacity verification



3.4. **Requested data and documents**

In accordance with FP7 RP, the term 'legal entity' shall include both legal persons and natural persons.

3.4.1. *Legal persons*

At the negotiation stage, and in compliance with FP7 RP:

— Each legal person subject to a verification of its financial capacity shall provide the validation services for the last financial year for which the accounts are closed:

  — Balance sheet;

— Profit and loss account;

— Statutory audit report on the 2 above financial statements if available. If the statutory reports are available, no further audit report is required ([1]).

— Each legal person subject to a verification of its financial capacity is required - by the validation services - to complete the synthesis of its last available balance sheet and profit and loss account in a specific format called 'Simplified accounts' (via the Research Participant Portal or by other means).

— Each legal person subject to a verification of its financial capacity requesting an estimated EU financial contribution exceeding EUR 500 000 shall provide the validation services with a full audit report certifying the accounts of the last available financial year ([2]). It can only be delivered by a professionally qualified external auditor.

As a general rule, no prospective financial data should be used, except in the case of 'young' legal entities (such as start-up companies) without any closed accounts. For these legal entities, a Business Plan will be required (especially 'young' SMEs) or (a) similar relevant document(s) of prospective activities.

Only the non-consolidated financial statements related to the validated entity are accepted for the purpose of financial viability checks even if the entity has linked or partner enterprises.

If the entity, in its capacity as a parent company (upstream enterprise) of a group of enterprises, is exempt from publishing a non-consolidated profit and loss account under its national legislation, the validation services can require the synthesis of the non-consolidated profit and loss account in a specific format ('Simplified accounts').

If the entity, in its capacity as a subsidiary of a parent company (downstream linked applicants), is exempt from a statutory audit under its national legislation and only the consolidated statements are available, the validation services can limit their request to the synthesis of the non-consolidated balance sheet and the profit and loss account in a specific format ('Simplified accounts'), supported by a copy of the official consolidated financial reports of the parent company and the related audit reports. Nevertheless, if such entity requests more than EUR 500 000 EU contribution, a full audit report certifying the non-consolidated accounts of the last available financial year for the subsidiary has to be provided.

3.4.2. *Natural persons*

Even if the situations where a natural person will:

— request an estimated EU financial contribution exceeding EUR 500 000; and/or

— be a coordinator;

are theoretical, these possibilities must be foreseen, in order to comply with paragraph 6 of article 38 of the FP7 RP.

At the negotiation stage, and in compliance with FP7 RP and with the IR of the FR, each natural person subject to a verification of its financial capacity shall provide the validation services with:

— its last income tax declaration;

— a certified declaration of its current patrimony ([3]);

— an exhaustive list (with relevant dates and figures) of its debts, broken down in short-term debts (maximum one year) and medium/long-term debts (more than one year), as certified by its creditors;

— an audit report, as described in section 3.4.1, if requesting an estimated EU financial contribution exceeding EUR 500 000.

([1]) The requirement of the statutory audit reports can be waived for those legal entities which are exempted from such audit reports under their national legislation.

([2]) This report shall include the clear mandate to audit, the responsibilities of both the management and the auditor, the way of conducting the audit, including the reasonable assurance about whether the financial statements are free of material misstatement, and the auditor's opinion.

([3]) Patrimony includes notably:
'Fixed' patrimony like land, tenement, hereditament, medium/long-term time deposits (more than one year), stock options (if the right of exercise is not available within one year), etc.
'Current' patrimony like available cash, savings, short-term time deposits (maximum of one year), stock-options (if the right of exercise is available within one year), etc.

3.4.3. *Other remarks*

The verified information of the 'Simplified accounts' is stored in the central Commission database and is available for the LEAR of each entity via the Research Participant Portal.

The financial data has to be provided at the beginning of negotiations and in some cases additional information may be required during the implementation of the project as well [1].

Subject to the decision of the responsible authorising officer, a legal entity that does not provide its requested data and documents in due time will not be able to participate in the FP7 indirect action in question.

3.5. **Financial viability check**

3.5.1. *Purpose*

In order to be financially viable, a legal entity must be:

— liquid: capable of covering its short-term commitments;

— solvent: capable of covering its medium and long-term commitments;

— profitable [2]: generating profits, or at least with self-financing capacity.

As a consequence, the liquidity, the financial autonomy, the profitability and the solvency of the legal entity must be assessed in the financial analysis.

The validation services provide a user-friendly electronic tool to applicants to carry out their financial viability check for their own information [3].

The following ratios, noteworthy value and thresholds apply for legal persons. Specific criteria will be used for natural persons (see section 3.5.4).

3.5.2. *Used ratios and noteworthy value*

The concise financial viability is based on the 3 financial ratios defined as follows:

Purpose	Indicators	Ratios	Concise Analysis
Liquidity	Quick ratio	$\frac{\text{Current assets} - \text{Stocks} - \text{Debtors} > 1 \text{ year}}{\text{Short-term debt (bank and non-bank)}}$	—
Profitability	Profitability (1)	$\frac{\text{GOP}}{\text{Turnover}}$	—
Solvency	Solvency	$\frac{\text{Total debt}}{\text{Equity (*)}}$	—

(*) ***Equity = Capital and reserves - 50 % of intangible assets***

Equity flag

In addition, a noteworthy value based on equity is used as a complementary data (Flag). The Equity flag will be considered 'positive' if the indicator 'Total debt / Equity' is superior or equal to 0 and inferior or equal to 10 (where Equity = Capital and reserves – 50 % of the intangible assets).

(1) The status of Small and Medium Enterprise (SME), in compliance with the Recommendation 2003/361/EC in the version of 6 May 2003, is defined according to financial criteria, some of which being linked to annual data provided through balance sheets and profit and loss accounts. See section 1.1.3.1(6) and section 1.1.4 point (e).
(2) The profitability is not relevant for natural persons.
(3) See the Research Participant Portal on http://ec.europa.eu/research/s/portal/page/lfvSimulation

3.5.3. *Thresholds*

According to the results obtained for each of the abovementioned ratios, the following quotes are given:

Purpose	Indicators	Weak	Acceptable	Good
		0	1	2
Liquidity	Quick ratio	i < 0,5	0,5 ≤ i ≤ 1	i > 1
Profitability	Profitability (1)	i < 0,05	0,05 ≤ i ≤ 0,15	i > 0,15
Solvency	Solvency	i > 6,00 or < 0	6,00 ≥ i ≥ 4,00	i < 4,00 and ≥ 0

The following rules are applied for the special cases where the ratio is negative, or contains a zero denominator or numerator:

Liquidity:

— If (Current assets-Stock-Debtors after one year) ≤ 0, the result shall be 0 with weak qualifications. The value for (Current assets-Stock-Debtors after one year) cannot be negative.

— If the short term debt (bank and non-bank) = 0, and the above (Current assets-Stock-Debtors after one year) is not zero, the result shall be 2 with good qualifications.

Profitability (1): [1]

— If GOP ≤ 0, the result shall be 0 with weak qualifications.

— If the Turnover = 0, the Operating income shall be used for the calculation.

— If the Operating Income = 0 or negative, the result shall be 0 with weak qualifications.

— Turnover cannot be negative.

Solvency:

— If Equity = 0, the result shall be –1 with weak qualifications in all cases.

— If Total debt = 0 and the Equity is positive, the result shall be 0 with good qualifications.

— If Total debt = 0 and the Equity is negative, the result shall be -1 with weak qualifications.

— The calculation of the Equity flag is based on the same principles, but it will be considered 'positive' if the indicator 'Total debt/Equity' is superior or equal to 0 and inferior or equal to 10.

3.5.4. *Particular case of natural persons*

For natural persons, the financial viability will be assessed as follows:

[1] When deciding about the financial viability of non-profit entities, their non-profit-making nature can be taken into account.

3.5.4.1. Used ratios

The financial viability is based on the 2 financial ratios as follows:

Purpose	Indicators	Ratios
Liquidity	Quick ratio	$\frac{\text{Current patrimony } (*) + \text{annual revenues } (**)}{\text{Short-term debt (bank and non-bank) } (***)}$
Solvency	Solvency	$\frac{\text{Total of doubts } (***)}{\text{Patrimony } (*)}$

(*) ***as indicated in the declaration of patrimony***
(**) ***as indicated in the income tax declaration***
(***) ***as indicated in the list(s) of debts certified by creditors***

3.5.4.2. Thresholds

According to the results obtained for each of the abovementioned ratios, the following quotes are given:

Purpose	Indicators	Weak	Acceptable	Good
		0	1,5	3
Liquidity	Quickratio	$i < 2$	$2 \leq i \leq 3$	$i > 3$
Solvency	Solvency	$i > 1$	$1 \geq i \geq 0,5$	$i < 0,5$

3.6. **Co-financing capacity check**

3.6.1. *Purpose*

The purpose of this check is to assess the co-financing capacity of an applicant.

This check will only be performed if an audit report [1] of the accounts has been issued (i.e.: only in the case of a legal entity requesting for its participation in this FP7 indirect action an estimated EU financial contribution exceeding EUR 500 000) and this report raised also serious qualifications in terms of co-financing capacity appreciated by the Authorising Officer.

The co-financing capacity of an applicant will not only be judged on the basis of the relating FP7 indirect action, but at least on the basis of all on-going indirect actions supported by the Union requesting co-financing that the authorising officer is aware of. In this context, the authorising officer may request from an applicant a list of projects supported by the EU budget in which it is involved [2].This check will however not be performed for applicants authorised to receive an EU financial contribution of up to 100 % of their eligible costs.

The following ratios, noteworthy value and thresholds apply for legal persons. Specific criteria will be used for natural persons (see section 3.6.4).

3.6.2. *Used ratios and noteworthy value*

The co-financing capacity check is based on the financial ratios as follows:

[1] See section 3.4.1.
[2] If appropriate, the Commission or bodies implementing FP7 can examine the co-financing capacity of any entity on the basis of the available information in their IT systems.

Co-financing capacity indicators:

Purpose	Indicators	Ratios
Co-financing capacity	CashFlow Indicator	$$\frac{\text{CashFlow}}{\Sigma_p \left(\frac{EligibleCost_p - EUcontribution_p}{Duration\ project_p} \times \frac{Min(365, DaysLeft_p)}{365} \right)}$$
	NetOperating Profit Indicator	$$\frac{\text{NOP}}{\Sigma_p \left(\frac{EligibleCost_p - EUcontribution_p}{Duration\ project_p} \times \frac{Min(365, DaysLeft_p)}{365} \right)}$$

p: on-going project where the legal entity is participating

$Durationproject_p$: Total Duration of the project p in Years

$EligibleCost_p$: Total Eligible Cost for the participant in the project p

$EU\ contribution_p$: Total EU Contribution for the participant in the project p

$DaysLeft_p$: number of days left for the project p

Cash flow: (gross operating profit + financial income) – (interest paid + similar charges)

Not taken into account for this calculation: ended projects and projects where the EU contribution = Eligible costs of the project.

Financial exposure flag:

In addition, and for coordinators only, a noteworthy value based on the project total pre-financing and the coordinators turnover is used as complementary data (Flag). The Financial Exposure Flag will be considered 'positive' if the indicator 'project total pre-financing/turnover' is equal or inferior to 0,5. (If the turnover is 0, the operating income shall be used for the calculation.)

3.6.3. *Thresholds*

According to the results obtained for each of the abovementioned ratios, the following quotes are given:

Purpose	Indicators	Weak	Good
		0	1
Co-financing capacity	Cash Flow Indicator	< 1	> = 1
	Net Operating Profit Indicator	< 1	> = 1

An overall score of less than 1 will be considered as a 'weak' co-financing capacity.

3.6.4. *Particular case of natural persons*

For natural persons, the co-financing capacity check will be assessed as follows:

3.6.4.1. Used ratios

Purpose	Indicators	Ratios
Co-financing capacity	Short term	$\frac{\text{Current patrimony } (^{*}) + \text{annual revenues } (^{**})}{(Projecteligiblecost - EUcontribution(CP)\ (^{***}))inaverageperyear}$
	Medium/Long Term	$\frac{\text{Patrimony } (^{*})}{(Projecteligiblecost - EUcontribution(CP)\ (^{**}))}$

(*) as indicated in the declaration of patrimony
(**) as indicated in the income tax declaration
(***) CP: Costs and EU contribution of all projects of the participant with the EU.

3.6.4.2. Thresholds

According to the results obtained for each of the abovementioned ratios, the following quotes are given:

Purpose	Indicators	Weak	Good
		0	1
Co-financing capacity	Short Term	< 1	> = 1
	Medium/Long Term	< 1	> = 1

4. VERIFICATION OF THE FINANCIAL CAPACITY: CONCLUSION OF THE ANALYSIS (CHECKS) AND POSSIBLE MEASURES TO BE TAKEN

4.1. **Assessment of the results of the concise analysis**

The concise financial assessment results in an overall score for the financial capacity of an applicant in the range of 'good', 'acceptable' or 'weak' on the basis of the above mentioned ratios.

As a general rule, any legal entity subject to a verification of its financial capacity which obtains under a concise analysis a minimum of **3 points** as a result of its financial viability check will be considered to have a 'positive' [1] financial capacity, unless it is subject to one (or several) of the situations mentioned hereafter.

Concise Analysis

	Weak	Acceptable	Good
Result of financial viability check	0-2	3	4-6

Despite of the abovementioned results, the financial capacity of a legal entity will in any case be considered as 'weak', and therefore be subject to a more in-depth analysis, if:

— an audit report (cf. section 3.4) of the accounts has been issued with serious qualification (not only on co-financing capacity);

— the result(s) obtained through Equity Flag (section 3.5.2) and/or Co-financing capacity check and/or Financial Exposure Flag (section 3.6) (if relevant) is(are) 'weak';

[1] 'Positive' means 'good' or 'acceptable'.

— the legal entity has been subject to substantial financial findings relating to its financial capacity following a financial audit carried out by the Commission (including OLAF [1]), the Court of Auditors or their duly authorised representatives within the last 2 years (cf. section 3.3).

If the legal entity obtained a 'positive' result under a concise financial analysis but there are findings of serious administrative errors or fraud involving the entity; or the entity is subject to pending legal procedures or judicial proceedings for serious administrative errors or fraud; or the entity is subject to an attachment order or significant recovery order for an outstanding amount issued by the Commission on which the payment is significantly overdue, it will be considered as having a 'weak' financial capacity but will not be subject to a more in-depth financial analysis. For this kind of entity, the authorising officer in charge will have to consider protection measures as defined under section 4.2.2.

4.2. **Actions to be taken in case of 'weak' result**

If the result of the concise financial viability check is 'weak', the authorising officer in charge will have first of all to conduct a more in-depth financial analysis (see section 4.2.1).

If, according to the results of this more in-depth analysis, the financial capacity of the applicant:

— is 'acceptable' or 'good', the applicant can participate in the indirect action, without any other action to be taken.

— remains 'weak', the authorising officer in charge will have to consider protection measures as defined under section 4.2.2.

— is 'insufficient' [2] (see section 4.2.1), the applicant cannot participate in the indirect action, except if duly justified reasons are provided by the authorising officer according to his/her own risk assessment.

For other cases ('positive' financial viability but with 'weak' results for co-financing check, Equity Flag, Financial Exposure Flag; audit report with serious qualification; substantial financial findings relating to the financial capacity of a legal entity following a financial audit carried out within the last 2 years), the authorising officer in charge will have to consider protection measures as defined under section 4.2.2.

4.2.1. *A more in-depth financial analysis*

4.2.1.1. For legal persons

This more in-depth financial analysis will consist of an extended analysis of the financial viability of the legal entity.

The 5 following ratios will be used:

Purpose	Indicators	Ratios	More in depth analysis
Liquidity	Quick ratio	$\frac{\text{Current assets–Stocks–Debtors} > 1 \text{ year}}{\text{Short-term debt (bank and non-bank)}}$	—
Financial autonomy	Gross Operating Profit Ratio	$\frac{\text{Interest}}{\text{GOP}}$	—
Profitability	Profitability (1)	$\frac{\text{GOP}}{\text{Turnover}}$	—
	Profitability (2)	$\frac{\text{NOP}}{\text{Turnover}}$	—
Solvency	Solvency	$\frac{\text{Total debt}}{\text{Equity (*)}}$	—

(*) ***Equity = Capital and reserves – 50 % of intangible assets***

Correction: Gross Operating Profit Ratio is calculated as: Interest paid/GOP.

[1] OLAF stands for European Anti-Fraud Office.

[2] Both in terms of financial viability and, if relevant, of co-financing capacity.

According to the results obtained for each of the abovementioned ratios, the following quotes are given:

Purpose	Indicators	Weak & Unsufficient	Acceptable	Good
		0	1	2
Liquidity	Quick ratio	i < 0,5	0,5 ≤ i ≤l	i > 1
Financial autonomy	Gross Operating Profit Ratio	i > 0,40 or < 0	0,40 ≥ i ≥ 0,30	0 ≤ i ≤ 0,30
Profitability	Profitability (1)	i < 0,05	0,05 ≤ i ≤ 0,15	i > 0,15
	Profitability (2)	i < 0,02	0,025 ≤ i ≤ 0,04	i > 0,04
Solvency	Solvency	i > 6,00 or < 0	6.00 ≥ i ≥ 4,00	0 ≤ i < 4,00

Exceptions:

The following rules are applied for the special cases where the ratio contains a zero denominator or numerator:

Financial autonomy:

— If GOP ≤ 0, the result shall be -1 with weak qualifications.

— The Interest paid cannot be negative.

Profitability (2):

— If NOP = 0, the result shall be 0 with weak qualifications.

— If the Turnover = 0, the Operating income shall be used for the calculation.

— If the Operating Income = 0 or negative, the result shall be 0 with weak qualifications.

— Turnover cannot be negative.

Any legal entity subject to a verification of its financial capacity who obtains under a more in depth financial analysis a minimum of **4 points** as a result of its financial viability check will be considered to have a 'positive' ([1]) financial capacity, unless it is subject to one (or several) of the situations mentioned in section 4.1.

More in Depth Analysis

	Insufficient	Weak	Acceptable	Good
Result of financial viability check	0	1-3	4-5	6-10

4.2.1.2. For natural persons

There will be no more in-depth financial analysis for a natural person.

However, if the result of the concise financial analysis has shown:

— Either a quick ratio (liquidity) inferior to 1,5;

— Or a solvency ratio superior to 1,2

the financial capacity will be considered as 'insufficient' and, as a consequence, the applicant cannot participate in the indirect action, except if duly justified reasons are provided by the authorising officer according to his/her own risk assessment.

([1]) 'Positive' means 'good' or 'acceptable'.

4.2.2. *Protection measures*

In compliance with article 38(7) of the FP7 RP, the Participants' Guarantee Fund (PGF) shall be considered as a sufficient guarantee under the FR. As a consequence, no additional financial guarantee or security (e.g. reduction of pre-financing, trust accounts, blocked accounts, financial guarantees from a bank/financial institution/mother company, etc.) may be requested from the participants or imposed on them.

Notwithstanding the previous paragraph, if the application of protection measures is deemed necessary, one or several protection measures, as listed below, may be implemented:

— A natural person cannot be the coordinator of an indirect action.

— A legal entity with a 'weak' financial capacity following a more in-depth analysis based on the 5 financial ratios (Liquidity, Financial Autonomy, Profitability 1, Profitability 2 and Solvency) as described in section 4.2.1 shall not be accepted as a coordinator by the services implementing FP7 ([1]) ([2]). This legal entity will nonetheless be able to be a participant.

— For any legal entity and without prejudice to the provisions of the respective Grant Agreement, the services implementing FP7 reserve the right to systematically initiate, during the implementation of the relating FP7 indirect action, a financial audit, which may be accompanied if necessary by a technical audit, carried out by the services implementing FP7 (including OLAF), or its duly authorised representatives, or by the Court of Auditors, if:

  — it is considered as 'weak' after a more in-depth financial analysis of its financial viability; or

  — the result of its co-financing capacity check is 'weak' (*if relevant*); or

  — the results obtained through Equity Flag or Financial Exposure Flag are 'weak'; or

  — an audit report of the accounts has been issued with serious qualification;

  — it has been subject to substantial financial findings relating to its financial capacity following a financial audit carried out by the Commission (including OLAF), the Court of Auditors or their duly authorised representatives within the last 2 years; or

  — if there are findings of serious administrative errors or fraud involving the entity; or the entity is subject to pending legal procedures or judicial proceedings for serious administrative errors or fraud; or the entity is subject to an attachment order or significant recovery order for an outstanding amount issued by the Commission on which the payment is significantly overdue.

— Any legal entity with a 'weak' financial capacity will be subject to a reinforced monitoring during the implementation of the project (e.g.: appropriate additional reviews by the services implementing FP7 and/or independent external expert(s), including on the spot check(s)). The authorising officer could always exclude a 'weak' entity from being coordinator of an indirect action.

The services implementing FP7 will immediately inform:

— the coordinator of the consortium that, due to its 'insufficient' financial capacity, (a) legal entity(ies) involved in the proposal cannot participate in the FP7 indirect action. The coordinator will inform the consortium;

— the relevant applicant(s) of an FP7 indirect action of the results and consequences, especially any necessary protection measure, of the verification of its (their) financial capacity, if the latter is 'weak'. However, this shall not allow the consortium to exclude this (these) applicant(s) for that single reason.

([1]) For grant agreements with a single beneficiary, the latter will be subject to the other protection measures. The purpose of protection measures for a coordinator is only relevant in the case of a consortium, due to the fact that the coordinator receives the EU financial contribution for all the participants.

([2]) Except if the legal person provides on a voluntary basis a guarantee which can be considered to be 'equivalent to a guarantee by a Member State or an Associated State'.

4.3. **Additional protection measures, including sanctions**

In order to reinforce the requirement of proposals submitted by solid consortia with effective and appropriate governance mechanisms and internal controls, the Union will not simply rely on recovering amounts due from the PGF to ensure the protection of its financial interests.

Indeed, and in addition to the abovementioned actions regarding the verification of the legal existence, the legal status/category, the operational capacity and the financial capacity of applicants, the following actions will be implemented, where appropriate, and in compliance with the FR, its IR and the FP7 model grant agreement [1]:

— recovery orders issued against defaulting participants to the benefit of the PGF shall be enforced in all cases and by all means foreseen by regulations relating to the protection of the financial interests of the Union. In addition, when signing/joining the grant agreement, any participant will accept that any amount due from it to the Union will be assigned to the PGF;

— in accordance with the FR and its IR, sanctions - including the exclusion from the benefit of any EU grant for a number of years - will be enforced, and the FP7 model grant agreement will foresee appropriate financial and administrative penalties (in particular Articles II.24 and II.25).

[1] **FP7 MGA** – Commission Decision C(2007) 1509 of 10 April 2007. See http://cordis.europa.eu/fp7/calls-grant-agreement_en.html.

DECISION OF THE EUROPEAN CENTRAL BANK

of 19 December 2012

on temporary measures relating to the eligibility of marketable debt instruments issued or fully guaranteed by the Hellenic Republic

(ECB/2012/32)

(2012/839/EU)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first indent of Article 127(2) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular the first indent of Article 3.1, Article 12.1, Article 18 and the second indent of Article 34.1,

Having regard to Guideline ECB/2011/14 of 20 September 2011 on monetary policy instruments and procedures of the Eurosystem [1], and in particular Section 1.6 and Sections 6.3.1, 6.3.2 and 6.4.2 of Annex I thereof,

Whereas:

(1) Pursuant to Article 18.1 of the Statute of the European System of Central Banks and of the European Central Bank, the European Central Bank (ECB) and the national central banks of Member States whose currency is the euro (NCBs) may conduct credit operations with credit institutions and other market participants, with lending being based on adequate collateral. The criteria determining the eligibility of collateral for the purposes of Eurosystem monetary policy operations are laid down in Annex I to Guideline ECB/2011/14.

(2) Pursuant to Section 1.6 of Annex I to Guideline ECB/2011/14, the Governing Council may, at any time, change the instruments, conditions, criteria and procedures for the execution of Eurosystem monetary policy operations. Pursuant to Section 6.3.1 of Annex I to Guideline ECB/2011/14, the Eurosystem reserves the right to determine whether an issue, issuer, debtor or guarantor fulfils its requirements for high standards on the basis of any information it may consider relevant.

(3) Decision ECB/2012/3 of 5 March 2012 on the eligibility of marketable debt instruments issued or fully guaranteed by the Hellenic Republic in the context of the Hellenic Republic's debt exchange offer [2] temporarily suspended the Eurosystem's minimum requirements for credit quality thresholds applicable to marketable debt instruments issued or fully guaranteed by the Hellenic Republic, declaring them eligible for the duration of the collateral enhancement provided by the Hellenic Republic to the NCBs. On termination of the collateral enhancement, given that the adequacy as collateral of marketable debt instruments issued or fully guaranteed by the Hellenic Republic was at the time not ensured, the Governing Council adopted Decision ECB/2012/14 [3] repealing Decision ECB/2012/3 with effect from 25 July 2012, thereby making such instruments ineligible.

(4) The Governing Council has now taken into consideration the positive assessment by the Eurogroup of the policy package for the first review of the Second Economic Adjustment Programme for Greece.

(5) The Governing Council considers this policy package to be appropriate, so that the marketable debt instruments issued or fully guaranteed by the Hellenic Republic have a quality standard sufficient to warrant their eligibility as collateral for Eurosystem monetary policy operations, irrespective of any external credit assessment.

(6) The Governing Council has therefore decided to restore the eligibility of marketable debt instruments issued or fully guaranteed by the Hellenic Republic for Eurosystem's monetary policy operations, subject to applying specific haircuts to such instruments different from those provided for in Section 6.4.2 of Annex I to Guideline ECB/2011/14.

(7) This exceptional measure will apply temporarily until the Governing Council considers that the normal application of the Eurosystem's eligibility criteria and risk control framework for monetary policy operations can be reintroduced,

[1] OJ L 331, 14.12.2011, p. 1.

[2] OJ L 77, 16.3.2012, p. 19.

[3] OJ L 199, 26.7.2012, p. 26.

HAS ADOPTED THIS DECISION:

Article 1

Suspension of certain provisions of Guideline ECB/2011/14 and eligibility of marketable debt instruments issued or fully guaranteed by the Hellenic Republic

1. The Eurosystem's minimum requirements for credit quality, as specified in the Eurosystem credit assessment framework rules for certain marketable assets in Section 6.3.2 of Annex I to Guideline ECB/2011/14, shall be suspended for marketable debt instruments issued or fully guaranteed by the Hellenic Republic.

2. Marketable debt instruments issued or fully guaranteed by the Hellenic Republic shall constitute eligible collateral for the purposes of Eurosystem monetary policy operations, subject to the specific haircuts set out in the Annex to this Decision.

3. In the event of any discrepancy between this Decision and Guideline ECB/2011/14, this Decision shall prevail.

Article 2

Entry into force

This Decision shall enter into force on 21 December 2012.

Done at Frankfurt am Main, 19 December 2012.

The President of the ECB

Mario DRAGHI

ANNEX

Haircut schedule applying to marketable debt instruments issued or fully guaranteed by the Hellenic Republic

	Maturity bucket	Haircuts for fixed coupons and floaters	Haircuts for zero coupon
Greek government bonds (GGBs)	**0-1**	15,0	15,0
	1-3	33,0	35,5
	3-5	45,0	48,5
	5-7	54,0	58,5
	7-10	56,0	62,0
	> 10	57,0	71,0
Government-guaranteed bank bonds (GGBBs) and government-guaranteed non-financial corporate bonds	**Maturity bucket**	**Haircuts for fixed coupons and floaters**	**Haircuts for zero coupon**
	0-1	23,0	23,0
	1-3	42,5	45,0
	3-5	55,5	59,0
	5-7	64,5	69,5
	7-10	67,0	72,5
	> 10	67,5	81,0

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