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[1] Text with EEA relevance

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.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 911/2010 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2010

on the European Earth monitoring programme (GMES) and its initial operations (2011 to 2013)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 189 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) At its meeting of 15 and 16 June 2001 in Gothenburg, the European Council agreed on a strategy for sustainable development, in order to mutually reinforce economic, social and environmental policies and added an environmental dimension to the Lisbon process.

(2) In its Resolution of 21 May 2007 on the European Space Policy [3] adopted at the fourth joint and concomitant meeting of the Council of the European Union and of the Council of the European Space Agency at ministerial level established in accordance with Article 8(1) of the Framework Agreement between the European Community and the European Space Agency [4] (the 'Space Council'), the Council recognised the actual and potential contributions from space activities towards the Lisbon strategy for growth and employment by providing enabling technologies and services for the emerging European knowledge society and contributing to European cohesion, and underlined that space represents a significant element of Europe's Sustainable Development Strategy.

(3) The Resolution 'Taking forward the European Space Policy' [5] of 26 September 2008 adopted at the fifth joint and concomitant meeting of the Space Council stressed the need to develop adequate EU instruments and funding schemes, taking into account the specificities of the space sector, the need to strengthen its overall and its industry's competitiveness and the necessity of a balanced industrial structure; and to allow appropriate long-term Union investment for space-related research and for the operation of sustainable space-based applications for the benefit of the Union and its citizens, in particular by examining all space-related policy consequences within the framework of the next financial perspective.

(4) The European Parliament resolution of 20 November 2008 on the European space policy: how to bring space down to earth [6] stressed the need to find adequate EU instruments and funding schemes for the European Space Policy to supplement the allocations from the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (the Seventh Framework Programme), so as to allow the different economic actors to plan their actions in the medium and long term and emphasised that the next financial framework should take into account adequate EU instruments and funding schemes to allow long-term Union investment for space-related research and for the operation of sustainable space-based applications for the benefit of the Union and its citizens.

[1] Opinion of 20 January 2010 (not yet published in the Official Journal).
[2] Position of the European Parliament of 16 June 2010 (not yet published in the Official Journal) and decision of the Council of 13 September 2010.
[3] OJ C 136, 20.6.2007, p. 1.
[4] OJ L 261, 6.8.2004, p. 64.
[5] OJ C 268, 23.10.2008, p. 1.
[6] OJ C 16 E, 22.1.2010, p. 57.

(5) Global Monitoring for Environment and Security (GMES) has been an Earth monitoring initiative led by the Union and carried out in partnership with the Member States and the European Space Agency (ESA). Its primary objective is to provide, under Union control, information services which give access to accurate data and information in the field of the environment and security and are tailored to the needs of users. In doing so, GMES should foster better exploitation of the industrial potential of policies of innovation, research and technological development in the field of Earth observation. GMES should be, inter alia, a key tool to support biodiversity, ecosystem management, and climate change mitigation and adaptation.

(6) In order to achieve the objective of GMES on a sustainable basis, it is necessary to coordinate the activities of the various partners involved in GMES, and to develop, establish and operate service and observation capacity meeting the demands of users, without prejudice to relevant national and European security restrictions.

(7) In this context, a committee should assist the Commission in ensuring the coordination of contributions to GMES by the Union, the Member States and inter-governmental agencies, making the best use of existing capacities and identifying gaps to be addressed at Union level. It should also assist the Commission in monitoring the coherent implementation of GMES. It should monitor the evolution of policy and enable exchanges of good practice in GMES.

(8) The Commission should be responsible for the implementation of the GMES security policy, assisted by the Committee. For that purpose, a specific configuration of the Committee (the 'Security Board') should be set up.

(9) GMES should be user driven, thus requiring the continuous, effective involvement of users, particularly regarding the definition and validation of service requirements. In order to increase the value of GMES to users, their input should be actively sought through regular consultation with end-users from the public and private sectors. A dedicated body (the 'User Forum') should also be established to facilitate the identification of user requirements, the verification of service compliance and the coordination of GMES with its public sector users.

(10) For the purpose of providing for a framework ensuring full and open access to information produced by GMES services and data collected through GMES infrastructure, while providing for the necessary protection of that information and data, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) in respect of registration and licensing conditions for GMES users and of criteria for restriction of access to GMES data and information, while taking into account the data and information policies of providers of data needed for GMES, and without prejudice to national rules and procedures applicable to space and *in-situ* infrastructures under national control. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(11) In order to ensure uniform conditions for implementation of this Regulation and of the delegated acts adopted on the basis of this Regulation, implementing powers should be conferred on the Commission to adopt, on the basis of the conditions and criteria established by delegated acts, specific measures on restricting access to the information produced by the GMES services and to data collected through the GMES dedicated infrastructure, including individual measures taking into account the sensitivity of the information and data in question. Implementing powers should also be conferred on the Commission to coordinate the voluntary contributions of Member States and the potential synergies with relevant national, Union and international initiatives, to set the maximum rate of co-financing for grants, to adopt measures laying down the technical requirements in order to ensure the control and integrity of the system within the GMES space component dedicated programme and to control the access to, and handling of, technologies that provide security to the GMES space component dedicated programme, and to adopt the annual work programme of GMES.

According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of its implementing powers shall be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1] continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(12) As GMES is based on a partnership between the Union, ESA and the Member States, the Commission should endeavour to continue the dialogue recently established with ESA and Member States owning relevant space assets.

(13) GMES services are necessary in order to foster the use of information sources by the private sector on a continuous basis, thus facilitating innovation, and thereby adding value, by service providers, many of which are small and medium-sized enterprises (SMEs).

[1] OJ L 184, 17.7.1999, p. 23.

(14) GMES comprises both development activities and operations. With regard to operations, in its third orientations adopted at the Space Council meeting of 28 November 2005, the Council supported a phased approach for the implementation of GMES based on clearly identified priorities, starting with the development of three fast-track services in the field of emergency response, land monitoring and marine services.

(15) The first operational services in the field of emergency response and land monitoring were financed as preparatory actions in accordance with Article 49(6)(b) of 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).

(16) In addition to the development activities financed under the space thematic area included in the Seventh Framework Programme, Union action is necessary in the period 2011-2013 to ensure continuity with the preparatory actions and to establish operational services on a more permanent basis in areas of sufficient technical maturity with a proven potential for the development of downstream services.

(17) In its Communication of 12 November 2008 entitled 'Global Monitoring for Environment and Security (GMES): we care for a safer planet', the Commission outlined its approach to the governance and financing of GMES and indicated its intention to delegate the technical implementation of GMES to specialised entities, including ESA for the GMES space component, owing to its unique position and expertise.

(18) The Commission should entrust the coordination of the technical implementation of the GMES services, where appropriate, to competent Union bodies or intergovernmental organisations, such as the European Environment Agency and the European Centre for Medium-Range Weather Forecasts.

(19) Operational services in the field of emergency management and humanitarian responses are necessary in order to coordinate the existing capacity of the Union and its Member States to be better prepared for, to respond to and to recover from natural and man-made disasters, which often also have a negative impact on the environment. As climate change could lead to an increase in the number of emergencies, GMES will be essential for supporting climate change adaptation measures. GMES services should therefore deliver geospatial information to support emergency and humanitarian responses.

(20) Land monitoring services are important for monitoring biodiversity and ecosystems and support climate change mitigation and adaptation measures and the management of a wide range of resources and policies, most of which relate to the natural environment: soil, water, agriculture, forests, energy and utilities, built-up areas, recreational facilities, infrastructure and transport. Operational land monitoring services are necessary at both European and global levels, developed in collaboration with Member States, third countries in Europe and partners outside Europe and the United Nations.

(21) GMES services in the field of the marine environment are important for the support of an integrated European capacity for ocean forecasting and monitoring and the future provision of Essential Climate Variables (ECVs). They are an essential element for climate change monitoring, marine environment monitoring and transport policy support.

(22) Atmosphere monitoring services are important for monitoring air quality, atmospheric chemistry and composition. They are also an essential element for climate change monitoring and the future provision of ECVs. The provision of information on the state of the atmosphere is necessary on a regular basis and at regional and global levels.

(23) Security services are an important part of the GMES initiative. Europe will benefit from the use of space and *in-situ* assets in support of the implementation of services responding to the challenges which Europe is facing in the security field, notably border control, maritime surveillance and support to Union external actions.

(24) Monitoring of climate change should allow for the adaptation and mitigation of its effects. It should in particular contribute to the provision of ECVs, climate analysis and projections on a scale relevant to adaptation and mitigation, and relevant service delivery.

(25) The provision of operational services financed under this Regulation depends on access to data collected via space infrastructure and airborne, seaborne and ground-based facilities (*in-situ* infrastructure) and survey programmes. With full respect for the principles of subsidiarity and proportionality, access to the required data should therefore be ensured, and where necessary *in-situ* data collection complementary to existing Union and national activities may be supported. The continuous availability of the underlying *in-situ* and space observation infrastructure needs to be ensured, including space infrastructure specifically developed for GMES within the framework of the ESA GMES space component programme (the 'Sentinels'). The first Sentinels should enter their initial operations phase in 2012.

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

(26) The Commission should ensure the complementarity of GMES-related research and development activities under the Seventh Framework Programme, the Union contribution to GMES initial operations, the activities of GMES partners and pre-existing structures, such as the European Data Centres.

(27) GMES initial operations should be implemented consistently with other relevant Union policies, instruments and action, in particular with environmental, security, competitiveness and innovation, cohesion, research, transport, competition and international co-operation policies, the European Global Navigation Satellite Systems (GNSS) programme and the protection of personal data. Furthermore, GMES data should maintain coherence with Member States' spatial reference data and support the development of the infrastructure for spatial information in the Union established by Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) [1]. GMES should also complement the Shared Environmental Information System (SEIS) and Union activities in the field of emergency response.

(28) GMES and its initial operations should be considered as a European contribution to building the Global Earth Observation System of Systems (GEOSS) developed within the framework of the Group on Earth Observations (GEO).

(29) The Agreement on the European Economic Area and the Framework Agreements with candidate and potential candidate countries provide for participation by those countries in Union programmes. Participation by other third countries and international organisations should be made possible by the conclusion of international agreements to that effect.

(30) This Regulation lays down, for the entire duration of GMES initial operations, a financial envelope of EUR 107 million constituting the prime reference, within the meaning of point 37 of the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management [2] (Interinstitutional Agreement), for the budgetary authority during the annual budgetary procedure. It is envisaged that this financial envelope will be complemented by an amount of EUR 209 million from the space theme of the Seventh Framework Programme for research actions accompanying GMES initial operations that should be managed in accordance with applicable rules and decision-making procedures in the Seventh Framework Programme. These two funding sources should be managed in a coordinated manner in order to ensure consistent progress in the implementation of GMES.

(31) That financial envelope is compatible with the ceiling for subheading 1a of the multiannual financial framework (MFF) 2007-2013, but the margin remaining in subheading 1a for 2011-2013 is very small. It should be emphasised that the annual amount will be determined during the annual budgetary procedure, in accordance with point 37 of the Interinstitutional Agreement.

(32) The fund should if possible be further increased so that commitment appropriations can be allocated for the space component during the current MFF. In specific terms, this concerns the operation of the A series of Sentinel satellites and the launch of the B series and the procurement of crucial components for the C series.

(33) To that end, the Commission should, in the context of the mid-term review of the current MFF, and before the end of 2010, examine the possibility of additional funding for GMES, within the overall Union budget during the MFF 2007-2013.

(34) The allocation of any additional funding to this Regulation on top of the EUR 107 million already allocated should be considered in the context of discussions on the future of European space policy, notably on procurement and governance.

(35) The Commission should also submit a long-term financing strategy for the future MFF during the first semester of 2011, without prejudice to the outcome of the negotiations on the MFF 2014-2020.

(36) In its financial planning, the Commission should ensure that data continuity is maintained both during and after the end of the period of the initial GMES operations (2011 to 2013), and that the services can be used uninterruptedly and without restrictions.

(37) In accordance with the Financial Regulation, Member States, third countries and international organisations should be free to contribute to the programmes on the basis of appropriate agreements.

(38) GMES information should be fully and openly accessible, without prejudice to relevant security restrictions or to the data policies of Member States and other organisations contributing data and information to GMES. This is necessary to promote the use and sharing of Earth observation data and information in accordance with the principles of SEIS, INSPIRE and GEOSS. Full and open access to data should also take into account existing commercial data provision and should promote stronger Earth observation markets in Europe, in particular in downstream sectors, to increase growth and employment.

[1] OJ L 108, 25.4.2007, p. 1.
[2] OJ C 139, 14.6.2006, p. 1.

(39) According to the Commission Communication of 28 October 2009 entitled 'Global Monitoring for Environment and Security (GMES): Challenges and Next Steps for the Space Component', there should be a full and open access data policy for the Sentinels through a free-of-charge licensing and online access scheme, subject to security concerns. Such an approach aims at maximising the beneficial use of Sentinel data for the widest range of applications and is intended to stimulate the uptake of information based on Earth observation data for end users.

(40) The action financed under this Regulation should be monitored and evaluated in order to allow for readjustments.

(41) Appropriate measures should also 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 Regulations (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests [1] and (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 [2] 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) [3].

(42) Since the objective of this Regulation, namely the establishment of the programme GMES and its initial operations, cannot be sufficiently achieved by the Member States because GMES initial operations will also comprise pan-European capacity and depend on the coordinated provision of services throughout the Member States that needs to be coordinated at Union level and can therefore, by reason of the scale 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 in order to achieve that objective, especially regarding the Commission's role as coordinator of national activities,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes the European Earth monitoring programme called GMES and the rules for the implementation of its initial operations during the period 2011-2013.

Article 2

Scope of GMES

1. The GMES programme shall build on the research activities carried out under Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) [4] and the GMES Space Component Programme of ESA.

2. The GMES programme shall comprise the following:

(a) a service component ensuring access to information in support of the following areas:

— atmosphere monitoring,

— climate change monitoring in support of adaptation and mitigation policies,

— emergency management,

— land monitoring,

— marine environment monitoring,

— security;

(b) a space component ensuring sustainable spaceborne observations for the service areas referred to in point (a);

(c) an *in-situ* component ensuring observations through airborne, seaborne and ground-based installations for the service areas referred to in point (a).

Article 3

GMES initial operations (2011 to 2013)

1. GMES initial operations shall cover the period 2011–2013 and may comprise operational actions in the following fields:

1. the service areas referred to in Article 2(2)(a);

2. measures to support take-up of services by users;

3. data access;

4. support for *in-situ* data collection;

5. the GMES space component.

2. The objectives of the operational actions referred to in paragraph 1 are defined in the Annex.

[1] OJ L 312, 23.12.1995, p. 1.
[2] OJ L 292, 15.11.1996, p. 2.
[3] OJ L 136, 31.5.1999, p. 1.
[4] OJ L 412, 30.12.2006, p. 1.

Article 4

Organisational arrangements

1. The Commission shall ensure the coordination of the GMES programme with activities at national, Union and international levels, notably GEOSS. The implementation and operation of GMES shall be based on partnerships between the Union and the Member States, in compliance with their respective rules and procedures. The voluntary contributions of Member States, and the potential synergies with relevant national, Union and international initiatives, shall be coordinated in accordance with the advisory procedure referred to in Article 16(5).

2. The Commission shall manage the funds allocated to the activities under this Regulation in accordance with the Financial Regulation and with the management procedure referred to in Article 16(4). It shall ensure the complementarity and consistency of the GMES programme with other relevant Union policies, instruments and actions, relating in particular to the environment, security, competitiveness and innovation, cohesion, research (in particular the activities of the Seventh Framework Programme linked to GMES, without prejudice to Decision No 1982/2006/EC), transport and competition, international cooperation, the European Global Navigation Satellite Systems (GNSS) programmes, the protection of personal data and existing intellectual property rights, Directive 2007/2/EC, the Shared Environmental Information System (SEIS) and Union activities in the field of emergency response.

3. Since GMES is a user-driven programme, the Commission shall ensure that service specifications match user needs. To that end, it shall establish a transparent mechanism for regular user involvement and consultation, enabling identification of user requirements at Union and national level. The Commission shall ensure coordination with relevant public sector users in Member States, third countries and international organisations. Service data requirements shall be established independently by the Commission after consultation of the User Forum.

4. Technical coordination and implementation of the GMES space component shall be delegated to ESA, relying on the European Organisation for the Exploitation of Meteorological Satellites (EUMETSAT) where necessary.

5. The Commission shall entrust the coordination of the technical implementation of the GMES services, where appropriate, to competent Union bodies or intergovernmental organisations.

Article 5

Service delivery

1. The Commission shall take adequate measures to ensure effective competition in the provision of GMES services and to promote the participation of SMEs. The Commission shall facilitate the use of the GMES services output to develop the downstream sector.

2. The provision of GMES services shall be decentralised, where appropriate, to integrate at European level existing space, *in-situ* and reference data inventories and capacities in Member States, thus avoiding duplication. Procurement of new data that duplicate existing sources shall be avoided unless the use of existing or upgradable data sets is not technically feasible or cost-effective.

3. The Commission, taking into account the opinion of the User Forum, may define or validate appropriate procedures for the certification of the production of data within the framework of the GMES programme. Those procedures shall be transparent, verifiable and auditable to ensure authenticity, traceability and data integrity for the user. In its contractual arrangements with GMES service operators, the Commission shall ensure that those procedures are implemented.

4. The Commission shall report annually on the results achieved in the implementation of this Article.

Article 6

Forms of Union funding

1. Union funding may take the following legal forms:

(a) delegation agreements;

(b) grants;

(c) public procurement contracts.

2. Genuine competition, transparency and equal treatment shall be ensured in the provision of funding by the Union. Where justified, Union grants may be provided in specific forms, including framework partnership agreements, or co-funding of operating or action grants. Operating grants to bodies pursuing objectives of general European interest shall not be subject to the degressivity provisions of the Financial Regulation. For grants, the maximum rate of co-financing shall be set in accordance with the management procedure referred to in Article 16(4).

3. The Commission shall report on the allocation of Union funds to each of the activities specified in Article 3(1) and on the evaluation process and results of the procurement tenders and of the contracts concluded on the basis of this Article, after the award of the contracts.

Article 7

Participation of third countries

The following countries may participate in the operational actions referred to in Article 3:

1. European Free Trade Association (EFTA) countries which are Contracting Parties to the EEA Agreement in accordance with the conditions laid down in the EEA Agreement;

2. the candidate countries, as well as potential candidates included in the stabilisation and association process in accordance with the Framework Agreements, or a Protocol to an Association Agreement, on the general principles for the participation of those countries in Union programmes, concluded with those countries;

3. the Swiss Confederation, other third countries not referred to in points 1 and 2, and international organisations, in accordance with agreements concluded by the Union with such third countries or international organisations pursuant to Article 218 TFEU, which shall lay down the conditions and detailed rules for their involvement.

Article 8

Funding

1. The financial envelope allocated to the operational actions referred to in Article 3(1) shall be EUR 107 million.

2. Appropriations shall be authorised annually by the budgetary authority within the limits laid down in the MFF.

3. Third countries or international organisations may also provide additional funding for the GMES programme.

The additional funding referred to in the first subparagraph shall be treated as assigned revenue, in accordance with Article 18 of the Financial Regulation.

Article 9

GMES data and information policy

1. The data and information policy for actions financed under the GMES programme shall have the following objectives:

(a) promoting the use and sharing of GMES information and data;

(b) full and open access to information produced by GMES services and data collected through GMES infrastructure, subject to relevant international agreements, security restrictions and licensing conditions, including registration and acceptance of user licences;

(c) strengthening Earth observation markets in Europe, in particular the downstream sector, with a view to enabling growth and job creation;

(d) contributing to the sustainability and continuity of the provision of GMES data and information;

(e) supporting the European research, technology and innovation communities.

2. For the purpose of providing for a framework to ensure the attainment of the GMES information and data policy objective referred to in point (b) of paragraph 1 while providing for the necessary protection of the information produced by the GMES services and of data collected through the GMES dedicated infrastructure, the Commission may adopt, by means of delegated acts in accordance with Article 10 and subject to the conditions specified in Articles 11 and 12, the following measures, taking into account the data and information policies of providers of data needed for GMES, and without prejudice to national rules and procedures applicable to space and *in-situ* infrastructures under national control:

(a) measures establishing registration and licensing conditions for GMES users;

(b) measures defining criteria for restricting access to the information produced by the GMES services and to data collected through the GMES dedicated infrastructure.

Article 10

Exercise of the delegation

1. The powers to adopt the delegated acts referred to in Article 9(2) shall be conferred on the Commission until 31 December 2013.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 11 and 12.

Article 11

Revocation of the delegation

1. The delegation of powers referred to in Article 9(2) may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 12

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council, that period shall be extended by 2 months.

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 13

Implementing measures on data and information policy and on the governance of the security of GMES components and information

1. On the basis of the criteria referred to in point (b) of Article 9(2), the Commission shall adopt specific measures in accordance with the regulatory procedure referred to in Article 16(3), for restricting access to the information produced by GMES services and data collected through the GMES dedicated infrastructure.

2. The Commission shall ensure overall coordination with regard to the security of the GMES components and services, taking into account the need for oversight and integration of the security requirements of all its elements, without prejudice to national rules and procedures applicable to space and *in-situ* infrastructures under national control. In particular, the Commission shall adopt measures, in accordance with the regulatory procedure referred to in Article 16(3), laying down technical requirements in order to ensure the control and integrity of the system within the GMES space component dedicated programme, and to control the access to, and handling of, technologies that provide security to the GMES space component dedicated programme.

Article 14

Monitoring and evaluation

1. The Commission shall monitor and evaluate the implementation of the operational actions referred to in Article 3(1).

2. The Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions an interim evaluation report by 31 December 2012 and an ex-post evaluation report by 31 December 2015.

Article 15

Implementing measures

1. The Commission shall adopt the annual work programme pursuant to Article 110 of the Financial Regulation and Articles 90 and 166 of 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 [1] in accordance with the management procedure referred to in Article 16(4) of this Regulation.

2. The financial allocation for the GMES programme may also cover expenses relating to preparatory, monitoring, control, audit and evaluation activities which are required directly for the management of the GMES programme and the achievement of its objectives, and in particular studies, meetings, information and publication actions, together with all other technical and administrative assistance expenses that the Commission may incur for the management of the GMES programme.

[1] OJ L 357, 31.12.2002, p. 1.

Article 16

GMES Committee

1. The Commission shall be assisted by a committee (the 'GMES Committee').

2. The GMES Committee may meet in specific configurations to deal with concrete issues, notably those relating to security (the 'Security Board').

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 2 months.

4. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at 2 months.

5. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 17

User Forum

1. The User Forum is hereby set up as a dedicated body. It shall advise the Commission with regard to the definition and validation of user requirements, and to the coordination of the GMES programme with its public sector users.

2. The User Forum shall be chaired by the Commission. It shall consist of GMES public sector users appointed by the Member States.

3. The Secretariat of the User Forum shall be provided by the Commission.

4. The User Forum shall adopt its rules of procedure.

5. The GMES Committee shall be kept fully informed of the advice of the User Forum for the implementation of the GMES programme.

Article 18

Protection of the Union's financial interests

1. The Commission shall ensure that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by means of effective checks and by the recovery of amounts unduly paid and, if irregularities are detected, by effective, proportional and dissuasive penalties, in accordance with Regulation (EC, Euratom) No 2988/95, Regulation (Euratom, EC) No 2185/96 and Regulation (EC) No 1073/1999.

2. For the Union actions financed under this Regulation, the notion of irregularity referred to in Article 1(2) of Regulation (EC, Euratom) No 2988/95 shall mean any infringement of a provision of Union law or any breach of a contractual obligation resulting from an act or omission by an economic operator which has, or would have, the effect of prejudicing the general budget of the European Union by an unjustified item of expenditure.

3. Agreements resulting from this Regulation, including agreements concluded with participating third countries and international organisations, shall provide for supervision and financial control by the Commission, or any representative authorised by it, and audits by the Court of Auditors, if necessary on-the-spot audits.

Article 19

Entry into force

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

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

Done at Strasbourg, 22 September 2010.

For the European Parliament
The President
J. BUZEK

For the Council
The President
O. CHASTEL

ANNEX

OBJECTIVES OF GMES INITIAL OPERATIONS (2011–2013)

The operational actions referred to in Article 3(1) shall contribute to the following objectives:

1. emergency response services, based on existing activities in Europe, shall ensure that Earth observation data and derived products are made available for the benefit of emergency response players at international, European, national and regional levels in relation to different types of disasters, including meteorological hazards (including storms, fires and floods), geophysical hazards (including earthquakes, tsunamis, volcanic eruptions and landslides), deliberate and accidental man-made disasters and other humanitarian disasters. As climate change could lead to an increase in emergencies, GMES emergency response will be essential to support climate change adaptation measures in this area as a part of the prevention, preparedness, response and recovery activities in Europe;

2. land monitoring services shall ensure that Earth observation data and derived products are made available for the benefit of European, national, regional and international authorities responsible for the global-to-local environmental monitoring of biodiversity, soil, water, forests and national resources, as well as in general implementation of environmental policies, collection of geographical information, agriculture, energy, urban planning, infrastructure and transport. Land monitoring services shall include monitoring of climate change variables;

3. marine monitoring services shall provide information on the state of physical ocean and marine ecosystems for the global ocean and the European regional areas. The application areas of the GMES marine services include maritime safety, the marine environment and coastal regions, marine resources as well as seasonal meteorological forecasting and climate monitoring;

4. atmosphere environmental services shall ensure the monitoring of air quality on a European scale and of the chemical composition of the atmosphere on a global scale. It shall in particular provide information for air quality monitoring systems at the local to national scales, and should contribute to the monitoring of atmospheric chemistry climate variables;

5. security services shall provide useful information in support of the challenges which Europe is facing in the security field, notably border control, maritime surveillance and support for EU external actions;

6. monitoring of climate change shall allow for the adaptation and mitigation of its effects. It should in particular contribute to the provision of ECVs, climate analyses and projections on a scale relevant to adaptation and mitigation and relevant service delivery;

7. measures to support take-up of services by users shall include implementation of technical interfaces adapted to the specific user environment, training, communication and development of the downstream sector;

8. data access shall ensure that Earth observation data from a wide range of European missions and other types of observation infrastructure, are collected and made available to achieve the objectives of GMES;

9. the *in-situ* component shall ensure coordination of *in-situ* data collection and *in-situ* data access for GMES services;

10. GMES initial operations shall ensure the operations and development of the GMES space component, which consists of space-borne Earth observation infrastructure and aims at ensuring observation of Earth sub-systems (including land surfaces, atmosphere and oceans). GMES initial operations shall draw on existing or planned national and European space infrastructure and on space infrastructure developed in the GMES Space Component Programme.

REGULATION (EU) No 912/2010 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2010

setting up the European GNSS Agency, repealing Council Regulation (EC) No 1321/2004 on the establishment of structures for the management of the European satellite radio navigation programmes and amending Regulation (EC) No 683/2008 of the European Parliament and of the Council

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 172 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having consulted the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) The European satellite radio-navigation policy is presently implemented through the EGNOS and Galileo programmes (hereinafter the 'programmes').

(2) Council Regulation (EC) No 1321/2004 of 12 July 2004 on the establishment of structures for the management of the European satellite radio-navigation programmes [3], established a Community agency, called the European GNSS Supervisory Authority (hereinafter the 'Authority').

(3) Regulation (EC) No 683/2008 of the European Parliament and of the Council of 9 July 2008 on the further implementation of the European satellite navigation programmes (EGNOS and Galileo) [4] defines the new framework for the public governance and financing of the programmes. It sets out the principle of the strict division of responsibilities between the European Union, represented by the Commission, the Authority and the European Space Agency (hereinafter the 'ESA'), granting the Commission responsibility for the management of the programmes and attributing to it the tasks originally assigned to the Authority. It also provides that the Authority, when accomplishing the tasks entrusted to it, will ensure that the role of the Commission as manager of the programmes is respected and that the Authority acts in accordance with guidelines issued by the Commission.

(4) In Regulation (EC) No 683/2008 of the European Parliament and of the Council invited the Commission to put forward a proposal to align formally the management structures of the programmes as set out in Regulation (EC) No 1321/2004 with the new roles of the Commission and the Authority as set out in Regulation (EC) No 683/2008.

(5) In view of its reduced sphere of activity, the Authority should no longer be called the 'European GNSS Supervisory Authority', but rather the 'European GNSS Agency' (hereinafter the 'Agency'). However, the continuity of the activities of the Authority, including continuity as regards rights and obligations, staff and the validity of any decisions taken, should be ensured under the Agency.

(6) The aims and objectives of Regulation (EC) No 1321/2004 should also be adjusted in order to reflect the fact that the Agency is no longer responsible for the management of public interests relating to the European Global Navigation Satellite System (GNSS) programmes and for regulating such programmes.

(7) The legal status of the Agency should be such as to enable it to act as a legal person in the discharge of its tasks.

(8) It is also important to modify the tasks of the Agency, and, in this regard, to ensure that its tasks are defined in accordance with those set out in Article 16 of Regulation (EC) No 683/2008, including the possibility for the Agency to accomplish other activities that may be entrusted to it by the Commission, in order to support the Commission in the implementation of the programmes. In accordance with Article 54(2)(b) of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [5], such activities could for example include following the

[1] OJ C 317, 23.12.2009, p. 103.
[2] Position of the European Parliament of 16 June 2010 (not yet published in the Official Journal) and decision of the Council of 13 September 2010.
[3] OJ L 246, 20.7.2004, p. 1.
[4] OJ L 196, 24.7.2008, p. 1.
[5] OJ L 248, 16.9.2002, p. 1.

development of coordination and consultation procedures on security-related matters, carrying out research of benefit to the development and promotion of the programmes and providing support in the development and implementation of the Public Regulated Service (PRS) pilot project.

(9) Within its scope, its objectives and in the performance of its tasks, the Agency should comply in particular with the provisions applicable to Union institutions.

(10) The Commission should, in the context of its mid-term review of the Galileo programme planned for 2010 as referred to in Article 22 of Regulation (EC) No 683/2008, also address the issue of the governance of the programmes in the operating and exploitation phase and the role of the Agency in this context.

(11) In order to ensure effectively the accomplishment of the tasks of the Agency, the Member States and the Commission should be represented on an Administrative Board entrusted with the necessary powers to establish the budget, verify its execution, adopt the appropriate financial rules, establish transparent working procedures for decision making by the Agency, approve its work programme and appoint the Executive Director.

(12) It is also appropriate to include a representative of the European Parliament in the Administrative Board as a non-voting member, in view of the fact that Regulation (EC) No 683/2008 highlighted the usefulness of close cooperation between the European Parliament, the Council and the Commission.

(13) In order to ensure that the Agency accomplishes its tasks whilst respecting the role of the Commission as manager of the programmes and in accordance with guidelines issued by the Commission, it is also important to state explicitly that the Agency should be managed by an Executive Director under the supervision of the Administrative Board, in accordance with the guidelines issued to the Agency by the Commission. It is equally important to specify that the Commission should have five representatives on the Administrative Board and that decisions regarding a limited number of tasks of the Administrative Board should not be adopted without the favourable vote of the representatives of the Commission.

(14) The smooth functioning of the Agency requires that its Executive Director be appointed on the grounds of merit and documented administrative and managerial skills, as well as relevant competence and experience, and that he performs his duties with complete independence and flexibility in relation to the organisation of the internal functioning of the Agency. Except as regards certain activities and measures relating to security accreditation, the Executive Director should prepare and take all necessary measures to ensure the proper accomplishment of the work programme of the Agency, should prepare each year a draft general report to be submitted to the Administrative Board, should draw up a draft statement of estimates of revenues and expenditure of the Agency and implement the budget.

(15) The Administrative Board should be empowered to take any decision which may ensure that the Agency is able to accomplish its tasks with the exception of the security accreditation tasks, which should be entrusted to a Security Accreditation Board for European GNSS systems (hereinafter the 'Security Accreditation Board'). In respect of such accreditation tasks the Administrative Board should be responsible only for resource and budget matters. Sound governance of the programmes also requires that the tasks of the Administrative Board be compliant with the new missions assigned to the Agency under Article 16 of Regulation (EC) No 683/2008, notably regarding the operation of the Galileo security centre and the instructions given pursuant to Council Joint Action 2004/552/CFSP of 12 July 2004 on aspects of the operation of the European satellite radio-navigation system affecting the security of the European Union [1].

(16) Procedures for the appointment of office-holders should be transparent.

(17) In view of the scope of the tasks entrusted to the Agency, which include security accreditation, the Scientific and Technical Committee set up in accordance with Article 9 of Regulation (EC) No 1321/2004 should be disbanded and the System Security and Safety Committee established in accordance with Article 10 of that Regulation should be replaced by the Security Accreditation Board, which will be responsible for security accreditation, and composed of representatives from the Member States and the Commission. The High Representative for Foreign Affairs and Security Policy (hereinafter the 'HR') and the ESA should have an observer role in the Security Accreditation Board.

(18) Security accreditation activities should be carried out independently of the authorities responsible for managing the programmes, notably the Commission, the other bodies of the Agency, the ESA, and other entities responsible for implementing provisions with regard to security. In order to ensure such independence, the Security Accreditation Board should be established as the security accreditation authority for the European GNSS systems (hereinafter the 'systems') and for receivers containing PRS technology. It should be an autonomous body which, within the Agency, takes its decisions independently and objectively, in the interest of the citizens.

[1] OJ L 246, 20.7.2004, p. 30.

(19) Given that the Commission, in accordance with Regulation (EC) No 683/2008, manages all aspects relating to system security, and in order to ensure efficient governance of security issues and compliance with the principle of strict division of responsibilities provided for under that Regulation, it is essential that the activities of the Security Accreditation Board be strictly limited to the security accreditation activities of systems and that they do not under any circumstances encroach on the tasks entrusted to the Commission under Article 13 of Regulation (EC) No 683/2008.

(20) The decisions taken by the Commission in accordance with procedures involving the European GNSS Programmes Committee will in no way affect the existing rules on budgetary matters or the specific competence of Member States on security matters.

(21) In accordance with Article 13(4) of Regulation (EC) No 683/2008, in cases where the security of the Union or of the Member States may be affected by the operation of the systems, the procedures set out in Joint Action 2004/552/CFSP apply. In particular, in the event of a threat to the security of the Union or of a Member State arising from the operation or use of the systems, or in the event of a threat to the operation of the systems, in particular as a result of an international crisis, the Council, acting unanimously, is able to decide on the necessary instructions to give to the Agency and to the Commission. Any member of the Council, the HR or the Commission is able to request a Council discussion to agree on such instructions.

(22) In application of the principle of subsidiarity, security accreditation decisions should, following the process defined in the security accreditation strategy, be based on local security accreditation decisions taken by the respective national security accreditation authorities of the Member States.

(23) In order for it to carry out all of its activities quickly and effectively, the Security Accreditation Board should be able to set up appropriate subordinate bodies acting on its instructions. It should accordingly set up a panel to assist it in preparing its decisions and a Crypto Distribution Authority, managing and preparing crypto material issues, including a Flight Key Cell dedicated to operational flight keys for launches, as well as other bodies, if necessary, to deal with specific issues. In doing so, special consideration should be given to the necessary continuity of the work in those bodies.

(24) It is also important for security accreditation activities to be coordinated with the work of the authorities responsible for managing the programmes and other entities responsible for implementing security provisions.

(25) Given the specific nature and complexity of the systems, it is essential for the security accreditation activities to be carried out in a context of collective responsibility for the security of the Union and of the Member States, by making efforts to reach a consensus and by involving all parties with an interest in security, and for permanent risk monitoring. It is also imperative that technical security accreditation activities be entrusted to professionals who are duly qualified in the field of accrediting complex systems and who have an adequate level of security clearance.

(26) In order to ensure that the Security Accreditation Board is able to accomplish its tasks, it should also be provided that Member States supply that Board with any necessary documentation, grant access to classified information and to any areas falling within their jurisdiction to duly authorised persons, and that they should be responsible at local level for the accreditation of the security of areas that are located within their territory.

(27) The systems established within the framework of the programmes are infrastructures the use of which extends well beyond the national boundaries of the Member States, and which are set up as trans-European networks in accordance with the provisions of Article 172 of the Treaty on the Functioning of the European Union. Furthermore, the services provided via such systems contribute to the development of trans-European networks in the areas of transport, telecommunications and energy infrastructures.

(28) The Commission is to assess the budgetary implications of the financing of the Agency for the expenditure heading concerned. On the basis of the information and without prejudice to the relevant legislative procedure, the two arms of the budgetary authority need to achieve, in the framework of budgetary co-operation, a timely agreement on the financing of the Agency. The Union budgetary procedure is applicable to the Union contribution charged to the general budget of the European Union. In addition, auditing of accounts are to be undertaken by the European Court of Auditors in accordance with Title VIII of Regulation (EC, Euratom) No 1605/2002.

(29) The Agency should apply the relevant Union legislation concerning public access to documents and the protection of individuals with regard to the processing of personal data. It should also comply with the security principles applicable to the Council and the Commission services.

(30) It should be possible for third countries to participate in the Agency, provided that they have concluded a prior agreement to this effect with the Union, particularly when such countries have been involved in the previous phases of the Galileo programme through their contribution to the Galileosat programme of the ESA.

(31) Since the objectives of this Regulation, namely to establish and ensure the functioning of an agency with responsibility in particular for security accreditation of the systems, 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 in order to achieve those objectives.

(32) Since the name of the Agency is to be changed, Regulation (EC) No 683/2008 should be amended accordingly.

(33) Regulation (EC) No 1321/2004 has previously been amended. Considering the amendments that are now being introduced, it is appropriate, for the sake of clarity, to repeal that Regulation and replace it with a new Regulation,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT, TASKS, BODIES

Article 1

Subject matter

This Regulation sets up a Union agency called the European GNSS Agency (hereinafter the 'Agency').

Article 2

Tasks

The tasks of the Agency shall be as set out in Article 16 of Regulation (EC) No 683/2008.

Article 3

Bodies

The bodies of the Agency shall be the Administrative Board, the Security Accreditation Board for European GNSS systems and the Executive Director. They shall accomplish their tasks in accordance with the guidelines issued by the Commission as set out in Article 16 of Regulation (EC) No 683/2008.

Article 4

Legal status, local offices

1. The Agency shall be a body of the Union. It shall have legal personality.

2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under their law. It may, in particular, acquire or dispose of movable and immovable property and be a party to legal proceedings.

3. The Agency may decide to establish local offices in Member States subject to their consent, or in third countries participating in the work of the Agency in accordance with Article 23.

4. Subject to Article 11(9), the Agency shall be represented by its Executive Director.

Article 5

Administrative Board

1. An Administrative Board is hereby set up to carry out the tasks listed in Article 6.

2. The Administrative Board shall be composed of one representative appointed by each Member State, five representatives appointed by the Commission and a non-voting representative appointed by the European Parliament. The duration of the term of office of the Administrative Board members shall be 5 years. The term of office may be renewed for a maximum of 5 years. A representative of the HR and a representative of the ESA shall be invited to attend the Administrative Board's meetings as observers.

3. Where appropriate, the participation of representatives of third countries and the conditions thereof shall be established in the arrangements referred to in Article 23.

4. The Administrative Board shall elect a Chairperson and a Deputy Chairperson from among its members. The Deputy Chairperson shall automatically take the place of the Chairperson where the Chairperson is prevented from attending to his duties. The term of office of the Chairperson and of the Deputy Chairperson shall be 2,5 years, renewable once, and shall expire when they cease to be members of the Administrative Board.

5. The meetings of the Administrative Board shall be convened by its Chairperson.

The Executive Director shall normally take part in the deliberations, unless the Chairperson decides otherwise.

The Administrative Board shall hold an ordinary meeting twice a year. In addition, it shall meet on the initiative of its Chairperson or at the request of at least a third of its members.

The Administrative Board may invite any person whose opinion may be of interest to attend its meetings as an observer. The members of the Administrative Board may, subject to the provisions of its rules of procedure, be assisted by advisers or experts.

The secretariat of the Administrative Board shall be provided by the Agency.

6. Unless otherwise provided in this Regulation, the Administrative Board shall take its decisions by a two-thirds majority of its members.

7. Each representative of the Member States and of the Commission shall have one vote. Decisions based on Article 6(b) and (e) shall not be adopted without a favourable vote of the representatives of the Commission. The Executive Director shall not vote.

The rules of procedure of the Administrative Board shall establish more detailed voting arrangements, in particular the conditions for a member to act on behalf of another member.

Article 6

Tasks of the Administrative Board

The Administrative Board shall ensure that the Agency carries out the work entrusted to it, under the conditions set out in this Regulation, and shall take any necessary decision to this end. In respect of security accreditation tasks and decisions provided for in Chapter III, the Administrative Board shall be responsible only for resources and budgetary matters. The Administrative Board shall also:

(a) appoint the Executive Director pursuant to Article 7(2);

(b) adopt by 15 November each year, and after receiving the Commission's opinion, the work programme of the Agency for the coming year;

(c) perform its duties in relation to the Agency's budget pursuant to Articles 13 and 14;

(d) oversee the operation of the Galileo security centre (hereinafter the 'Galileo Security Monitoring Centre' or the 'GSMC') as referred to in Article 16(a)(ii) of Regulation (EC) No 683/2008;

(e) exercise disciplinary authority over the Executive Director;

(f) adopt the special provisions necessary for the implementation of the right of access to the documents of the Agency, in accordance with Article 21;

(g) adopt the annual report on the activities and prospects of the Agency and forward it, by 1 July, to the Member States, the European Parliament, the Council, the Commission, the Court of Auditors and the European Economic and Social Committee; the Agency shall forward to the budgetary authority all information relevant to the outcome of the evaluation procedures;

(h) adopt its rules of procedure.

Article 7

Executive Director

1. The Agency shall be managed by its Executive Director, who shall carry out his duties under the supervision of the Administrative Board.

2. The Executive Director shall be appointed by the Administrative Board on the grounds of merit and documented administrative and managerial skills, as well as relevant competence and experience, from a list of at least three candidates proposed by the Commission, after an open competition, following publication in the *Official Journal of the European Union* and elsewhere of a call for expressions of interest. The Administrative Board shall take its decision to appoint the Executive Director by a three-quarters majority of its members.

The Administrative Board shall have the power to dismiss the Executive Director and shall adopt its decision to that effect by a three-quarters majority of its members.

The term of office of the Executive Director shall be 5 years. This term of office may be renewed once for a further 5-year period.

3. The European Parliament or the Council may call upon the Executive Director to submit a report on the performance of his tasks, and to make a statement before those institutions.

Article 8

Tasks of the Executive Director

The Executive Director:

(a) shall be responsible for representing the Agency, except in respect of activities and decisions undertaken in accordance with Chapters II and III, and shall be in charge of its management;

(b) shall prepare the work of the Administrative Board. He shall participate, without having the right to vote, in the work of the Administrative Board;

(c) shall be responsible for implementing the annual work programme of the Agency under the control of the Administrative Board;

(d) shall take all necessary measures, including the adoption of internal administrative instructions and the publication of notices, to ensure the functioning of the Agency in accordance with this Regulation;

(e) shall draw up estimates of the Agency's revenue and expenditure in accordance with Article 13, and shall implement the budget in accordance with Article 14;

(f) shall prepare a draft general report each year and submit it to the Administrative Board;

(g) shall ensure that the Agency, as the operator of the GSMC, is able to respond to instructions provided under Joint Action 2004/552/CFSP;

(h) shall define the organisational structure of the Agency and submit it for approval to the Administrative Board;

(i) shall exercise, in respect of staff, the powers laid down in Article 18;

(j) may adopt, after approval of the Administrative Board, the necessary measures to establish local offices in Member States in accordance with Article 4;

(k) shall ensure that the secretariat and all the resources necessary for proper functioning are provided to the Security Accreditation Board and to the bodies set up under its authority referred to in Article 11(11).

CHAPTER II

ASPECTS RELATING TO THE SECURITY OF THE EUROPEAN UNION OR OF THE MEMBER STATES

Article 9

Joint Action

1. In accordance with Article 13(4) of Regulation (EC) No 683/2008, whenever the security of the Union or of the Member States may be affected by the operation of the systems, the procedures set out in Joint Action 2004/552/CFSP shall apply.

2. The security accreditation decisions taken pursuant to Chapter III, as well as the residual risks identified, shall be communicated by the Commission to the Council for information.

CHAPTER III

SECURITY ACCREDITATION FOR EUROPEAN GNSS SYSTEMS

Article 10

General principles

The security accreditation activities referred to in this Chapter shall be carried out in accordance with the following principles:

(a) security accreditation activities and decisions are undertaken in a context of collective responsibility for the security of the Union and of the Member States;

(b) efforts shall be made for decisions to be reached by consensus and for all relevant parties with an interest in security issues to be involved;

(c) tasks shall be carried out in respect of relevant security rules applicable to the Council and the Commission [1];

(d) a permanent monitoring process shall ensure that security risks are known, security measures are defined to reduce such risks to an acceptable level in accordance with the basic principles and minimum standards set out in the security rules applicable to the Council and the Commission and that these measures are applied in line with the concept of defence in depth. The effectiveness of such measures shall be continuously evaluated;

[1] Council Decision 2001/264/EC of 19 March 2001 adopting the Council's security regulations (OJ L 101, 11.4.2001, p. 1). Commission's rules on security set out in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom of 29 November 2001 amending its internal Rules of Procedure (OJ L 317, 3.12.2001, p. 1).

(e) security accreditation decisions shall, following the process defined in the security accreditation strategy, be based on local security accreditation decisions taken by the respective national security accreditation authorities of the Member States;

(f) the technical security accreditation activities shall be entrusted to professionals who are duly qualified in the field of accrediting complex systems, who have an appropriate level of security clearance, and who shall act objectively;

(g) security accreditation decisions shall be taken independently of the Commission, without prejudice to Article 3, and of the entities responsible for implementing the programmes. As a result, a security accreditation authority for European GNSS systems shall be, within the Agency, an autonomous body that takes its decisions independently;

(h) security accreditation activities shall be carried out while reconciling the requirement for independence with the need for adequate coordination, between the Commission and the authorities responsible for implementing security provisions.

Article 11

Security Accreditation Board

1. A Security Accreditation Board for European GNSS systems (hereinafter the 'Security Accreditation Board') shall be established within the Agency. In relation to the European GNSS systems, the Security Accreditation Board shall have the tasks of the security accreditation authority, as referred to in the relevant security rules applicable to the Council and the Commission.

2. The Security Accreditation Board shall perform the tasks entrusted to the Agency with regard to security accreditation under Article 16(a)(i) of Regulation (EC) No 683/2008 and take 'security accreditation decisions' as provided for in the present Article, in particular on the approval of the security accreditation strategy and of satellite launches, the authorisation to operate the systems in their different configurations and for the various services, the authorisation to operate the ground stations and in particular the sensor stations located in third countries, as well as the authorisation to manufacture receivers containing PRS technology and their components.

3. The security accreditation of the systems by the Security Accreditation Board shall consist of the establishment of compliance of the systems with the security requirements referred to in Article 13 of Regulation (EC) No 683/2008 and in accordance with the relevant security rules and regulations applicable to the Council and the Commission.

4. On the basis of the risk reports referred to in paragraph 11, the Security Accreditation Board shall inform the Commission of its risk assessment and provide advice to the Commission on residual risk treatment options for a given security accreditation decision.

5. The Commission shall keep the Security Accreditation Board continuously informed of the impact of any envisaged decisions of the Security Accreditation Board on the proper conduct of the programmes and of the implementation of residual risk treatment plans. The Security Accreditation Board shall take note of any such opinion of the Commission.

6. The decisions of the Security Accreditation Board shall be addressed to the Commission.

7. The Security Accreditation Board shall be composed of one representative per Member State, one representative from the Commission and one from the HR. A representative of ESA shall be invited to attend the meetings of the Security Accreditation Board as an observer.

8. The Security Accreditation Board shall establish its rules of procedure and shall appoint its Chairperson.

9. The Chairperson of the Security Accreditation Board shall be responsible for representing the Agency insofar as the Executive Director, according to Article 8, is not responsible.

10. The Security Accreditation Board shall have access to all the human and material resources required to provide appropriate administrative support functions and to enable it, together with the bodies referred to in paragraph 11, to perform its tasks independently, in particular when handling files, initiating and monitoring the implementation of security procedures and performing system security audits, preparing decisions and organising its meetings.

11. The Security Accreditation Board shall set up special subordinate bodies, acting on its instructions, to deal with specific issues. In particular, while ensuring necessary continuity of work, it shall set up:

— a panel to conduct security analysis reviews and tests to produce the relevant risk reports in order to assist it in preparing its decisions,

— a Crypto Distribution Authority (CDA) to assist the Security Accreditation Board in particular with regard to questions related to flight keys.

12. If consensus according to the general principles referred to in Article 10 of this Regulation cannot be reached, the Security Accreditation Board shall take decisions on the basis of majority voting, as provided for in Article 16 of the Treaty on European Union and without prejudice to Article 9 of this Regulation. The representative of the Commission and the representative of the HR shall not vote. The Chairperson of the Security Accreditation Board shall sign, on behalf of the Security Accreditation Board, the decisions adopted by the Security Accreditation Board.

13. The Commission shall keep the European Parliament and the Council informed, without undue delay, about the impact of the adoption of the security accreditation decisions on the proper conduct of the programmes. If the Commission considers that a decision taken by the Security Accreditation Board may have a significant effect on the proper conduct of the programmes, for example in terms of costs and schedule, it shall immediately inform the European Parliament and the Council.

14. Taking into account the views of the European Parliament and of the Council, which should be expressed within 1 month, the Commission may adopt any adequate measures in accordance with Regulation (EC) No 683/2008.

15. The Administrative Board shall be regularly kept informed of the evolution of the work of the Security Accreditation Board.

16. The timetable for the work of the Security Accreditation Board shall respect the GNSS work programme of the Commission.

Article 12

Role of Member States

Member States shall:

(a) transmit to the Security Accreditation Board all information they consider relevant for the purposes of security accreditation;

(b) permit duly authorised persons appointed by the Security Accreditation Board to have access to any classified information and to any areas/sites related to the security of systems falling within their jurisdiction, in accordance with their national laws and regulations, and without any discrimination on ground of nationality, including for the purposes of security audits and tests as decided by the Security Accreditation Board;

(c) each be responsible for devising a template for access control, which is to outline or list the areas/sites to be accredited, and which shall be agreed in advance between the Member States and the Security Accreditation Board, thereby ensuring that the same level of access control is being provided by all Member States;

(d) be responsible, at local level, for the accreditation of the security of areas that are located within their territory and form part of the security accreditation area for European GNSS systems, and report, to this end, to the Security Accreditation Board.

CHAPTER IV

BUDGETARY AND FINANCIAL PROVISIONS

Article 13

Budget

1. Without prejudice to other resources and dues yet to be defined, revenue of the Agency shall include a Union subsidy entered in the general budget of the European Union in order to ensure a balance between revenue and expenditure.

2. The expenditure of the Agency shall cover staff, administrative and infrastructure expenditure, operating costs and expenditure associated with the functioning of the Security Accreditation Board, including the bodies referred to in Article 11(11), and the contracts and agreements concluded by the Agency in order to accomplish the tasks entrusted to it.

3. The Executive Director shall draw up a draft statement of estimates of the revenue and expenditure of the Agency for the following year and shall forward it to the Administrative Board, together with a draft establishment plan.

4. Revenue and expenditure shall be in balance.

5. Each year the Administrative Board, on the basis of the draft statement of revenue and expenditure, shall produce a statement of estimates of revenue and expenditure for the Agency for the following financial year.

6. This statement of estimates, which shall include a draft establishment plan together with the provisional work programme, shall, by 31 March, be forwarded by the Administrative Board to the Commission and to the third countries with which the Union has concluded agreements in accordance with Article 23.

7. The statement of estimates shall be forwarded by the Commission to the European Parliament and to the Council (hereinafter the 'budgetary authority') together with the draft general budget of the European Union.

8. On the basis of the statement of estimates, the Commission shall enter in the draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 314 of the Treaty on the Functioning of the European Union.

9. The budgetary authority shall authorise the appropriations for the subsidy to the Agency and shall adopt the establishment plan for the Agency.

10. The budget shall be adopted by the Administrative Board. It shall become final following definitive adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.

11. The Administrative Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which will have significant financial implications for the funding of the budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

12. Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Administrative Board within a period of 6 weeks from the date of notification of the project.

Article 14

Implementation and control of the budget

1. The Executive Director shall implement the budget of the Agency.

2. By 1 March following each financial year, the accounting officer of the Agency shall communicate the provisional accounts to the Commission's accounting officer, together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of Regulation (EC, Euratom) No 1605/2002.

3. By 31 March following each financial year, the Commission's accounting officer shall forward the provisional accounts of the Agency to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report shall also be forwarded to the European Parliament and the Council.

4. On receipt of the Court of Auditors' observations on the provisional accounts of the Agency, under Article 129 of Regulation (EC, Euratom) No 1605/2002, the Executive Director shall draw up the final accounts of the Agency under his own responsibility and submit them to the Administrative Board for an opinion.

5. The Administrative Board shall deliver an opinion on the final accounts of the Agency.

6. The Executive Director shall, by 1 July following each financial year, forward the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Administrative Board's opinion.

7. The final accounts shall be published.

8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September. He shall also send this reply to the Administrative Board.

9. The Executive Director shall submit to the European Parliament, at the latter's request, all information necessary for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 146(3) of Regulation (EC, Euratom) No 1605/2002.

10. The European Parliament, on a recommendation from the Council acting on a qualified majority, shall, before 30 April of the year N + 2, grant discharge to the Executive Director in respect of the implementation of the budget for year N.

Article 15

Financial provisions

The financial rules applicable to the Agency shall be adopted by the Administrative Board after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities [1] unless such departure is specifically required for the operation of the Agency and the Commission has given its prior consent.

[1] OJ L 357, 31.12.2002, p. 72.

CHAPTER V

MISCELLANEOUS PROVISIONS

Article 16

Anti-fraud measures

1. In order to combat fraud, corruption and other unlawful activities, the provisions of 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) [1] shall apply without restriction.

2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti Fraud Office (OLAF) [2] and shall issue, without delay, appropriate provisions applicable to all staff of the Agency.

3. The decisions concerning funding, and the implementing agreements and instruments resulting there from, shall explicitly stipulate that the Court of Auditors and OLAF may, if necessary, carry out on-the-spot checks on the recipients of funding of the Agency and the agents responsible for allocating it.

Article 17

Privileges and immunities

The Protocol on Privileges and Immunities of the European Union shall apply to the Agency.

Article 18

Staff

1. The Staff Regulations of Officials of the European Union, the Conditions of employment of other servants of the European Union and the rules adopted jointly by the institutions of the European Union for the purposes of the application of those Staff Regulations and Conditions of employment shall apply to the staff of the Agency. The Administrative Board, in agreement with the Commission, shall adopt the necessary detailed rules of application.

2. Without prejudice to Article 8, the powers conferred on the appointing authority by the Staff Regulations and the Conditions of employment of other servants shall be exercised by the Agency with respect to its own staff.

3. The staff of the Agency shall consist of servants recruited by the Agency as necessary to perform its tasks, but may also include officials with the appropriate clearance who have been assigned or seconded by the Commission or the Member States on a temporary basis.

4. The provisions laid down in paragraphs 1 and 3 shall also apply to the staff of the GSMC.

Article 19

Liability

1. The contractual liability of the Agency shall be governed by the law applicable to the contract in question. The Court of Justice shall have jurisdiction to give judgement pursuant to any arbitration clause contained in a contract concluded by the Agency.

2. In the event of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its departments or by its servants in the performance of their duties.

3. The Court of Justice shall have jurisdiction in any dispute relating to compensation for damage referred to in paragraph 2.

4. The personal liability of its servants towards the Agency shall be governed by the provisions laid down in the Staff Regulations or Conditions of employment applicable to them.

Article 20

Languages

1. The provisions laid down in Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community [3] shall apply to the Agency.

2. The translation services required for the functioning of the Agency shall be provided by the Translation Centre for the bodies of the European Union.

Article 21

Access to documents and protection of data of a personal character

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [4] shall apply to documents held by the Agency.

[1] OJ L 136, 31.5.1999, p. 1.
[2] OJ L 136, 31.5.1999, p. 15.
[3] OJ 17, 6.10.1958, p. 385/58.
[4] OJ L 145, 31.5.2001, p. 43.

2. The Administrative Board shall adopt arrangements for implementing Regulation (EC) No 1049/2001 within 6 months from the entry into force of this Regulation.

3. Decisions taken by the Agency in pursuance of Article 8 of Regulation (EC) No 1049/2001 may be the subject of a complaint to the Ombudsman or an action before the Court of Justice of the European Union, under Articles 228 and 263 of the Treaty on the Functioning of the European Union respectively.

4. When processing data relating to individuals, the Agency shall be subject to the provisions of 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]).

Article 22

Security rules

The Agency shall apply the security principles contained in Commission Decision 2001/844/EC, ECSC, Euratom. This shall cover, inter alia, provisions for the exchange, handling and storage of classified information.

Article 23

Participation of third countries

1. The Agency shall be open to the participation of third countries that have entered into agreements with the European Union to this effect.

2. Under the relevant provisions of these agreements, arrangements shall be developed specifying, in particular, the nature, extent and manner in which these countries will participate in the work of the Agency, including provisions relating to participation in the initiatives undertaken by the Agency, financial contributions and staff.

CHAPTER VI

FINAL PROVISIONS

Article 24

Amendments to Regulation (EC) No 683/2008

Throughout Regulation (EC) No 683/2008, the words 'European GNSS Supervisory Authority' and 'Authority' shall be replaced by 'European GNSS Agency' and 'Agency' respectively.

Article 25

Repeal and validity of measures taken

Regulation (EC) No 1321/2004 is hereby repealed. References to the repealed Regulation shall be construed as references to this Regulation. Any measure adopted on the basis of Regulation (EC) No 1321/2004 shall remain valid.

Article 26

Evaluation

By 2012, the Commission shall evaluate this Regulation, particularly as regards the Agency's tasks laid down in Article 2, and, if necessary, make proposals.

Article 27

Entry into force

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

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

Done at Strasbourg, 22 September 2010.

For the European Parliament
The President
J. BUZEK

For the Council
The President
O. CHASTEL

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

REGULATION (EU) No 913/2010 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2010

concerning a European rail network for competitive freight

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) Within the framework of the European Union new Strategy for jobs and growth, the creation of an internal rail market, in particular with regard to freight transport, is an essential factor in making progress towards sustainable mobility.

(2) Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways ([4]) and Directive 2001/14/EC of the European Parliament and of the Council of 26 February 2001 on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure ([5]) have been important steps in the creation of the internal rail market.

(3) In order to be competitive with other modes of transport, international and national rail freight services, which have been opened up to competition since 1 January 2007, must be able to benefit from a good quality and sufficiently financed railway infrastructure, namely, one which allows freight transport services to be provided under good conditions in terms of commercial speed and journey times and to be reliable, namely, that the service it provides actually corresponds to the contractual agreements entered into with the railway undertakings.

(4) Although the opening of the rail freight market has made it possible for new operators to enter the rail network, market mechanisms have not been and are not sufficient to organise, regulate and secure rail freight traffic. To optimise the use of the network and ensure its reliability it is useful to introduce additional procedures to strengthen cooperation on allocation of international train paths for freight trains between infrastructure managers.

(5) In this context, the establishment of international rail corridors for a European rail network for competitive freight on which freight trains can run under good conditions and easily pass from one national network to another would allow for improvements in the conditions of use of the infrastructure.

(6) In order to establish international rail corridors for a European rail network for competitive freight, the initiatives already taken in terms of railway infrastructure show that the establishment of international corridors, which meet specific needs in one or more clearly identified segments of the freight market, is the most appropriate method.

(7) This Regulation should, unless otherwise provided, be without prejudice to the rights and obligations of infrastructure managers set out in Directive 91/440/EEC and Directive 2001/14/EC and, where relevant, allocation bodies as referred to in Article 14(2) of Directive 2001/14/EC. Those acts remain in force, including in respect of provisions which affect freight corridors.

(8) The establishment of a freight corridor should take into account, where appropriate, the need for better interconnections with the rail infrastructure of European third countries.

([1]) OJ C 317, 23.12.2009, p. 94.
([2]) OJ C 79, 27.3.2010, p. 45.
([3]) Position of the European Parliament of 23 April 2009 (OJ C 184 E, 8.7.2010, p. 354), position of the Council at first reading of 22 February 2010 (OJ C 114 E, 4.5.2010, p. 1), position of the European Parliament of 15 June 2010 (not yet published in the Official Journal) and decision of the Council of 13 September 2010.
([4]) OJ L 237, 24.8.1991, p. 25.
([5]) OJ L 75, 15.3.2001, p. 29.

(9) The design of freight corridors should seek to ensure continuity along the corridors by enabling the required interconnections between existing railway infrastructure.

(10) The implementation of international rail freight corridors forming a European rail network for competitive freight should be conducted in a manner consistent with the trans-European Transport Network (TEN-T) and/or the European Railway Traffic Management System (ERTMS) corridors. To that end, the coordinated development of the networks is necessary, and in particular as regards the integration of the international corridors for rail freight into the existing TEN-T and the ERTMS corridors. Furthermore, harmonising rules relating to those freight corridors should be established at Union level. Projects aimed at reducing noise from freight trains should be encouraged. If necessary, the establishment of those corridors should be supported financially within the framework of the TEN-T, research and Marco Polo programmes, and other Union policies and funds, such as the European Regional Development Fund or the Cohesion Fund as well as the European Investment Bank.

(11) Within the framework of a freight corridor, good co-ordination between the Member States and the infrastructure managers concerned should be ensured, sufficient priority should be given to rail freight traffic, effective and adequate links to other modes of transport should be set up and conditions should be created which are favourable to the development of competition between rail freight service providers.

(12) Further to the freight corridors set up in accordance with Article 3, the establishment of additional freight corridors should be examined and approved at Union level in accordance with clearly defined transparent procedures and criteria which allow Member States and infrastructure managers sufficient decision-making and management scope so that they can take into account existing initiatives for special corridors, e.g. ERTMS, RailNetEurope (RNE) and TEN-T, and take measures adapted to their specific needs.

(13) In order to stimulate coordination between the Member States and the infrastructure managers and to provide continuity along the corridor, an appropriate governance structure for each freight corridor should be established, taking into account the need to avoid duplication with already existing governance structures.

(14) In order to meet market needs, the methods for establishing a freight corridor should be presented in an implementation plan, which should include identifying and setting a schedule for measures which would improve the performance of rail freight. Furthermore, to ensure that planned or implemented measures for the establishment of a freight corridor meet the needs or expectations of all of the users of the freight corridor, the applicants likely to use the freight corridor must be regularly consulted in accordance with procedures defined by the management board.

(15) The development of intermodal freight terminals should also be considered necessary to support the establishment of rail freight corridors in the Union.

(16) In order to guarantee the consistency and continuity of the infrastructure capacities available along the freight corridor, investment in the freight corridor should be coordinated between Member States and the infrastructure managers concerned, as well as, where appropriate, between Member States and European third countries, and planned in a way which meets, subject to economic viability, the needs of the freight corridor. The schedule for carrying out the investment should be published to ensure that applicants who may operate in the corridor are well informed. The investment should include projects relating to the development of interoperable systems and the increase in capacity of the trains.

(17) For the same reasons, all the works on infrastructure and its equipment that would restrict available capacity on the freight corridor should also be coordinated at the level of the freight corridor and be the subject of updated publications.

(18) In order to facilitate requests for infrastructure capacities for international rail freight services, it is appropriate to designate or establish a one-stop shop for each freight corridor. For this, existing initiatives should be built upon, in particular those undertaken by RNE, a body which acts as a coordination tool for the infrastructure managers and provides a number of services to international freight undertakings.

(19) The management of freight corridors should also include procedures for the allocation of the infrastructure capacity for international freight trains running on such corridors. Those procedures should recognise the need for capacity of other types of transport, including passenger transport.

(20) To ensure that the railway infrastructure is better used, the operation of that infrastructure and the terminals along the freight corridor need to be coordinated.

(21) Priority rules may also mean priority targets depending on the situation in the respective Member State.

(22) Freight trains running on the freight corridor should be able to enjoy, as far as possible, sufficient punctuality in the event of disturbance with regard to the needs of all types of transport.

(23) In order to promote the development of competition between providers of rail freight services on the freight corridor, applicants other than railway undertakings or their groupings should be allowed to request infrastructure capacity on the freight corridors.

(24) In order to evaluate objectively the benefits of the measures aimed at the establishment of the freight corridor, the performance of the rail freight services along the freight corridor should be monitored and quality reports should be published regularly. The evaluation of the performance should include the outcome of satisfaction surveys of the users of the freight corridor.

(25) In order to ensure non-discriminatory access to international rail services, it is necessary to ensure efficient coordination between the regulatory bodies with regard to the different networks covered by the freight corridor.

(26) To facilitate access to information concerning the use of all the main infrastructure on the freight corridor and to guarantee non-discriminatory access to that corridor, the management board should draw up, regularly update and publish a document containing all of this information.

(27) Since the objective of this Regulation, namely the establishment of a European rail network for competitive freight made up of freight corridors, cannot be sufficiently achieved by the Member States alone and can therefore by reason of its scale and effects 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 in order to achieve that objective.

(28) Fair rules based on cooperation between the infrastructure managers, who must provide a quality service to freight undertakings within the framework of an international rail corridor, should be introduced in respect of the coordination of investment and the management of capacities and traffic.

(29) As international trains need to run itineraries combining several corridors, as defined in this Regulation, the infrastructure managers of several corridors may also coordinate their activities in order to ensure, on the corridors concerned, the availability of capacity, fluid movements and a coherent application of priority rules to the different types of traffic in the event of disturbance.

(30) The aim of this Regulation is to improve the efficiency of rail freight transport relative to other modes of transport. Coordination should be ensured between Member States and infrastructure managers in order to guarantee the most efficient functioning of freight corridors. To allow this, operational measures should be taken in parallel with investments in infrastructure and in technical equipment such as ERTMS that should aim at increasing rail freight capacity and efficiency.

(31) The implementation of the rules on the establishment and modification of the freight corridors and on the exemptions granted to the Member States needs to be achieved under uniform conditions in order to ensure the compliance of the proposals for the establishment of freight corridors with the criteria set out in this Regulation and should therefore be conferred upon the Commission. In accordance with Article 291 of the Treaty on the Functioning of the European Union, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers shall be laid down in advance by means of a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1] continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL

Article 1

Purpose and scope

1. This Regulation lays down rules for the establishment and organisation of international rail corridors for competitive rail freight with a view to the development of a European rail network for competitive freight. It sets out rules for the selection, organisation, management and the indicative investment planning of freight corridors.

2. This Regulation shall apply to the management and use of railway infrastructure included in freight corridors.

[1] OJ L 184, 17.7.1999, p. 23.

Article 2

Definitions

1. For the purposes of this Regulation, the definitions laid down in Article 2 of Directive 2001/14/EC shall apply.

2. In addition to the definitions referred to in paragraph 1:

(a) 'freight corridor' means all designated railway lines, including railway ferry lines, on the territory of or between Member States, and, where appropriate, European third countries, linking two or more terminals, along a principal route and, where appropriate, diversionary routes and sections connecting them, including the railway infrastructure and its equipment and relevant rail services in accordance with Article 5 of Directive 2001/14/EC;

(b) 'implementation plan' means the document presenting the means and the strategy that the parties concerned intend to implement in order to develop over a specified period the measures which are necessary and sufficient to establish the freight corridor;

(c) 'terminal' means the installation provided along the freight corridor which has been specially arranged to allow either the loading and/or the unloading of goods onto/from freight trains, and the integration of rail freight services with road, maritime, river and air services, and either the forming or modification of the composition of freight trains; and, where necessary, performing border procedures at borders with European third countries.

CHAPTER II

DESIGNATION AND GOVERNANCE OF THE INTERNATIONAL RAIL CORRIDORS FOR COMPETITIVE FREIGHT

Article 3

Designation of initial freight corridors

The Member States referred to in the Annex shall make operational by the dates set out therein the initial freight corridors set out in the Annex. The Member States concerned shall inform the Commission about the establishment of the freight corridors.

Article 4

Criteria for further freight corridors

The selection of further freight corridors referred to in Article 5 and the modification of freight corridors referred to in Article 6 shall take account of the following criteria:

(a) the crossing by the freight corridor of the territory of at least three Member States, or of two Member States if the distance between the terminals served by the freight corridor is greater than 500 km;

(b) the consistency of the freight corridor with the TEN-T, the ERTMS corridors and/or the corridors defined by RNE;

(c) the integration of TEN-T priority projects [1] into the freight corridor;

(d) the balance between the socio-economic costs and benefits stemming from the establishment of the freight corridor;

(e) the consistency of all of the freight corridors proposed by the Member States in order to set up a European rail network for competitive freight;

(f) the development of rail freight traffic and major trade flows and goods traffic along the freight corridor;

(g) if appropriate, better interconnections between Member States and European third countries;

(h) the interest of the applicants in the freight corridor;

(i) the existence of good interconnections with other modes of transport, in particular due to an adequate network of terminals, including in maritime and inland ports.

Article 5

Selection of further freight corridors

1. Each Member State with a rail border with another Member State shall participate in the establishment of at least one freight corridor, unless this obligation has already been met under Article 3.

2. Notwithstanding paragraph 1, Member States shall, upon request from a Member State, participate in the establishment of the freight corridor as referred to in that paragraph or the prolongation of an existing corridor, in order to allow a neighbouring Member State to fulfil its obligation under that paragraph.

[1] See Annex III to Decision No 661/2010/EU of the European Parliament and of the Council of 7 July 2010 on Union guidelines for the development of the trans-European transport network (OJ L 204, 5.8.2010, p. 1).

3. Without prejudice to the obligations of Member States under Article 7 of Directive 91/440/EEC, where a Member State considers, after having provided a socio-economic analysis, that the establishment of a freight corridor would not be in the interest of the applicants likely to use the freight corridor or would not bring significant socio-economic benefits or would cause a disproportionate burden, the Member State concerned shall not be obliged to participate as referred to in paragraphs 1 and 2 of this Article, subject to a decision of the Commission acting in accordance with the advisory procedure referred to in Article 21(2).

4. A Member State shall not be obliged to participate as referred to in paragraphs 1 and 2 if it has a rail network which has a track gauge which is different from that of the main rail network within the Union.

5. The establishment of a freight corridor shall be proposed by the Member States concerned. For this purpose they shall send jointly to the Commission a letter of intent including a proposal drawn up after consultation of the infrastructure managers and applicants concerned, taking into account the criteria set out in Article 4.

In order to meet the obligation under paragraphs 1 and 2, the Member States concerned shall send jointly to the Commission a letter of intent by 10 November 2012.

6. The Commission shall examine the proposals for the establishment of a freight corridor as referred to in paragraph 5 and, in accordance with the regulatory procedure referred to in Article 21(3), adopt a decision on the compliance of such a proposal with this Article at the latest 9 months after submission of the proposal.

7. The Member States concerned shall establish the freight corridor at the latest two years after the decision of the Commission referred to in paragraph 6.

Article 6

Modification of further freight corridors

1. The freight corridors referred to in Article 5 may be modified on the basis of a joint proposal by the Member States concerned to the Commission after consulting the infrastructure managers and applicants concerned.

2. The Commission shall, in accordance with the regulatory procedure referred to in Article 21(3), adopt a decision on the proposal taking into account the criteria set out in Article 4.

Article 7

Reconciliation

When two or more Member States concerned do not agree on the establishment or modification of a freight corridor, and with regard to the railway infrastructure located on their territory, the Commission, at the request of one of the Member States concerned, shall consult the Committee referred to in Article 21 on this matter. The opinion of the Commission shall be sent to the Member States concerned. The Member States concerned shall take this opinion into account in order to find a solution and shall take a decision on the basis of mutual consent.

Article 8

Governance of freight corridors

1. For each freight corridor, Member States concerned shall establish an executive board responsible for defining the general objectives of the freight corridor, supervising and taking the measures as expressly provided for in paragraph 7 of this Article, and in Articles 9 and 11, Article 14(1) and Article 22. The executive board shall be composed of representatives of the authorities of the Member States concerned.

2. For each freight corridor, the infrastructure managers concerned and, where relevant, the allocation bodies as referred to in Article 14(2) of Directive 2001/14/EC, shall establish a management board responsible for taking the measures as expressly provided for in paragraphs 5, 7, 8 and 9 of this Article, and in Articles 9 to 12, Article 13(1), Article 14(2), (6) and (9), Article 16(1), Article 17(1) and Articles 18 and 19 of this Regulation. The management board shall be composed of the representatives of the infrastructure managers.

3. The Member States and infrastructure managers concerned by a freight corridor shall cooperate within the boards referred to in paragraphs 1 and 2 to ensure the development of the freight corridor in accordance with its implementation plan.

4. The executive board shall take its decisions on the basis of mutual consent of the representatives of the authorities of the Member States concerned.

5. The management board shall take its decisions, including decisions regarding its legal status, the establishment of its organisational structure, resources and staffing, on the basis of mutual consent of the infrastructure managers concerned. The management board may be an independent legal entity. It may take the form of a European economic interest grouping within the meaning of Council Regulation (EEC) No 2137/85 of 25 July 1985 on the European Economic Interest Grouping (EEIG) [1].

[1] OJ L 199, 31.7.1985, p. 1.

6. The responsibilities of the executive and management boards shall be without prejudice to the independence of infrastructure managers as provided for in Article 4(2) of Directive 91/440/EEC.

7. The management board shall set up an advisory group made up of managers and owners of the terminals of the freight corridor including, where necessary, sea and inland waterway ports. This advisory group may issue an opinion on any proposal by the management board which has direct consequences for investment and the management of terminals. It may also issue own-initiative opinions. The management board shall take any of these opinions into account. In the event of disagreement between the management board and the advisory group, the latter may refer the matter to the executive board. The executive board shall act as an intermediary and provide its opinion in due time. The final decision however shall be taken by the management board.

8. The management board shall set up a further advisory group made up of railway undertakings interested in the use of the freight corridor. This advisory group may issue an opinion on any proposal by the management board which has consequences for these undertakings. It may also issue own-initiative opinions. The management board shall take any of these opinions into account.

9. The management board shall coordinate in accordance with national and European deployment plans the use of interoperable IT applications or alternative solutions that may become available in the future to handle requests for international train paths and the operation of international traffic on the freight corridor.

Article 9

Measures for implementing the freight corridor plan

1. The management board shall draw up an implementation plan at the latest 6 months before making the freight corridor operational and shall submit it for approval to the executive board. This plan shall include:

(a) a description of the characteristics of the freight corridor, including bottlenecks, and the programme of measures necessary for creating the freight corridor;

(b) the essential elements of the study referred to in paragraph 3;

(c) the objectives for the freight corridors, in particular in terms of performance of the freight corridor expressed as the quality of the service and the capacity of the freight corridor in accordance with the provisions of Article 19;

(d) the investment plan referred to in Article 11; and

(e) the measures to implement the provisions of Articles 12 to 19.

2. The management board shall periodically review the implementation plan taking into account progress made in its implementation, the rail freight market on the freight corridor and performance measured in accordance with the objectives referred to in point (c) of paragraph 1.

3. The management board shall carry out and periodically update a transport market study relating to the observed and expected changes in the traffic on the freight corridor, as a consequence of its being established, covering the different types of traffic, both regarding the transport of freight and the transport of passengers. This study shall also review, where necessary, the socio-economic costs and benefits stemming from the establishment of the freight corridor.

4. The implementation plan shall take into account the development of terminals to meet the needs of rail freight running on the freight corridor, in particular by acting as intermodal nodes along the freight corridors.

5. The management board shall, as appropriate, take measures to cooperate with regional and/or local administrations in respect of the implementation plan.

Article 10

Consulting applicants

The management board shall introduce consultation mechanisms with a view to the proper participation of the applicants likely to use the freight corridor. In particular, it shall ensure that applicants are consulted before the implementation plan referred to in Article 9 is submitted to the executive board.

CHAPTER III

INVESTMENT IN THE FREIGHT CORRIDOR

Article 11

Investment planning

1. The management board shall draw up and periodically review an investment plan, which includes details of indicative medium and long-term investment for infrastructure in the freight corridor, and shall submit it for approval to the executive board. This plan shall include:

(a) the list of the projects foreseen for the extension, renewal or redeployment of railway infrastructure and its equipment along the freight corridor and the relevant financial requirements and sources of finance;

(b) a deployment plan relating to the interoperable systems along the freight corridor which satisfies the essential requirements and the technical specifications for interoperability which apply to the network as defined in Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community [1]. This deployment plan shall be based on a cost-benefit analysis of the use of interoperable systems;

(c) a plan for the management of the capacity of freight trains which may run on the freight corridor, which includes removing the identified bottlenecks. This plan may be based on improving speed management and on increasing the length, loading gauge, and load hauled or axle load authorised for the trains running on the freight corridor; and

(d) where applicable, reference to the contribution of the Union envisaged under financial programmes of the Union.

2. The application of this Regulation shall be without prejudice to the competence of the Member States regarding planning of and funding for rail infrastructure.

Article 12

Coordination of works

The management board shall coordinate and ensure the publication in one place, in an appropriate manner and timeframe, of their schedule for carrying out all the works on the infrastructure and its equipment that would restrict available capacity on the freight corridor.

CHAPTER IV

MANAGEMENT OF THE FREIGHT CORRIDOR

Article 13

One-stop shop for application for infrastructure capacity

1. The management board for a freight corridor shall designate or set up a joint body for applicants to request and to receive answers, in a single place and in a single operation, regarding infrastructure capacity for freight trains crossing at least one border along the freight corridor (hereinafter referred to as a 'one-stop shop').

2. The one-stop shop shall, as a coordination tool, also provide basic information concerning the allocation of the infrastructure capacity, including the information referred in Article 18. It shall display infrastructure capacity available at the time of request and its characteristics in accordance with pre-defined parameters, such as speed, length, loading gauge or axle load authorised for trains running on the freight corridor.

3. The one-stop shop shall take a decision with regard to applications for pre-arranged train paths specified in Article 14(3) and for the reserve capacity specified in Article 14(5). It shall allocate the capacity in line with rules regarding capacity allocation as set out in Directive 2001/14/EC. It shall inform the competent infrastructure managers of these applications and the decision taken without delay.

4. For any request of infrastructure capacity which cannot be met pursuant to paragraph 3, the one-stop shop shall forward the application for infrastructure capacity without any delay to the competent infrastructure managers and, where relevant, the allocation bodies as referred to in Article 14(2) of Directive 2001/14/EC, who shall take a decision on that application in accordance with Article 13 and Chapter III of that Directive and communicate this decision to the one-stop shop for further processing.

5. The activities of the one-stop shop shall be carried out in a transparent and non-discriminatory manner. To this end a register shall be kept which shall be made freely available to all interested parties. It shall contain the dates of the requests, names of the applicants, details of documentation supplied and of incidents which have occurred. These activities shall be subject to the control of the regulatory bodies in accordance with Article 20.

Article 14

Capacity allocated to freight trains

1. The executive board shall define the framework for the allocation of the infrastructure capacity on the freight corridor in accordance with Article 14(1) of Directive 2001/14/EC.

2. The management board shall evaluate the need for capacity to be allocated to freight trains running on the freight corridor taking into account the transport market study referred to in Article 9(3) of this Regulation, the requests for infrastructure capacity relating to the past and present working timetables and the framework agreements.

3. On the basis of the evaluation specified in paragraph 2 of this Article, infrastructure managers of the freight corridor shall jointly define and organise international pre-arranged train paths for freight trains following the procedure referred to in Article 15 of Directive 2001/14/EC recognising the need for capacity of other types of transport, including passenger transport. They shall facilitate journey times, frequencies, times of departure and destination and routings suitable for freight transport services with a view to increasing the transport of goods by freight trains running on the freight corridor. These pre-arranged train paths shall be published not later than 3 months before the final date for receipt of requests for capacity referred to in Annex III to Directive 2001/14/EC. The infrastructure managers of several freight corridors may, if necessary, coordinate international prearranged train paths offering capacity on the freight corridors concerned.

[1] OJ L 191, 18.7.2008, p. 1.

4. These pre-arranged train paths shall be allocated first to freight trains which cross at least one border.

5. Infrastructure managers shall, if justified by market need and the evaluation as referred to in paragraph 2 of this Article, jointly define the reserve capacity for international freight trains running on the freight corridors recognising the need for capacity of other types of transport, including passenger transport and keep this reserve available within their final working timetables to allow for a quick and appropriate response to ad hoc requests for capacity as referred to in Article 23 of Directive 2001/14/EC. This capacity shall be reserved until the time limit before its scheduled time as decided by the management board. This time limit shall not exceed 60 days.

6. The management board shall promote coordination of priority rules relating to capacity allocation on the freight corridor.

7. Infrastructure managers may include in their conditions of use a fee for train paths that are allocated but ultimately not used. The level of this fee shall be appropriate, dissuasive and effective.

8. Save in the case of force majeure, including urgent and unforeseeable safety-critical work, a train path allocated to a freight operation pursuant to this Article may not be cancelled less than 2 months before its scheduled time in the working timetable if the applicant concerned does not give its approval for such cancellation. In such a case the infrastructure manager concerned shall make an effort to propose to the applicant a train path of an equivalent quality and reliability which the applicant has the right to accept or refuse. This provision shall be without prejudice to any rights the applicant may have under an agreement as referred to in Article 19(1) of Directive 2001/14/EC. In any case, the applicant may refer the matter to the regulatory body referred to in Article 20 of this Regulation.

9. The management board of the freight corridor and the advisory group referred to in Article 8(7) shall put in place procedures to ensure optimal coordination of the allocation of capacity between infrastructure managers, both for requests as referred to in Article 13(1) and for requests received by infrastructure managers concerned. This shall also take account of access to terminals.

10. In paragraphs 4 and 9 of this Article, references to infrastructure managers shall include, where relevant, allocation bodies as referred to in Article 14(2) of Directive 2001/14/EC.

Article 15

Authorised applicants

Notwithstanding Article 16(1) of Directive 2001/14/EC, applicants other than railway undertakings or the international groupings that they make up, such as shippers, freight forwarders and combined transport operators, may request international pre-arranged train paths specified in Article 14(3) and the reserve capacity specified in Article 14(5). In order to use such a train path for freight transport on the freight corridor these applicants shall appoint a railway undertaking to conclude an agreement with the infrastructure manager in accordance with Article 10(5) of Directive 91/440/EEC.

Article 16

Traffic management

1. The management board of the freight corridor shall put in place procedures for coordinating traffic management along the freight corridor. The management boards of connected freight corridors shall put in place procedures for coordinating traffic along such freight corridors.

2. The infrastructure managers of the freight corridor and the advisory group referred to in Article 8(7) shall put in place procedures to ensure optimal coordination between the operation of the railway infrastructure and the terminals.

Article 17

Traffic management in the event of disturbance

1. The management board shall adopt common targets for punctuality and/or guidelines for traffic management in the event of disturbance to train movements on the freight corridor.

2. Each infrastructure manager concerned shall draw up priority rules for the management between the different types of traffic in the part of the freight corridors within the responsibility of that infrastructure manager in accordance with the common targets and/or guidelines referred to in paragraph 1 of this Article. Those priority rules shall be published in the network statement referred to in Article 3 of Directive 2001/14/EC.

3. The principles for establishing the priority rules shall at least provide that the train path referred to in Article 14(3) and (4) allocated to freight trains which comply with their scheduled time in the working timetable shall not be modified, as far as possible. The principles for establishing the priority rules shall aim at minimising the overall network recovery time with regard to the needs of all types of transport. For this purpose, infrastructure managers may coordinate the management between the different types of traffic along several freight corridors.

Article 18

Information on the conditions of use of the freight corridor

The management board shall draw up, regularly update and publish a document containing:

(a) all the information contained in the network statement for national networks regarding the freight corridor, drawn up in accordance with the procedure set out in Article 3 of Directive 2001/14/EC;

(b) the list and characteristics of terminals, in particular information concerning the conditions and methods of accessing the terminals;

(c) the information concerning the procedures referred to in Articles 13 to 17 of this Regulation; and

(d) the implementation plan.

Article 19

Quality of service on the freight corridor

1. The management board of the freight corridor shall promote compatibility between the performance schemes along the freight corridor, as referred to in Article 11 of Directive 2001/14/EC.

2. The management board shall monitor the performance of rail freight services on the freight corridor and publish the results of this monitoring once a year.

3. The management board shall organise a satisfaction survey of the users of the freight corridor and shall publish the results of it once a year.

Article 20

Regulatory bodies

1. The regulatory bodies referred to in Article 30 of Directive 2001/14/EC shall cooperate in monitoring the competition in the rail freight corridor. In particular, they shall ensure non-discriminatory access to the corridor and shall be the appeal bodies provided for under Article 30(2) of that Directive. They shall exchange the necessary information obtained from infrastructure managers and other relevant parties.

2. Member States, in order to foster free and fair competition on the freight corridors, shall endeavour to establish a comparable regulatory level. Regulatory bodies shall be easily accessible to the market players, and shall be able to take decisions independently and efficiently.

3. In the event of a complaint to a regulatory body from an applicant regarding international rail freight services, or within the framework of an own-initiative investigation by a regulatory body, this regulatory body shall consult the regulatory bodies of all other Member States through which the international train path for freight train concerned runs and request all necessary information from them before taking its decision.

4. The regulatory bodies consulted under paragraph 3 shall provide all the information that they themselves have the right to request under their national legislation to the regulatory body concerned. This information may only be used for the purpose of the handling of the complaint or the investigation referred to in paragraph 3.

5. The regulatory body receiving the complaint or having initiated the own-initiative investigation shall transfer relevant information to the regulatory body responsible in order for that body to take measures regarding the parties concerned.

6. Any associated representatives of infrastructure managers as referred to in Article 15(1) of Directive 2001/14/EC shall ensure provision, without delay, of all the information necessary for the purpose of the handling of the complaint or the investigation referred to in paragraph 3 of this Article and requested by the regulatory body of the Member State in which the associated representative is located. This regulatory body shall be entitled to transfer such information regarding the international train path concerned to the regulatory bodies mentioned in paragraph 3 of this Article.

CHAPTER V

FINAL PROVISIONS

Article 21

Committee procedure

1. The Commission shall be assisted by the Committee referred to in Article 11a of Directive 91/440/EEC.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

Article 22

Monitoring implementation

Every two years from the time of the establishment of a freight corridor, the executive board referred to in Article 8(1) shall present to the Commission the results of the implementation plan for that corridor. The Commission shall analyse those results and notify the Committee referred to in Article 21 of its analysis.

Article 23

Report

The Commission shall periodically examine the application of this Regulation. It shall submit a report to the European Parliament and the Council, for the first time by 10 November 2015, and every three years thereafter.

Article 24

Transitional measures

This Regulation shall not apply to the Republic of Cyprus and Malta for as long as no railway system is established within their territory.

Article 25

Entry into force

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

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

Done at Strasbourg, 22 September 2010.

For the European Parliament
The President
J. BUZEK

For the Council
The President
O. CHASTEL

ANNEX

List of initial freight corridors

	Member States	Principal routes [1]	Establishment of freight corridors:
1.	NL, BE, DE, IT	Zeebrugge-Antwerp/Rotterdam-Duisburg-[*Basel*]-Milan-Genoa	By 10 November 2013
2.	NL, BE, LU, FR	Rotterdam-Antwerp-Luxembourg-Metz-Dijon-Lyon/[*Basel*]	By 10 November 2013
3.	SE, DK, DE, AT, IT	Stockholm-Malmö-Copenhagen-Hamburg-Innsbruck-Verona-Palermo	By 10 November 2015
4.	PT, ES, FR	Sines-Lisbon/Leixões — Madrid-Medina del Campo/Bilbao/San Sebastian-Irun-Bordeaux-Paris/Le Havre/Metz Sines-Elvas/Algeciras	By 10 November 2013
5.	PL, CZ, SK, AT, IT, SI	Gdynia-Katowice-Ostrava/Žilina-Bratislava/Vienna/ Klagenfurt-Udine-Venice/ Trieste/ /Bologna/Ravenna/ Graz-Maribor-Ljubljana-Koper/Trieste	By 10 November 2015
6.	ES, FR, IT, SI, HU	Almería-Valencia/Madrid-Zaragoza/Barcelona-Marseille-Lyon-Turin-Milan-Verona-Padua/Venice-Trieste/Koper-Ljubljana-Budapest-Zahony (Hungarian-Ukrainian border)	By 10 November 2013
7.	CZ, AT, SK, HU, RO, BG, EL	— Bucharest-Constanta Prague-Vienna/Bratislava-Budapest — Vidin-Sofia-Thessaloniki-Athens	By 10 November 2013
8.	DE, NL, BE, PL, LT	Bremerhaven/Rotterdam/Antwerp-Aachen/Berlin-Warsaw-Terespol (Poland-Belarus border)/Kaunas	By 10 November 2015
9.	CZ, SK	Prague-Horní Lideč-Žilina-Košice-Čierna nad Tisou (Slovak/ Ukrainian border)	By 10 November 2013

[1] '/' means alternative routes. In line with the TEN-T priority projects, routes 4 and 6 should in the future be completed by Project 16, the Sines/Algeciras-Madrid-Paris freight axis which takes in the central Pyrenees crossing via a low elevation tunnel.

DIRECTIVES

DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2010

on the protection of animals used for scientific purposes

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) On 24 November 1986 the Council adopted Directive 86/609/EEC [3] in order to eliminate disparities between laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Since the adoption of that Directive, further disparities between Member States have emerged. Certain Member States have adopted national implementing measures that ensure a high level of protection of animals used for scientific purposes, while others only apply the minimum requirements laid down in Directive 86/609/EEC. These disparities are liable to constitute barriers to trade in products and substances the development of which involves experiments on animals. Accordingly, this Directive should provide for more detailed rules in order to reduce such disparities by approximating the rules applicable in that area and to ensure a proper functioning of the internal market.

(2) Animal welfare is a value of the Union that is enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU).

(3) On 23 March 1998 the Council adopted Decision 1999/575/EC concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes [4]. By becoming party to that Convention, the Community acknowledged the importance of the protection and welfare of animals used for scientific purposes at international level.

(4) The European Parliament in its resolution of 5 December 2002 on Directive 86/609/EEC called for the Commission to come forward with a proposal for a revision of that Directive with more stringent and transparent measures in the area of animal experimentation.

(5) On 15 June 2006, the Fourth Multilateral Consultation of Parties to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes adopted a revised Appendix A to that Convention, which set out guidelines for the accommodation and care of experimental animals. Commission Recommendation 2007/526/EC of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes [5] incorporated those guidelines.

(6) New scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm. It is therefore necessary to improve the welfare of animals used in scientific procedures by raising the minimum standards for their protection in line with the latest scientific developments.

(7) Attitudes towards animals also depend on national perceptions, and there is a demand in certain Member States to maintain more extensive animal-welfare rules than those agreed upon at the level of the Union. In the interests of the animals, and provided it does not affect the functioning of the internal market, it is appropriate to allow the Member States certain flexibility to maintain national rules aimed at more extensive protection of animals in so far as they are compatible with the TFEU.

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[1] OJ C 277, 17.11.2009, p. 51.
[2] Position of the European Parliament of 5 May 2009 (OJ C 212 E, 5.8.2010, p. 170), position of the Council of 13 September 2010 (not yet published in the Official Journal) and position of the European Parliament of 8 September 2010 (not yet published in the Official Journal).
[3] OJ L 358, 18.12.1986, p. 1.
[4] OJ L 222, 24.8.1999, p. 29.
[5] OJ L 197, 30.7.2007, p. 1.

(8) In addition to vertebrate animals including cyclostomes, cephalopods should also be included in the scope of this Directive, as there is scientific evidence of their ability to experience pain, suffering, distress and lasting harm.

(9) This Directive should also cover foetal forms of mammals, as there is scientific evidence showing that such forms in the last third of the period of their development are at an increased risk of experiencing pain, suffering and distress, which may also affect negatively their subsequent development. Scientific evidence also shows that procedures carried out on embryonic and foetal forms at an earlier stage of development could result in pain, suffering, distress or lasting harm, should the developmental forms be allowed to live beyond the first two thirds of their development.

(10) While it is desirable to replace the use of live animals in procedures by other methods not entailing the use of live animals, the use of live animals continues to be necessary to protect human and animal health and the environment. However, this Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so. To that end, it seeks to facilitate and promote the advancement of alternative approaches. It also seeks to ensure a high level of protection for animals that still need to be used in procedures. This Directive should be reviewed regularly in light of evolving science and animal-protection measures.

(11) The care and use of live animals for scientific purposes is governed by internationally established principles of replacement, reduction and refinement. To ensure that the way in which animals are bred, cared for and used in procedures within the Union is in line with that of the other international and national standards applicable outside the Union, the principles of replacement, reduction and refinement should be considered systematically when implementing this Directive. When choosing methods, the principles of replacement, reduction and refinement should be implemented through a strict hierarchy of the requirement to use alternative methods. Where no alternative method is recognised by the legislation of the Union, the numbers of animals used may be reduced by resorting to other methods and by implementing testing strategies, such as the use of *in vitro* and other methods that would reduce and refine the use of animals.

(12) Animals have an intrinsic value which must be respected. There are also the ethical concerns of the general public as regards the use of animals in procedures. Therefore, animals should always be treated as sentient creatures and their use in procedures should be restricted to areas which may ultimately benefit human or animal health, or the environment. The use of animals for scientific or educational purposes should therefore only be considered where a non-animal alternative is unavailable. Use of animals for scientific procedures in other areas under the competence of the Union should be prohibited.

(13) The choice of methods and the species to be used have a direct impact on both the numbers of animals used and their welfare. The choice of methods should therefore ensure the selection of the method that is able to provide the most satisfactory results and is likely to cause the minimum pain, suffering or distress. The methods selected should use the minimum number of animals that would provide reliable results and require the use of species with the lowest capacity to experience pain, suffering, distress or lasting harm that are optimal for extrapolation into target species.

(14) The methods selected should avoid, as far as possible, death as an end-point due to the severe suffering experienced during the period before death. Where possible, it should be substituted by more humane end-points using clinical signs that determine the impending death, thereby allowing the animal to be killed without any further suffering.

(15) The use of inappropriate methods for killing an animal can cause significant pain, distress and suffering to the animal. The level of competence of the person carrying out this operation is equally important. Animals should therefore be killed only by a competent person using a method that is appropriate to the species.

(16) It is necessary to ensure that the use of animals in procedures does not pose a threat to biodiversity. Therefore, the use of endangered species in procedures should be limited to a strict minimum.

(17) Having regard to the present state of scientific knowledge, the use of non-human primates in scientific procedures is still necessary in biomedical research. Due to their genetic proximity to human beings and to their highly developed social skills, the use of non-human primates in scientific procedures raises specific ethical and practical problems in terms of meeting their behavioural, environmental and social needs in a laboratory environment. Furthermore, the use of non-human primates is of the greatest concern to the public. Therefore the use of non-human primates should be permitted only in those biomedical areas essential for the benefit of human beings, for which no other

alternative replacement methods are yet available. Their use should be permitted only for basic research, the preservation of the respective non-human primate species or when the work, including xenotransplantation, is carried out in relation to potentially life-threatening conditions in humans or in relation to cases having a substantial impact on a person's day-to-day functioning, i.e. debilitating conditions.

(18) The use of great apes, as the closest species to human beings with the most advanced social and behavioural skills, should be permitted only for the purposes of research aimed at the preservation of those species and where action in relation to a life-threatening, debilitating condition endangering human beings is warranted, and no other species or alternative method would suffice in order to achieve the aims of the procedure. The Member State claiming such a need should provide information necessary for the Commission to take a decision.

(19) The capture of non-human primates from the wild is highly stressful for the animals concerned and carries an elevated risk of injury and suffering during capture and transport. In order to end the capturing of animals from the wild for breeding purposes, only animals that are the offspring of an animal which has been bred in captivity, or that are sourced from self-sustaining colonies, should be used in procedures after an appropriate transition period. A feasibility study should be carried out to that effect and the transition period adopted if necessary. The feasibility of moving towards sourcing non-human primates only from self-sustaining colonies as an ultimate goal should also be examined.

(20) There is a need for certain species of vertebrate animals used in procedures to be bred specifically for that purpose so that their genetic, biological and behavioural background is well-known to persons undertaking the procedures. Such knowledge both increases the scientific quality and reliability of the results and decreases the variability, ultimately resulting in fewer procedures and reduced animal use. Furthermore, for reasons of animal welfare and conservation, the use of animals taken from the wild in procedures should be limited to cases where the purpose of the procedures cannot be achieved using animals bred specifically for use in procedures.

(21) Since the background of stray and feral animals of domestic species is not known, and since capture and placement into establishments increases distress for such animals, they should not, as a general rule, be used in procedures.

(22) To enhance transparency, facilitate the project authorisation, and provide tools for monitoring compliance, a severity classification of procedures should be introduced on the basis of estimated levels of pain, suffering, distress and lasting harm that is inflicted on the animals.

(23) From an ethical standpoint, there should be an upper limit of pain, suffering and distress above which animals should not be subjected in scientific procedures. To that end, the performance of procedures that result in severe pain, suffering or distress, which is likely to be long-lasting and cannot be ameliorated, should be prohibited.

(24) When developing a common format for reporting purposes, the actual severity of the pain, suffering, distress or lasting harm experienced by the animal should be taken into account rather than the predicted severity at the time of the project evaluation.

(25) The number of animals used in procedures could be reduced by performing procedures on animals more than once, where this does not detract from the scientific objective or result in poor animal welfare. However, the benefit of reusing animals should be balanced against any adverse effects on their welfare, taking into account the lifetime experience of the individual animal. As a result of this potential conflict, the reuse of animals should be considered on a case-by-case basis.

(26) At the end of the procedure, the most appropriate decision should be taken as regards the future of the animal on the basis of animal welfare and potential risks to the environment. The animals whose welfare would be compromised should be killed. In some cases, animals should be returned to a suitable habitat or husbandry system or animals such as dogs and cats should be allowed to be rehomed in families as there is a high level of public concern as to the fate of such animals. Should Member States allow rehoming, it is essential that the breeder, supplier or user has a scheme in place to provide appropriate socialisation to those animals in order to ensure successful rehoming as well as to avoid unnecessary distress to the animals and to guarantee public safety.

(27) Animal tissue and organs are used for the development of *in vitro* methods. To promote the principle of reduction, Member States should, where appropriate, facilitate the establishment of programmes for sharing the organs and tissue of animals that are killed.

(28) The welfare of the animals used in procedures is highly dependent on the quality and professional competence of the personnel supervising procedures, as well as of those performing procedures or supervising those taking care of the animals on a daily basis. Member States should ensure through authorisation or by other means that staff are adequately educated, trained and competent. Furthermore, it is important that staff are supervised until they have obtained and demonstrated the requisite competence. Non-binding guidelines at the level of the Union concerning educational requirements would, in the long run, promote the free movement of personnel.

(29) The establishments of breeders, suppliers and users should have adequate installations and equipment in place to meet the accommodation requirements of the animal species concerned and to allow the procedures to be performed efficiently and with the least distress to the animals. The breeders, suppliers and users should operate only if they are authorised by the competent authorities.

(30) To ensure the ongoing monitoring of animal-welfare needs, appropriate veterinary care should be available at all times and a staff member should be made responsible for the care and welfare of animals in each establishment.

(31) Animal-welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. Breeders, suppliers and users should therefore have an animal-welfare body in place with the primary task of focusing on giving advice on animal-welfare issues. The body should also follow the development and outcome of projects at establishment level, foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals. The advice given by the animal-welfare body should be properly documented and open to scrutiny during inspections.

(32) In order to enable competent authorities to monitor compliance with this Directive, each breeder, supplier and user should maintain accurate records of the numbers of animals, their origins and fate.

(33) Non-human primates, dogs and cats should have a personal history file from birth covering their lifetimes in order to be able to receive the care, accommodation and treatment that meet their individual needs and characteristics.

(34) The accommodation and care of animals should be based on the specific needs and characteristics of each species.

(35) There are differences in the requirements for the accommodation and care of animals between Member States, which contribute to the distortion of the internal market. Furthermore, some of those requirements no longer reflect the most recent knowledge on the impacts of accommodation and care conditions on both the animal welfare and the scientific results of procedures. It is therefore necessary to establish in this Directive harmonised requirements for accommodation and care. These requirements should be updated on the basis of scientific and technical development.

(36) To monitor compliance with this Directive, Member States should carry out regular inspections of breeders, suppliers and users on a risk basis. To ensure public confidence and promote transparency, an appropriate proportion of the inspections should be carried out without prior warning.

(37) To assist the Member States in the enforcement of this Directive and on the basis of the findings in the reports on the operation of the national inspections, the Commission should, when there is reason for concern, carry out controls of the national inspection systems. Member States should address any weaknesses identified in the findings of these controls.

(38) Comprehensive project evaluation, taking into account ethical considerations in the use of animals, forms the core of project authorisation and should ensure the implementation of principles of replacement, reduction and refinement in those projects.

(39) It is also essential, both on moral and scientific grounds, to ensure that each use of an animal is carefully evaluated as to the scientific or educational validity, usefulness and relevance of the expected result of that use. The likely harm to the animal should be balanced against the expected benefits of the project. Therefore, an impartial project evaluation independent of those involved in the study should be carried out as part of the authorisation process of projects involving the use of live animals. Effective implementation of a project evaluation should also allow for an appropriate assessment of the use of any new scientific experimental techniques as they emerge.

(40) Due to the nature of the project, the type of species used and the likelihood of achieving the desired objectives of the project, it might be necessary to carry out a retrospective assessment. Since projects may vary significantly in terms of complexity, length, and the time period for obtaining the results, it is necessary that the decision on retrospective assessment should be made taking those aspects fully into account.

(41) To ensure that the public is informed, it is important that objective information concerning projects using live animals is made publicly available. This should not violate proprietary rights or expose confidential information. Therefore, users should provide anonymous non-technical summaries of those projects, which Member States should publish. The published details should not breach the anonymity of the users.

(42) To manage risks to human and animal health and the environment, the legislation of the Union provides that substances and products can be marketed only after appropriate safety and efficacy data have been submitted. Some of those requirements can be fulfilled only by resorting to animal testing, hereinafter referred to as 'regulatory testing'. It is necessary to introduce specific measures in order to increase the use of alternative approaches and to eliminate unnecessary duplication of regulatory testing. For that purpose Member States should recognise the validity of test data produced using test methods provided for under the legislation of the Union.

(43) To reduce the administrative workload and enhance the competitiveness of research and industry in the Union, it should be possible to authorise multiple generic projects when carried out using established methods for testing, diagnostic or production purposes under one group authorisation, albeit without exempting any of these procedures from the project evaluation.

(44) To ensure effective examination of authorisation applications and to enhance the competitiveness of research and industry in the Union, a time-limit should be set for the competent authorities to evaluate project proposals and take decisions on the authorisation of such projects. In order not to compromise the quality of the project evaluation, additional time might be required for more complex project proposals due to the number of disciplines involved, the novel characteristics and more complex techniques of the proposed project. However, the extension of deadlines for project evaluation should remain the exception.

(45) Given the routine or repetitive nature of certain procedures, it is appropriate to provide for a regulatory option whereby the Member States could introduce a simplified administrative procedure for the evaluation of projects containing such procedures, provided certain requirements laid down in this Directive are complied with.

(46) The availability of alternative methods is highly dependent on the progress of the research into the development of alternatives. The Community Framework Programmes for Research and Technological Development provided increasing funding for projects which aim to replace, reduce and refine the use of animals in procedures. In order to increase competitiveness of research and industry in the Union and to replace, reduce and refine the use of animals in procedures, the Commission and the Member States should contribute through research and by other means to the development and validation of alternative approaches.

(47) The European Centre for the Validation of Alternative Methods, a policy action within the Joint Research Centre of the Commission, has coordinated the validation of alternative approaches in the Union since 1991. However, there is an increasing need for new methods to be developed and proposed for validation, which requires a reference laboratory of the Union for the validation of alternative methods to be established formally. This laboratory should be referred to as the European Centre for the Validation of Alternative Methods (ECVAM). It is necessary for the Commission to cooperate with the Member States when setting priorities for validation studies. The Member States should assist the Commission in identifying and nominating suitable laboratories to carry out such validation studies. For validation studies that are similar to previously validated methods and in respect of which a validation represents a significant competitive advantage, ECVAM should be able to collect charges from those who submit their methods for validation. Such charges should not be prohibitive of healthy competition in the testing industry.

(48) There is a need to ensure a coherent approach to project evaluation and review strategies at national level. Member States should establish national committees for the protection of animals used for scientific purposes to give advice to the competent authorities and animal-welfare bodies in order to promote the principles of replacement, reduction and refinement. A network of national committees should play a role in the exchange of best practice at the level of the Union.

(49) Technical and scientific advancements in biomedical research can be rapid, as can the increase in knowledge of factors influencing animal welfare. It is therefore necessary to provide for a review of this Directive. Such review should examine the possible replacement of the use of animals, and in particular non-human primates, as a matter of priority where it is possible, taking into account the advancement of science. The Commission should also conduct periodic thematic reviews concerning the replacement, reduction and refinement of the use of animals in procedures.

(50) In order to ensure uniform conditions for implementation, implementing powers should be conferred on the Commission to adopt guidelines at the level of the Union on the requirements with regard to education, training and competence of breeders', suppliers' and users' staff, to adopt detailed rules regarding the Union Reference Laboratory, its duties and tasks and the charges it may collect, to establish a common format for submitting the information by Member States to the Commission on the implementation of this Directive, statistical information and other specific information, and for the application of safeguard clauses. According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers shall be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1] continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(51) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in respect of the following: modifications of the list of species falling under the obligation of being specifically bred for use in procedures; modifications of the care and accommodation standards; modifications of methods of killing, including their specifications; modifications of the elements to be used for the establishment by Member States of requirements with regard to education, training and competence of breeders', suppliers' and users' personnel; modifications of certain obligatory elements of the application for authorisation; modifications regarding the Union Reference Laboratory, its duties and tasks; as well as modifications of examples of different types of procedures assigned to each of the severity categories on the basis of factors related to the type of procedure. It is of particular importance that the Commission carry out appropriate consultation during its preparatory work, including at expert level.

(52) Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(53) Directive 86/609/EEC should therefore be repealed. Certain modifications introduced by this Directive have a direct impact on the application of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption [2]. It is therefore appropriate to amend a provision of that Regulation accordingly.

(54) Benefits to animal welfare from applying project authorisation retrospectively, and the related administrative costs, can only be justified for long term ongoing projects. Therefore, it is necessary to include transitional measures for ongoing short and medium term projects to avoid the need for retrospective authorisation with only limited benefits.

(55) In accordance with paragraph 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures, and to make them public.

(56) Since the objective of this Directive, namely the harmonisation of legislation concerning the use of animals for scientific purposes, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, 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 Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Directive establishes measures for the protection of animals used for scientific or educational purposes.

To that end, it lays down rules on the following:

(a) the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures;

(b) the origin, breeding, marking, care and accommodation and killing of animals;

(c) the operations of breeders, suppliers and users;

(d) the evaluation and authorisation of projects involving the use of animals in procedures.

2. This Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes.

This Directive shall apply until the animals referred to in the first subparagraph have been killed, rehomed or returned to a suitable habitat or husbandry system.

[1] OJ L 184, 17.7.1999, p. 23.
[2] OJ L 300, 14.11.2009, p. 1.

The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of this Directive.

3. This Directive shall apply to the following animals:

(a) live non-human vertebrate animals, including:

(i) independently feeding larval forms; and

(ii) foetal forms of mammals as from the last third of their normal development;

(b) live cephalopods.

4. This Directive shall apply to animals used in procedures, which are at an earlier stage of development than that referred to in point (a) of paragraph 3, if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development.

5. This Directive shall not apply to the following:

(a) non-experimental agricultural practices;

(b) non-experimental clinical veterinary practices;

(c) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;

(d) practices undertaken for the purposes of recognised animal husbandry;

(e) practices undertaken for the primary purpose of identification of an animal;

(f) practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

6. This Directive shall apply without prejudice to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ([1]).

Article 2

Stricter national measures

1. Member States may, while observing the general rules laid down in the TFEU, maintain provisions in force on 9 November 2010, aimed at ensuring more extensive protection of animals falling within the scope of this Directive than those contained in this Directive.

Before 1 January 2013 Member States shall inform the Commission about such national provisions. The Commission shall bring them to the attention of other Member States.

([1]) OJ L 262, 27.9.1976, p. 169. Directive recast by Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59), which applies as from 11 July 2013.

2. When acting pursuant to paragraph 1, a Member State shall not prohibit or impede the supply or use of animals bred or kept in another Member State in accordance with this Directive, nor shall it prohibit or impede the placing on the market of products developed with the use of such animals in accordance with this Directive.

Article 3

Definitions

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

1. 'procedure' means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

   This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues;

2. 'project' means a programme of work having a defined scientific objective and involving one or more procedures;

3. 'establishment' means any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered and mobile facilities;

4. 'breeder' means any natural or legal person breeding animals referred to in Annex I with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, or breeding other animals primarily for those purposes, whether for profit or not;

5. 'supplier' means any natural or legal person, other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not;

6. 'user' means any natural or legal person using animals in procedures, whether for profit or not;

7. 'competent authority' means an authority or authorities or bodies designated by a Member State to carry out the obligations arising from this Directive.

Article 4

Principle of replacement, reduction and refinement

1. Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.

2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.

3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.

4. This Article shall, in the choice of methods, be implemented in accordance with Article 13.

Article 5

Purposes of procedures

Procedures may be carried out for the following purposes only:

(a) basic research;

(b) translational or applied research with any of the following aims:

(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;

(ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or

(iii) the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;

(c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;

(d) protection of the natural environment in the interests of the health or welfare of human beings or animals;

(e) research aimed at preservation of the species;

(f) higher education, or training for the acquisition, maintenance or improvement of vocational skills;

(g) forensic inquiries.

Article 6

Methods of killing

1. Member States shall ensure that animals are killed with minimum pain, suffering and distress.

2. Member States shall ensure that animals are killed in the establishment of a breeder, supplier or user, by a competent person.

However, in the case of a field study an animal may be killed by a competent person outside of an establishment.

3. In relation to the animals covered by Annex IV, the appropriate method of killing as set out in that Annex shall be used.

4. Competent authorities may grant exemptions from the requirement in paragraph 3:

(a) to allow the use of another method provided that, on the basis of scientific evidence, the method is considered to be at least as humane; or

(b) when, on the basis of scientific justification, the purpose of the procedure cannot be achieved by the use of a method of killing set out in Annex IV.

5. Paragraphs 2 and 3 shall not apply where an animal has to be killed in emergency circumstances for animal-welfare, public-health, public-security, animal-health or environmental reasons.

CHAPTER II

PROVISIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES

Article 7

Endangered species

1. Specimens of those endangered species listed in Annex A to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein [1], which do not fall within the scope of Article 7(1) of that Regulation, shall not be used in procedures, with the exception of those procedures meeting the following conditions:

(a) the procedure has one of the purposes referred to in points (b)(i), (c) or (e) of Article 5 of this Directive; and

(b) there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than those listed in that Annex.

2. Paragraph 1 shall not apply to any species of non-human primates.

Article 8

Non-human primates

1. Subject to paragraph 2, specimens of non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions:

(a) the procedure has one of the purposes referred to in

(i) points (b)(i) or (c) of Article 5 of this Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or

(ii) points (a) or (e) of Article 5;

and

(b) there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates.

[1] OJ L 61, 3.3.1997, p. 1.

A debilitating clinical condition for the purposes of this Directive means a reduction in a person's normal physical or psychological ability to function.

2. Specimens of non-human primates listed in Annex A to Regulation (EC) No 338/97, which do not fall within the scope of Article 7(1) of that Regulation, shall not be used in procedures, with the exception of those procedures meeting the following conditions:

(a) the procedure has one of the purposes referred to in:

(i) points (b)(i) or (c) of Article 5 of this Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or

(ii) Article 5(e);

and

(b) there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates and by the use of species not listed in that Annex.

3. Notwithstanding paragraphs 1 and 2, great apes shall not be used in procedures, subject to the use of the safeguard clause in Article 55(2).

Article 9

Animals taken from the wild

1. Animals taken from the wild shall not be used in procedures.

2. Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of an animal which has been bred for use in procedures.

3. The capture of animals in the wild shall be carried out only by competent persons using methods which do not cause the animals avoidable pain, suffering, distress or lasting harm.

Any animal found, at or after capture, to be injured or in poor health shall be examined by a veterinarian or another competent person and action shall be taken to minimise the suffering of the animal. Competent authorities may grant exemptions from the requirement of taking action to minimise the suffering of the animal if there is scientific justification.

Article 10

Animals bred for use in procedures

1. Member States shall ensure that animals belonging to the species listed in Annex I may only be used in procedures where those animals have been bred for use in procedures.

However, from the dates set out in Annex II, Member States shall ensure that non-human primates listed therein may be used in procedures only where they are the offspring of non-human primates which have been bred in captivity or where they are sourced from self-sustaining colonies.

For the purposes of this Article a 'self-sustaining colony' means a colony in which animals are bred only within the colony or sourced from other colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans.

The Commission shall, in consultation with the Member States and stakeholders, conduct a feasibility study, which shall include an animal health and welfare assessment, of the requirement laid down in the second subparagraph. The study shall be published no later than 10 November 2017. It shall be accompanied, where appropriate, by proposals for amendments to Annex II.

2. The Commission shall keep under review the use of sourcing non-human primates from self-sustaining colonies and, in consultation with the Member States and stakeholders, conduct a study to analyse the feasibility of sourcing animals only from self-sustaining colonies.

The study shall be published no later than 10 November 2022.

3. Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification.

Article 11

Stray and feral animals of domestic species

1. Stray and feral animals of domestic species shall not be used in procedures.

2. The competent authorities may only grant exemptions from paragraph 1 subject to the following conditions:

(a) there is an essential need for studies concerning the health and welfare of the animals or serious threats to the environment or to human or animal health; and

(b) there is scientific justification to the effect that the purpose of the procedure can be achieved only by the use of a stray or a feral animal.

CHAPTER III

PROCEDURES

Article 12

Procedures

1. Member States shall ensure that procedures are carried out in a user's establishment.

The competent authority may grant an exemption from the first subparagraph on the basis of scientific justification.

2. Procedures may be carried out only within the framework of a project.

Article 13

Choice of methods

1. Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.

2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:

(a) use the minimum number of animals;

(b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;

(c) cause the least pain, suffering, distress or lasting harm;

and are most likely to provide satisfactory results.

3. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:

(a) result in the deaths of as few animals as possible; and

(b) reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.

Article 14

Anaesthesia

1. Member States shall ensure that, unless it is inappropriate, procedures are carried out under general or local anaesthesia, and that analgesia or another appropriate method is used to ensure that pain, suffering and distress are kept to a minimum.

Procedures that involve serious injuries that may cause severe pain shall not be carried out without anaesthesia.

2. When deciding on the appropriateness of using anaesthesia, the following shall be taken into account:

(a) whether anaesthesia is judged to be more traumatic to the animal than the procedure itself; and

(b) whether anaesthesia is incompatible with the purpose of the procedure.

3. Member States shall ensure that animals are not given any drug to stop or restrict their showing pain without an adequate level of anaesthesia or analgesia.

In these cases, a scientific justification shall be provided, accompanied by the details of the anaesthetic or analgesic regimen.

4. An animal, which may suffer pain once anaesthesia has worn off, shall be treated with pre-emptive and post-operative analgesics or other appropriate pain-relieving methods provided that it is compatible with the purpose of the procedure.

5. As soon as the purpose of the procedure has been achieved appropriate action shall be taken to minimise the suffering of the animal.

Article 15

Classification of severity of procedures

1. Member States shall ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate', or 'severe' on a case-by-case basis using the assignment criteria set out in Annex VIII.

2. Subject to the use of the safeguard clause in Article 55(3), Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.

Article 16

Reuse

1. Member States shall ensure that an animal already used in one or more procedures, when a different animal on which no procedure has previously been carried out could also be used, may only be reused in a new procedure provided that the following conditions are met:

(a) the actual severity of the previous procedures was 'mild' or 'moderate';

(b) it is demonstrated that the animal's general state of health and well-being has been fully restored;

(c) the further procedure is classified as 'mild', 'moderate' or 'non-recovery'; and

(d) it is in accordance with veterinary advice, taking into account the lifetime experience of the animal.

2. In exceptional circumstances, by way of derogation from point (a) of paragraph 1 and after a veterinary examination of the animal, the competent authority may allow reuse of an animal, provided the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.

Article 17

End of the procedure

1. A procedure shall be deemed to end when no further observations are to be made for that procedure or, as regards new genetically modified animal lines, when the progeny are no longer observed or expected to experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle.

2. At the end of a procedure, a decision to keep an animal alive shall be taken by a veterinarian or by another competent person. An animal shall be killed when it is likely to remain in moderate or severe pain, suffering, distress or lasting harm.

3. Where an animal is to be kept alive, it shall receive care and accommodation appropriate to its state of health.

Article 18

Sharing organs and tissues

Member States shall facilitate, where appropriate, the establishment of programmes for the sharing of organs and tissues of animals killed.

Article 19

Setting free of animals and rehoming

Member States may allow animals used or intended to be used in procedures to be rehomed, or returned to a suitable habitat or husbandry system appropriate to the species, provided that the following conditions are met:

(a) the state of health of the animal allows it;

(b) there is no danger to public health, animal health or the environment; and

(c) appropriate measures have been taken to safeguard the well-being of the animal.

CHAPTER IV

AUTHORISATION

Section 1

Requirements for breeders, suppliers and users

Article 20

Authorisation of breeders, suppliers and users

1. Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period.

Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive.

2. The authorisation shall specify the person responsible for ensuring compliance with the provisions of this Directive and the person or persons referred to in Article 24(1) and in Article 25.

3. Renewal of the authorisation shall be required for any significant change to the structure or the function of an establishment of a breeder, supplier or user that could negatively affect animal welfare.

4. Member States shall ensure that the competent authority is notified of any changes of the person or persons referred to in paragraph 2.

Article 21

Suspension and withdrawal of authorisation

1. Where a breeder, supplier or user no longer complies with the requirements set out in this Directive, the competent authority shall take appropriate remedial action, or require such action to be taken, or suspend or withdraw its authorisation.

2. Member States shall ensure that, where the authorisation is suspended or withdrawn, the welfare of the animals housed in the establishment is not adversely affected.

Article 22

Requirements for installations and equipment

1. Member States shall ensure that all establishments of a breeder, supplier or user have installations and equipment suited to the species of animals housed and, where procedures are carried out, to the performance of the procedures.

2. The design, construction and method of functioning of the installations and equipment referred to in paragraph 1 shall ensure that the procedures are carried out as effectively as possible, and aim at obtaining reliable results using the minimum number of animals and causing the minimum degree of pain, suffering, distress or lasting harm.

3. For the purposes of implementation of paragraphs 1 and 2, Member States shall ensure that the relevant requirements as set out in Annex III are complied with.

Article 23

Competence of personnel

1. Member States shall ensure that each breeder, supplier and user has sufficient staff on site.

2. The staff shall be adequately educated and trained before they perform any of the following functions:

(a) carrying out procedures on animals;

(b) designing procedures and projects;

(c) taking care of animals; or

(d) killing animals.

Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.

Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.

Member States shall ensure, through authorisation or by other means, that the requirements laid down in this paragraph are fulfilled.

3. Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions set out in paragraph 2.

4. Non-binding guidelines at the level of the Union on the requirements laid down in paragraph 2 may be adopted in accordance with the advisory procedure referred to in Article 56(2).

Article 24

Specific requirements for personnel

1. Member States shall ensure that each breeder, supplier and user has one or several persons on site who shall:

(a) be responsible for overseeing the welfare and care of the animals in the establishment;

(b) ensure that the staff dealing with animals have access to information specific to the species housed in the establishment;

(c) be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.

2. Member States shall ensure that persons specified in Article 40(2)(b) shall:

(a) ensure that any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of a procedure is stopped; and

(b) ensure that the projects are carried out in accordance with the project authorisation or, in the cases referred to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority, and ensure that in the event of non-compliance, the appropriate measures to rectify it are taken and recorded.

Article 25

Designated veterinarian

Member States shall ensure that each breeder, supplier and user has a designated veterinarian with expertise in laboratory animal medicine, or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals.

Article 26

Animal-welfare body

1. Member States shall ensure that each breeder, supplier and user sets up an animal-welfare body.

2. The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal-welfare body shall also receive input from the designated veterinarian or the expert referred to in Article 25.

3. Member States may allow small breeders, suppliers and users to fulfil the tasks laid down in Article 27(1) by other means.

Article 27

Tasks of the animal-welfare body

1. The animal-welfare body shall, as a minimum, carry out the following tasks:

(a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;

(b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;

(c) establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;

(d) follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and

(e) advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.

2. Member States shall ensure that the records of any advice given by the animal-welfare body and decisions taken regarding that advice are kept for at least 3 years.

The records shall be made available to the competent authority upon request.

Article 28

Breeding strategy for non-human primates

Member States shall ensure that breeders of non-human primates have a strategy in place for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity.

Article 29

Scheme for rehoming or setting free of animals

Where Member States allow rehoming, the breeders, suppliers and users from which animals are intended to be rehomed shall have a rehoming scheme in place that ensures socialisation of the animals that are rehomed. In the case of wild animals, where appropriate, a programme of rehabilitation shall be in place before they are returned to their habitat.

Article 30

Animal records

1. Member States shall ensure that all breeders, suppliers and users keep records of at least the following:

(a) the number and the species of animals bred, acquired, supplied, used in procedures, set-free or rehomed;

(b) the origin of the animals, including whether they are bred for use in procedures;

(c) the dates on which the animals are acquired, supplied, released or rehomed;

(d) from whom the animals are acquired;

(e) the name and address of the recipient of animals;

(f) the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and

(g) in the case of users, the projects in which animals are used.

2. The records referred to in paragraph 1 shall be kept for a minimum of 5 years and made available to the competent authority upon request.

Article 31

Information on dogs, cats and non-human primates

1. Member States shall ensure that all breeders, suppliers and users keep the following information on each dog, cat and non-human primate:

(a) identity;

(b) place and date of birth, when available;

(c) whether it is bred for use in procedures; and

(d) in the case of a non-human primate, whether it is the offspring of non-human primates that have been bred in captivity.

2. Each dog, cat and non-human primate shall have an individual history file, which follows the animal as long as it is kept for the purposes of this Directive.

The file shall be established at birth or as soon as possible thereafter and shall cover any relevant reproductive, veterinary and social information on the individual animal and the projects in which it has been used.

3. The information referred to in this Article shall be kept for a minimum of 3 years after the death or rehoming of the animal and shall be made available to the competent authority upon request.

In the case of rehoming, relevant veterinary care and social information from the individual history file referred to in paragraph 2 shall accompany the animal.

Article 32

Marking and identification of dogs, cats and non-human primates

1. Each dog, cat or non-human primate shall be provided, at the latest at the time of weaning, with a permanent individual identification mark in the least painful manner possible.

2. Where a dog, cat or non-human primate is transferred from one breeder, supplier or user to another before it is weaned, and it is not practicable to mark it beforehand, a record, specifying in particular its mother, must be maintained by the receiver until it is marked.

3. Where an unmarked dog, cat or non-human primate, which is weaned, is received by a breeder, supplier or user it shall be permanently marked as soon as possible and in the least painful manner possible.

4. The breeder, supplier and user shall provide, at the request of the competent authority, reasons for which the animal is unmarked.

Article 33

Care and accommodation

1. Member States shall, as far as the care and accommodation of animals is concerned, ensure that:

(a) all animals are provided with accommodation, an environment, food, water and care which are appropriate to their health and well-being;

(b) any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are kept to a minimum;

(c) the environmental conditions in which animals are bred, kept or used are checked daily;

(d) arrangements are made to ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible; and

(e) animals are transported under appropriate conditions.

2. For the purposes of paragraph 1, Member States shall ensure that the care and accommodation standards set out in Annex III are applied from the dates provided for therein.

3. Member States may allow exemptions from the requirements of paragraph 1(a) or paragraph 2 for scientific, animal-welfare or animal-health reasons.

Section 2

Inspections

Article 34

Inspections by the Member States

1. Member States shall ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of this Directive.

2. The competent authority shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of:

(a) the number and species of animals housed;

(b) the record of the breeder, supplier or user in complying with the requirements of this Directive;

(c) the number and types of projects carried out by the user in question; and

(d) any information that might indicate non-compliance.

3. Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in paragraph 2. However, breeders, suppliers and users of non-human primates shall be inspected at least once a year.

4. An appropriate proportion of the inspections shall be carried out without prior warning.

5. Records of all inspections shall be kept for at least 5 years.

Article 35

Controls of Member State inspections

1. The Commission shall, when there is due reason for concern, taking into account, inter alia, the proportion of inspections carried out without prior warning, undertake controls of the infrastructure and operation of national inspections in Member States.

2. The Member State in the territory of which the control referred to in paragraph 1 is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties. The Commission shall inform the competent authority of the Member State concerned of the results of the control.

3. The competent authority of the Member State concerned shall take measures to take account of the results of the control referred to in paragraph 1.

Section 3

Requirements for projects

Article 36

Project authorisation

1. Member States shall ensure, without prejudice to Article 42, that projects are not carried out without prior authorisation from the competent authority, and that projects are carried out in accordance with the authorisation or, in the cases referred to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority.

2. Member States shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Article 38.

Article 37

Application for project authorisation

1. Member States shall ensure that an application for project authorisation is submitted by the user or the person responsible for the project. The application shall include at least the following:

(a) the project proposal;

(b) a non-technical project summary; and

(c) information on the elements set out in Annex VI.

2. Member States may waive the requirement in paragraph 1(b) for projects referred to in Article 42(1).

Article 38

Project evaluation

1. The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:

(a) the project is justified from a scientific or educational point of view or required by law;

(b) the purposes of the project justify the use of animals; and

(c) the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.

2. The project evaluation shall consist in particular of the following:

(a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value;

(b) an assessment of the compliance of the project with the requirement of replacement, reduction and refinement;

(c) an assessment and assignment of the classification of the severity of procedures;

(d) a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment;

(e) an assessment of any justification referred to in Articles 6 to 12, 14, 16 and 33; and

(f) a determination as to whether and when the project should be assessed retrospectively.

3. The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:

(a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;

(b) experimental design, including statistics where appropriate;

(c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate;

(d) animal husbandry and care, in relation to the species that are intended to be used.

4. The project evaluation process shall be transparent.

Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties.

Article 39

Retrospective assessment

1. Member States shall ensure that when determined in accordance with Article 38(2)(f), the retrospective assessment shall be carried out by the competent authority which shall, on the basis of the necessary documentation submitted by the user, evaluate the following:

(a) whether the objectives of the project were achieved;

(b) the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and

(c) any elements that may contribute to the further implementation of the requirement of replacement, reduction and refinement.

2. All projects using non-human primates and projects involving procedures classified as 'severe', including those referred to in Article 15(2), shall undergo a retrospective assessment.

3. Without prejudice to paragraph 2 and by way of derogation from Article 38(2)(f), Member States may exempt projects involving only procedures classified as 'mild' or 'non-recovery' from the requirement for a retrospective assessment.

Article 40

Granting of project authorisation

1. The project authorisation shall be limited to procedures which have been subject to:

(a) a project evaluation; and

(b) the severity classifications assigned to those procedures.

2. The project authorisation shall specify the following:

(a) the user who undertakes the project;

(b) the persons responsible for the overall implementation of the project and its compliance with the project authorisation;

(c) the establishments in which the project will be undertaken, where applicable; and

(d) any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively.

3. Project authorisations shall be granted for a period not exceeding 5 years.

4. Member States may allow the authorisation of multiple generic projects carried out by the same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods.

Article 41

Authorisation decisions

1. Member States shall ensure that the decision regarding authorisation is taken and communicated to the applicant 40 working days at the latest from the receipt of the complete and correct application. This period shall include the project evaluation.

2. When justified by the complexity or the multi-disciplinary nature of the project, the competent authority may extend the period referred to in paragraph 1 once, by an additional period not exceeding 15 working days. The extension and its duration shall be duly motivated and shall be notified to the applicant before the expiry of the period referred to in paragraph 1.

3. Competent authorities shall acknowledge to the applicant all applications for authorisations as quickly as possible, and shall indicate the period referred to in paragraph 1 within which the decision is to be taken.

4. In the case of an incomplete or incorrect application, the competent authority shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

Article 42

Simplified administrative procedure

1. Member States may decide to introduce a simplified administrative procedure for projects containing procedures classified as 'non-recovery', 'mild' or 'moderate' and not using non-human primates, that are necessary to satisfy regulatory requirements, or which use animals for production or diagnostic purposes with established methods.

2. When introducing a simplified administrative procedure, Member States shall ensure that the following provisions are met:

(a) the application specifies elements referred to in Article 40(2)(a), (b) and (c);

(b) a project evaluation is performed in accordance with Article 38; and

(c) that the period referred to in Article 41(1) is not exceeded.

3. If a project is changed in a way that may have a negative impact on animal welfare, Member States shall require an additional project evaluation with a favourable outcome.

4. Article 40(3) and (4), Article 41(3) and Article 44(3), (4) and (5) shall apply mutatis mutandis to projects that are allowed to be carried out in accordance with this Article.

Article 43

Non-technical project summaries

1. Subject to safeguarding intellectual property and confidential information, the non-technical project summary shall provide the following:

(a) information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used;

(b) a demonstration of compliance with the requirement of replacement, reduction and refinement.

The non-technical project summary shall be anonymous and shall not contain the names and addresses of the user and its personnel.

2. Member States may require the non-technical project summary to specify whether a project is to undergo a retrospective assessment and by what deadline. In such a case, Member States shall ensure that the non-technical project summary is updated with the results of any retrospective assessment.

3. Member States shall publish the non-technical project summaries of authorised projects and any updates thereto.

Article 44

Amendment, renewal and withdrawal of a project authorisation

1. Member States shall ensure that amendment or renewal of the project authorisation is required for any change of the project that may have a negative impact on animal welfare.

2. Any amendment or renewal of a project authorisation shall be subject to a further favourable outcome of the project evaluation.

3. The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation.

4. Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project must not be adversely affected.

5. Member States shall establish and publish conditions for amendment and renewal of project authorisations.

Article 45

Documentation

1. Member States shall ensure that all relevant documentation, including project authorisations and the result of the project evaluation is kept for at least 3 years from the expiry date of the authorisation of the project or from the expiry of the period referred to in Article 41(1) and shall be available to the competent authority.

2. Without prejudice to paragraph 1, the documentation for projects which have to undergo retrospective assessment shall be kept until the retrospective assessment has been completed.

CHAPTER V

AVOIDANCE OF DUPLICATION AND ALTERNATIVE APPROACHES

Article 46

Avoidance of duplication of procedures

Each Member State shall accept data from other Member States that are generated by procedures recognised by the legislation of the Union, unless further procedures need to be carried out regarding that data for the protection of public health, safety or the environment.

Article 47

Alternative approaches

1. The Commission and the Member States shall contribute to the development and validation of alternative approaches which could provide the same or higher levels of information as those obtained in procedures using animals, but which do not involve the use of animals or use fewer animals or which entail less painful procedures, and they shall take such other steps as they consider appropriate to encourage research in this field.

2. Member States shall assist the Commission in identifying and nominating suitable specialised and qualified laboratories to carry out such validation studies.

3. After consulting the Member States, the Commission shall set the priorities for those validation studies and allocate the tasks between the laboratories for carrying out those studies.

4. Member States shall, at national level, ensure the promotion of alternative approaches and the dissemination of information thereon.

5. Member States shall nominate a single point of contact to provide advice on the regulatory relevance and suitability of alternative approaches proposed for validation.

6. The Commission shall take appropriate action with a view to obtaining international acceptance of alternative approaches validated in the Union.

Article 48

Union Reference Laboratory

1. The Union Reference Laboratory and its duties and tasks shall be those referred to in Annex VII.

2. The Union Reference Laboratory may collect charges for the services it provides that do not directly contribute to the further advancement of replacement, reduction and refinement.

3. Detailed rules necessary for the implementation of paragraph 2 of this Article and Annex VII may be adopted in accordance with the regulatory procedure referred to in Article 56(3).

Article 49

National committees for the protection of animals used for scientific purposes

1. Each Member State shall establish a national committee for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.

2. The national committees referred to in paragraph 1 shall exchange information on the operation of animal-welfare bodies and project evaluation and share best practice within the Union.

CHAPTER VI

FINAL PROVISIONS

Article 50

Adaptation of Annexes to technical progress

In order to ensure that the provisions of Annexes I and III to VIII reflect the state of technical or scientific progress, taking into account the experience gained in the implementation of this Directive, in particular through the reporting referred to in Article 54(1), the Commission may adopt, by means of delegated acts in accordance with Article 51 and subject to the conditions laid down in Articles 52 and 53, modifications of those Annexes, with the exception of provisions of Sections I and II of Annex VIII. The dates referred to in Section B of Annex III shall not be brought forward. When adopting such delegated acts, the Commission shall act in accordance with the relevant provisions of this Directive.

Article 51

Exercise of the delegation

1. The power to adopt delegated acts referred to in Article 50 shall be conferred on the Commission for a period of 8 years beginning on 9 November 2010. The Commission shall make a report in respect of the delegated power at the latest 12 months before the end of the 8-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 52.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 52 and 53.

Article 52

Revocation of the delegation

1. The delegation of power referred to in Article 50 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 53

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by 2 months.

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force at the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 54

Reporting

1. Member States shall by 10 November 2018, and every 5 years thereafter, send the information on the implementation of this Directive and in particular Articles 10(1), 26, 28, 34, 38, 39, 43 and 46 to the Commission.

2. Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures.

Member States shall submit that statistical information to the Commission by 10 November 2015 and every year thereafter.

3. Member States shall submit to the Commission, on annual basis, detailed information on exemptions granted under Article 6(4)(a).

4. The Commission shall by 10 May 2012 establish a common format for submitting the information referred to in paragraphs 1, 2, and 3 of this Article in accordance with the regulatory procedure referred to in Article 56(3).

Article 55

Safeguard clauses

1. Where a Member State has scientifically justifiable grounds for believing it is essential to use non-human primates for the purposes referred to in Article 8(1)(a)(i) with regard to human beings, but where the use is not undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, it may adopt a provisional measure allowing such use, provided the purpose cannot be achieved by the use of species other than non-human primates.

2. Where a Member State has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life-threatening or debilitating clinical condition in human beings, it may adopt a provisional measure allowing the use of great apes in procedures having one of the purposes referred to in points (b)(i), (c) or (e) of Article 5; provided that the purpose of the procedure cannot be achieved by the use of species other than great apes or by the use of alternative methods. However, the reference to Article 5(b)(i) shall not be taken to include the reference to animals and plants.

3. Where, for exceptional and scientifically justifiable reasons, a Member State deems it necessary to allow the use of a procedure involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2), it may adopt a provisional measure to allow such procedure. Member States may decide not to allow the use of non-human primates in such procedures.

4. A Member State which has adopted a provisional measure in accordance with paragraph 1, 2 or 3 shall immediately inform the Commission and the other Member States thereof, giving reasons for its decision and submitting evidence of the situation as described in paragraphs 1, 2 and 3 on which the provisional measure is based.

The Commission shall put the matter before the Committee referred to in Article 56(1) within 30 days of receipt of the information from the Member State and shall, in accordance with the regulatory procedure referred to in Article 56(3), either:

(a) authorise the provisional measure for a time period defined in the decision; or

(b) require the Member State to revoke the provisional measure.

Article 56

Committee

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.

Article 57

Commission report

1. By 10 November 2019 and every 5 years thereafter, the Commission shall, based on the information received from the Member States under Article 54(1), submit to the European Parliament and the Council a report on the implementation of this Directive.

2. By 10 November 2019 and every 3 years thereafter, the Commission shall, based on the statistical information submitted by Member States under Article 54(2), submit to the European Parliament and the Council a summary report on that information.

Article 58

Review

The Commission shall review this Directive by 10 November 2017, taking into account advancements in the development of alternative methods not entailing the use of animals, in particular of non-human primates, and shall propose amendments, where appropriate.

The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge.

Article 59

Competent authorities

1. Each Member State shall designate one or more competent authorities responsible for the implementation of this Directive.

Member States may designate bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof that the body:

(a) has the expertise and infrastructure required to carry out the tasks; and

(b) is free of any conflict of interests as regards the performance of the tasks.

Bodies thus designated shall be considered competent authorities for the purposes of this Directive.

2. Each Member State shall communicate details of a national authority serving as contact point for the purposes of this Directive to the Commission by 10 February 2011, as well as any update to such data.

The Commission shall make publicly available the list of those contact points.

Article 60

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 10 February 2013, and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 61

Transposition

1. Member States shall adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 January 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The method of making such reference shall be laid down by Member States.

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

Article 62

Repeal

1. Directive 86/609/EEC is repealed with effect from 1 January 2013 with the exception of Article 13, which shall be repealed with effect from 10 May 2013.

2. References to the repealed Directive shall be construed as references to this Directive.

Article 63

Amendment of Regulation (EC) No 1069/2009

Point (a)(iv) of Article 8 of Regulation (EC) No 1069/2009 is replaced by the following:

‘(iv) animals used in a procedure or procedures defined in Article 3 of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (*), in cases where the competent authority decides that such animals or any of their body parts have the potential to pose serious health risks to humans or to other animals, as a result of that procedure or those procedures without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;

(*) OJ L 276, 20.10.2010, p. 33’.

Article 64

Transitional provisions

1. Member States shall not apply laws, regulations and administrative provisions adopted in accordance with Articles 36 to 45 to projects which have been approved before 1 January 2013 and the duration of which does not extend beyond 1 January 2018.

2. Projects which have been approved before 1 January 2013 and the duration of which extends beyond 1 January 2018 shall obtain project authorisation by 1 January 2018.

Article 65

Entry into force

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

Article 66

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 22 September 2010.

For the European Parliament	*For the Council*
The President	*The President*
J. BUZEK	O. CHASTEL

ANNEX I

LIST OF ANIMALS REFERRED TO IN ARTICLE 10

1. Mouse (*Mus musculus*)
2. Rat (*Rattus norvegicus*)
3. Guinea pig (*Cavia porcellus*)
4. Syrian (golden) hamster (*Mesocricetus auratus*)
5. Chinese hamster (*Cricetulus griseus*)
6. Mongolian gerbil (*Meriones unguiculatus*)
7. Rabbit (*Oryctolagus cuniculus*)
8. Dog (*Canis familiaris*)
9. Cat (*Felis catus*)
10. All species of non-human primates
11. Frog (*Xenopus* (*laevis, tropicalis*), Rana (*temporaria, pipiens*))
12. Zebra fish (*Danio rerio*)

ANNEX II

LIST OF NON-HUMAN PRIMATES AND DATES REFERRED TO IN THE SECOND SUBPARAGRAPH OF ARTICLE 10(1)

Species	Dates
Marmoset (*Callithrix jacchus*)	1 January 2013
Cynomolgus monkey (*Macaca fascicularis*)	5 years after the publication of the feasibility study referred to in Article 10(1), fourth subparagraph, provided the study does not recommend an extended period
Rhesus monkey (*Macaca mulatta*)	5 years after the publication of the feasibility study referred to in Article 10(1), fourth subparagraph, provided the study does not recommend an extended period
Other species of non-human primates	5 years after the publication of the feasibility study referred to in Article 10(1), fourth subparagraph, provided the study does not recommend an extended period

ANNEX III

REQUIREMENTS FOR ESTABLISHMENTS AND FOR THE CARE AND ACCOMMODATION OF ANIMALS

Section A: General section

1. The physical facilities

1.1. Functions and general design

(a) All facilities shall be constructed so as to provide an environment which takes into account the physiological and ethological needs of the species kept in them. Facilities shall also be designed and managed to prevent access by unauthorised persons and the ingress or escape of animals.

(b) Establishments shall have an active maintenance programme to prevent and remedy any defect in buildings or equipment.

1.2. Holding rooms

(a) Establishments shall have a regular and efficient cleaning schedule for the rooms and shall maintain satisfactory hygienic standards.

(b) Walls and floors shall be surfaced with a material resistant to the heavy wear and tear caused by the animals and the cleaning process. The material shall not be detrimental to the health of the animals and shall be such that the animals cannot hurt themselves. Additional protection shall be given to any equipment or fixtures so that they are not damaged by the animals nor do they cause injury to the animals themselves.

(c) Species that are incompatible, for example predator and prey, or animals requiring different environmental conditions, shall not be housed in the same room nor, in the case of predator and prey, within sight, smell or sound of each other.

1.3. General and special purpose procedure rooms

(a) Establishments shall, where appropriate, have available laboratory facilities for the carrying out of simple diagnostic tests, post-mortem examinations, and/or the collection of samples that are to be subjected to more extensive laboratory investigations elsewhere. General and special purpose procedure rooms shall be available for situations where it is undesirable to carry out the procedures or observations in the holding rooms.

(b) Facilities shall be provided to enable newly-acquired animals to be isolated until their health status can be determined and the potential health risk to established animals assessed and minimised.

(c) There shall be accommodation for the separate housing of sick or injured animals.

1.4. Service rooms

(a) Store-rooms shall be designed, used and maintained to safeguard the quality of food and bedding. These rooms shall be vermin and insect-proof, as far as possible. Other materials, which may be contaminated or present a hazard to animals or staff, shall be stored separately.

(b) The cleaning and washing areas shall be large enough to accommodate the installations necessary to decontaminate and clean used equipment. The cleaning process shall be arranged so as to separate the flow of clean and dirty equipment to prevent the contamination of newly-cleaned equipment.

(c) Establishments shall provide for the hygienic storage and safe disposal of carcasses and animal waste.

(d) Where surgical procedures under aseptic conditions are required there shall be provision for one or more than one suitably equipped room, and facilities provided for postoperative recovery.

2. The environment and control thereof

2.1. Ventilation and temperature

(a) Insulation, heating and ventilation of the holding room shall ensure that the air circulation, dust levels, and gas concentrations are kept within limits that are not harmful to the animals housed.

(b) Temperature and relative humidity in the holding rooms shall be adapted to the species and age groups housed. The temperature shall be measured and logged on a daily basis.

(c) Animals shall not be restricted to outdoor areas under climatic conditions which may cause them distress.

2.2. Lighting

(a) Where natural light does not provide an appropriate light/dark cycle, controlled lighting shall be provided to satisfy the biological requirements of the animals and to provide a satisfactory working environment.

(b) Illumination shall satisfy the needs for the performance of husbandry procedures and inspection of the animals.

(c) Regular photoperiods and intensity of light adapted to the species shall be provided.

(d) When keeping albino animals, the lighting shall be adjusted to take into account their sensitivity to light.

2.3. Noise

(a) Noise levels including ultrasound, shall not adversely affect animal welfare.

(b) Establishments shall have alarm systems that sound outside the sensitive hearing range of the animals, where this does not conflict with their audibility to human beings.

(c) Holding rooms shall where appropriate be provided with noise insulation and absorption materials.

2.4. Alarm systems

(a) Establishments relying on electrical or mechanical equipment for environmental control and protection, shall have a stand-by system to maintain essential services and emergency lighting systems as well as to ensure that alarm systems themselves do not fail to operate.

(b) Heating and ventilation systems shall be equipped with monitoring devices and alarms.

(c) Clear instructions on emergency procedures shall be prominently displayed.

3. Care of animals

3.1. Health

(a) Establishments shall have a strategy in place to ensure that a health status of the animals is maintained that safeguards animal welfare and meets scientific requirements. This strategy shall include regular health monitoring, a microbiological surveillance programme and plans for dealing with health breakdowns and shall define health parameters and procedures for the introduction of new animals.

(b) Animals shall be checked at least daily by a competent person. These checks shall ensure that all sick or injured animals are identified and appropriate action is taken.

3.2. Animals taken from the wild

(a) Transport containers and means of transport adapted to the species concerned shall be available at capture sites, in case animals need to be moved for examination or treatment.

(b) Special consideration shall be given and appropriate measures taken for the acclimatisation, quarantine, housing, husbandry, care of animals taken from the wild and, as appropriate, provisions for setting them free at the end of procedures.

3.3. Housing and enrichment

(a) Housing

Animals, except those which are naturally solitary, shall be socially housed in stable groups of compatible individuals. In cases where single housing is allowed in accordance with article 33(3) the duration shall be limited to the minimum period necessary and visual, auditory, olfactory and/or tactile contact shall be maintained. The introduction or re-introduction of animals to established groups shall be carefully monitored to avoid problems of incompatibility and disrupted social relationships.

(b) Enrichment

All animals shall be provided with space of sufficient complexity to allow expression of a wide range of normal behaviour. They shall be given a degree of control and choice over their environment to reduce stress-induced behaviour. Establishments shall have appropriate enrichment techniques in place, to extend the range of activities available to the animals and increase their coping activities including physical exercise, foraging, manipulative and cognitive activities, as appropriate to the species. Environmental enrichment in animal enclosures shall be adapted to the species and individual needs of the animals concerned. The enrichment strategies in establishments shall be regularly reviewed and updated.

(c) Animal enclosures

Animal enclosures shall not be made out of materials detrimental to the health of the animals. Their design and construction shall be such that no injury to the animals is caused. Unless they are disposable, they shall be made from materials that will withstand cleaning and decontamination techniques. The design of animal enclosure floors shall be adapted to the species and age of the animals and be designed to facilitate the removal of excreta.

3.4. Feeding

(a) The form, content and presentation of the diet shall meet the nutritional and behavioural needs of the animal.

(b) The animals' diet shall be palatable and non-contaminated. In the selection of raw materials, production, preparation and presentation of feed, establishments shall take measures to minimise chemical, physical and microbiological contamination.

(c) Packing, transport and storage shall be such as to avoid contamination, deterioration or destruction. All feed hoppers, troughs or other utensils used for feeding shall be regularly cleaned and, if necessary, sterilised.

(d) Each animal shall be able to access the food, with sufficient feeding space provided to limit competition.

3.5. Watering

(a) Uncontaminated drinking water shall always be available to all animals.

(b) When automatic watering systems are used, they shall be regularly checked, serviced and flushed to avoid accidents. If solid-bottomed cages are used, care shall be taken to minimise the risk of flooding.

(c) Provision shall be made to adapt the water supply for aquaria and tanks to the needs and tolerance limits of the individual fish, amphibian and reptile species.

3.6. Resting and sleeping areas

(a) Bedding materials or sleeping structures adapted to the species shall always be provided, including nesting materials or structures for breeding animals.

(b) Within the animal enclosure, as appropriate to the species, a solid, comfortable resting area for all animals shall be provided. All sleeping areas shall be kept clean and dry.

3.7. Handling

Establishments shall set up habituation and training programmes suitable for the animals, the procedures and length of the project.

Section B: Species-specific section

1. Mice, rats, gerbils, hamsters and guinea pigs

In this and subsequent tables for mice, rats, gerbils, hamsters and guinea pigs, 'enclosure height' means the vertical distance between the enclosure floor and the top of the enclosure and this height applies over more than 50 % of the minimum enclosure floor area prior to the addition of enrichment devices.

When designing procedures, consideration shall be given to the potential growth of the animals to ensure adequate space is provided (as detailed in Tables 1.1 to 1.5) for the duration of the study.

Table 1.1.

Mice

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 33(2)
In stock and during procedures	up to 20	330	60	12	1 January 2017
	over 20 to 25	330	70	12	
	over 25 to 30	330	80	12	
	over 30	330	100	12	
Breeding		330 For a monogamous pair (outbred/inbred) or a trio (inbred). For each additional female plus litter 180 cm^2 shall be added.		12	
Stock at breeders (*) Enclosure size 950 cm^2	less than 20	950	40	12	
Enclosure size 1 500 cm^2	less than 20	1 500	30	12	

(*) Post-weaned mice may be kept at these higher stocking densities for the short period after weaning until issue, provided that the animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

Table 1.2.

Rats

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 33(2)
In stock and during procedures (*)	up to 200	800	200	18	1 January 2017
	over 200 to 300	800	250	18	
	over 300 to 400	800	350	18	
	over 400 to 600	800	450	18	
	over 600	1 500	600	18	

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 33(2)
Breeding		800 Mother and litter. For each additional adult animal permanently added to the enclosure add 400 cm^2		18	
Stock at breeders (**) Enclosure size 1 500 cm^2	up to 50	1 500	100	18	
	over 50 to 100	1 500	125	18	
	over 100 to 150	1 500	150	18	
	over 150 to 200	1 500	175	18	
Stock at breeders (**) Enclosure size 2 500 cm^2	up to 100	2 500	100	18	
	over 100 to 150	2 500	125	18	
	over 150 to 200	2 500	150	18	

(*) In long-term studies, if space allowances per individual animal fall below those indicated above towards the end of such studies, priority shall be given to maintaining stable social structures.

(**) Post-weaned rats may be kept at these higher stocking densities for the short period after weaning until issue, provided that the animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

Table 1.3.

Gerbils

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 33(2)
In stock and during procedures	up to 40	1 200	150	18	1 January 2017
	over 40	1 200	250	18	
Breeding		1 200 Monogamous pair or trio with offspring		18	

Table 1.4.

Hamsters

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 33(2)
In stock and during procedures	up to 60	800	150	14	1 January 2017
	over 60 to 100	800	200	14	
	over 100	800	250	14	

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimum enclosure height (cm)	Date referred to in Article 33(2)
Breeding		800 Mother or monogamous pair with litter		14	
Stock at breeders (*)	less than 60	1 500	100	14	

(*) Post-weaned hamsters may be kept at these higher stocking densities, for the short period after weaning until issue provided that the animals are housed in larger enclosures with adequate enrichment, and these housing conditions do not cause any welfare deficit such as increased levels of aggression, morbidity or mortality, stereotypes and other behavioural deficits, weight loss, or other physiological or behavioural stress responses.

Table 1.5.

Guinea pigs

	Body weight (g)	Minimum enclosure size (cm^2)	Floor area per animal (cm^2)	Minimumenclosure height (cm)	Date referred to in Article 33(2)
In stock and during procedures	up to 200	1 800	200	23	1 January 2017
	over 200 to 300	1 800	350	23	
	over 300 to 450	1 800	500	23	
	over 450 to 700	2 500	700	23	
	over 700	2 500	900	23	
Breeding		2 500 Pair with litter. For each additional breeding female add 1 000 cm^2		23	

2. Rabbits

During agricultural research, when the aim of the project requires that the animals are kept under similar conditions to those under which commercial farm animals are kept, the keeping of the animals shall at least follow the standards laid down in Directive 98/58/EC [1].

A raised area shall be provided within the enclosure. This raised area must allow the animal to lie and sit and easily move underneath, and shall not cover more than 40 % of the floor space. When for scientific or veterinary reasons a raised area cannot be used, the enclosure shall be 33 % larger for a single rabbit and 60 % larger for two rabbits. Where a raised area is provided for rabbits of less than 10 weeks of age, the size of the raised area shall be at least of 55 cm by 25 cm and the height above the floor shall be such that the animals can make use of it.

Table 2.1.

Rabbits over 10 weeks of age

Table 2.1 is to be used for both cages and pens. The additional floor area is as a minimum 3 000 cm^2 per rabbit for the third, the fourth, the fifth and the sixth rabbit, while 2 500 cm^2 as a minimum shall be added for each additional rabbit above a number of six.

[1] Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23).

Final body weight (kg)	Minimum floor area for one or two socially harmonious animals (cm^2)	Minimum height (cm)	Date referred to in Article 33(2)
less than 3	3 500	45	1 January 2017
from 3 to 5	4 200	45	
over 5	5 400	60	

Table 2.2.

Doe plus litter

Doe weight (kg)	Minimum enclosure size (cm^2)	Addition for nest boxes (cm^2)	Minimum height (cm)	Date referred to in Article 33(2)
less than 3	3 500	1 000	45	1 January 2017
from 3 to 5	4 200	1 200	45	
over 5	5 400	1 400	60	

Table 2.3.

Rabbits less than 10 weeks of age

Table 2.3 is to be used for both cages and pens.

Age	Minimum enclosure size (cm^2)	Minimum floor area per animal (cm^2)	Minimum height (cm)	Date referred to in Article 33(2)
Weaning to 7 weeks	4 000	800	40	1 January 2017
From 7 to 10 weeks	4 000	1 200	40	

Table 2.4.

Rabbits: Optimal dimensions for raised areas for enclosures having the dimensions indicated in Table 2.1.

Age in weeks	Final body weight (kg)	Optimum size (cm x cm)	Optimum height from the enclosure floor (cm)	Date referred to in Article 33(2)
over 10	less than 3	55 × 25	25	1 January 2017
	from 3 to 5	55 × 30	25	
	over 5	60 × 35	30	

3. Cats

Cats shall not be single-housed for more than 24 hours at a time. Cats that are repeatedly aggressive towards other cats shall be housed singly only if a compatible companion cannot be found. Social stress in all pair- or group-housed individuals shall be monitored at least weekly. Females with kittens under four weeks of age or in the last two weeks of pregnancy may be housed singly.

Table 3.

Cats

The minimum space in which a queen and litter may be held is the space for a single cat, which shall be gradually increased so that by 4 months of age litters have been rehoused following the space requirements for adults.

Areas for feeding and for litter trays shall not be less than 0,5 metres apart and shall not be interchanged.

	Floor (*) (m^2)	Shelves (m^2)	Height (m)	Date referred to in Article 33(2)
Minimum for one adult animal	1,5	0,5	2	1 January 2017
For each additional animal add	0,75	0,25	—	

(*) Floor area excluding shelves.

4. Dogs

Dogs shall where possible be provided with outside runs. Dogs shall not be single-housed for more than 4 hours at a time.

The internal enclosure shall represent at least 50 % of the minimum space to be made available to the dogs, as detailed in Table 4.1.

The space allowances detailed below are based on the requirements of beagles, but giant breeds such as St Bernards or Irish wolfhounds shall be provided with allowances significantly in excess of those detailed in Table 4.1. For breeds other than the laboratory beagle, space allowances shall be determined in consultation with veterinary staff.

Table 4.1.

Dogs

Dogs that are pair or group housed may each be constrained to half the total space provided (2 m^2 for a dog under 20 kg, 4 m^2 for a dog over 20 kg) while they are undergoing procedures as defined in this Directive, if this separation is essential for scientific purposes. The period for which a dog is so constrained shall not exceed 4 hours at a time.

A nursing bitch and litter shall have the same space allowance as a single bitch of equivalent weight. The whelping pen shall be designed so that the bitch can move to an additional compartment or raised area away from the puppies.

Weight (kg)	Minimum enclosure size (m^2)	Minimum floor area for one or two animals (m^2)	For each additional animal add a minimum of (m^2)	Minimum height (m)	Date referred to in Article 33(2)
up to 20	4	4	2	2	1 January 2017
over 20	8	8	4	2	

Table 4.2.

Dogs — post-weaned stock

Weight of dog (kg)	Minimum enclosure size (m^2)	Minimum floor area/ animal (m^2)	Minimum height (m)	Date referred to in Article 33(2)
up to 5	4	0,5	2	1 January 2017
over 5 to 10	4	1,0	2	
over 10 to 15	4	1,5	2	
over 15 to 20	4	2	2	
over 20	8	4	2	

5. Ferrets

Table 5.

Ferrets

	Minimum enclosure size (cm^2)	Minimum floor area per animal (cm^2)	Minimum height (cm)	Date referred to in Article 33(2)
Animals up to 600 g	4 500	1 500	50	1 January 2017
Animals over 600 g	4 500	3 000	50	
Adult males	6 000	6 000	50	
Jill and litter	5 400	5 400	50	

6. Non-human primates

Young non-human primates shall not be separated from their mothers until they are, depending on the species, 6 to 12 months old.

The environment shall enable non-human primates to carry out a complex daily programme of activity. The enclosure shall allow non-human primates to adopt as wide a behavioural repertoire as possible, provide it with a sense of security, and a suitably complex environment to allow the animal to run, walk, climb and jump.

Table 6.1.

Marmosets and tamarins

	Minimum floor area of enclosures for 1 (*) or 2 animals plus offspring up to 5 months old (m^2)	Minimum volume per additional animal over 5 months (m^3)	Minimum enclosure height (m) (**)	Date referred to in Article 33(2)
Marmosets	0,5	0,2	1,5	1 January 2017
Tamarins	1,5	0,2	1,5	

(*) Animals shall be kept singly only in exceptional circumstances.
(**) The top of the enclosure shall be at least 1,8 m from the floor.

For marmosets and tamarins, separation from the mother shall not take place before 8 months of age.

Table 6.2.

Squirrel monkeys

Minimum floor area for 1 (*) or 2 animals (m^2)	Minimum volume per additional animal over 6 months of age (m^3)	Minimum enclosure height (m)	Date referred to in Article 33(2)
2,0	0,5	1,8	1 January 2017

(*) Animals shall be kept singly only in exceptional circumstances.

For squirrel monkeys, separation from the mother shall not take place before 6 months of age.

Table 6.3.

Macaques and vervets (*)

	Minimum enclosure size (m^2)	Minimum enclosure volume (m^3)	Minimum volume per animal (m^3)	Minimum enclosure height (m)	Date referred to in Article 33(2)
Animals less than 3 yrs of age (**)	2,0	3,6	1,0	1,8	1 January 2017
Animals from 3 yrs of age (***)	2,0	3,6	1,8	1,8	
Animals held for breeding purposes (****)			3,5	2,0	

(*) Animals shall be kept singly only in exceptional circumstances.
(**) An enclosure of minimum dimensions may hold up to three animals.
(***) An enclosure of minimum dimensions may hold up to two animals.
(****) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mother.

For macaques and vervets, separation from the mother shall not take place before 8 months of age.

Table 6.4.

Baboons (*)

	Minimum enclosure size (m^2)	Minimum enclosure volume (m^3)	Minimum volume per animal (m^3)	Minimum enclosure height (m)	Date referred to in Article 33(2)
Animals less than 4 yrs of age (**)	4,0	7,2	3,0	1,8	1 January 2017
Animals from 4 yrs of age (**)	7,0	12,6	6,0	1,8	
Animals held for breeding purposes (***)			12,0	2,0	

(*) Animals shall be kept singly only in exceptional circumstances.
(**) An enclosure of minimum dimensions may hold up to 2 animals.
(***) In breeding colonies no additional space/volume allowance is required for young animals up to 2 years of age housed with their mothers.

For baboons, separation from the mother shall not take place before 8 months of age.

7. Farm animals

During agricultural research, when the aim of the project requires that the animals are kept under similar conditions to those under which commercial farm animals are kept, the keeping of the animals shall comply at least with the standards laid down in Directives 98/58/EC, 91/629/EEC [1] and 91/630/EEC [2].

[1] Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves (OJ L 340, 11.12.1991, p. 28).
[2] Council Directive 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs (OJ L 340, 11.12.1991, p. 33).

Table 7.1.

Cattle

Body weight (kg)	Minimum enclosure size (m^2)	Minimum floor area/ animal (m^2/animal)	Trough space for ad-libitum feeding of polled cattle (m/animal)	Trough space for restricted feeding of polled cattle (m/animal)	Date referred to in Article 33(2)
up to 100	2,50	2,30	0,10	0,30	1 January 2017
over 100 to 200	4,25	3,40	0,15	0,50	
over 200 to 400	6,00	4,80	0,18	0,60	
over 400 to 600	9,00	7,50	0,21	0,70	
over 600 to 800	11,00	8,75	0,24	0,80	
over 800	16,00	10,00	0,30	1,00	

Table 7.2.

Sheep and goats

Body weight (kg)	Minimum enclosure size (m^2)	Minimum floor area/animal (m^2/animal)	Minimum partition height (m)	Trough space for ad-libitum feeding (m/animal)	Trough space for restricted feeding (m/animal)	Date referred to in Article 33(2)
less than 20	1,0	0,7	1,0	0,10	0,25	1 January 2017
over 20 to 35	1,5	1,0	1,2	0,10	0,30	
over 35 to 60	2,0	1,5	1,2	0,12	0,40	
over 60	3,0	1,8	1,5	0,12	0,50	

Table 7.3.

Pigs and minipigs

Live weight (kg)	Minimum enclosure size (*) (m^2)	Minimum floor area per animal (m^2/animal)	Minimum lying space per animal (in, thermoneutral conditions) (m^2/animal)	Date referred to in Article 33(2)
Up to 5	2,0	0,20	0,10	1 January 2017
over 5 to 10	2,0	0,25	0,11	
over 10 to 20	2,0	0,35	0,18	
over 20 to 30	2,0	0,50	0,24	
over 30 to 50	2,0	0,70	0,33	
over 50 to 70	3,0	0,80	0,41	
over 70 to 100	3,0	1,00	0,53	

Live weight (kg)	Minimum enclosure size (*) (m^2)	Minimum floor area per animal (m^2/animal)	Minimum lying space per animal (in, thermoneutral conditions) (m^2/animal)	Date referred to in Article 33(2)
over 100 to 150	4,0	1,35	0,70	
over 150	5,0	2,50	0,95	
Adult (conventional) boars	7,5		1,30	

(*) Pigs may be confined in smaller enclosures for short periods of time, for example by partitioning the main enclosure using dividers, when justified on veterinary or experimental grounds, for example where individual food consumption is required.

Table 7.4.

Equines

The shortest side shall be a minimum of 1,5 times the wither height of the animal. The height of indoor enclosures shall allow animals to rear to their full height.

Wither height (m)	Minimum floor area/animal (m^2/animal)			Minimum enclosure height (m)	Date referred to in Article 33(2)
	For each animal held singly or in groups of up to 3 animals	For each animal held in groups of 4 or more animals	Foaling box/mare with foal		
1,00 to 1,40	9,0	6,0	16	3,00	1 January 2017
over 1,40 to 1,60	12,0	9,0	20	3,00	
over 1,60	16,0	$(2 \times WH)^2$ (*)	20	3,00	

(*) To ensure adequate space is provided, space allowances for each individual animal shall be based on height to withers (WH).

8. Birds

During agricultural research, when the aim of the project requires that the animals are kept under similar conditions to those under which commercial farm animals are kept, the keeping of the animals shall comply at least with the standards laid down in Directives 98/58/EC, 1999/74/EC [1] and 2007/43/EC [2].

Table 8.1.

Domestic fowl

Where these minimum enclosure sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0,75 m^2.

Body mass (g)	Minimum enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed trough per bird (cm)	Date referred to in Article 33(2)
Up to 200	1,00	0,025	30	3	1 January 2017
over 200 to 300	1,00	0,03	30	3	
over 300 to 600	1,00	0,05	40	7	

[1] Council Directive 1999/74/EC of 19 July 1999 laying down minimum standards for the protection of laying hens (OJ L 203, 3.8.1999, p. 53).
[2] Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production (OJ L 182, 12.7.2007, p. 19).

Body mass (g)	Minimum enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed trough per bird (cm)	Date referred to in Article 33(2)
over 600 to 1 200	2,00	0,09	50	15	
over 1 200 to 1 800	2,00	0,11	75	15	
over 1 800 to 2 400	2,00	0,13	75	15	
over 2 400	2,00	0,21	75	15	

Table 8.2.

Domestic turkeys

All enclosure sides shall be at least 1,5 m long. Where these minimum enclosures sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0,75 m^2 and a minimum height of 50 cm for birds below 0,6 kg, 75 cm for birds below 4 kg, and 100 cm for birds over 4 kg. These can be used to house small groups of birds in accordance with the space allowances given in table 8.2.

Body mass (kg)	Minimum enclosure size (m^2)	Minimum area per bird (m^2)	Minimum height (cm)	Minimum length of feed trough per bird (cm)	Date referred to in Article 33(2)
Up to 0,3	2,00	0,13	50	3	1 January 2017
over 0,3 to 0,6	2,00	0,17	50	7	
over 0,6 to 1	2,00	0,30	100	15	
over 1 to 4	2,00	0,35	100	15	
over 4 to 8	2,00	0,40	100	15	
over 8 to 12	2,00	0,50	150	20	
over 12 to 16	2,00	0,55	150	20	
over 16 to 20	2,00	0,60	150	20	
over 20	3,00	1,00	150	20	

Table 8.3.

Quails

Body mass (g)	Minimum enclosure size (m^2)	Area per bird pair-housed (m^2)	Area per additional bird group-housed (m^2)	Minimum height (cm)	Minimum length of trough per bird (cm)	Date referred to in Article 33(2)
Up to 150	1,00	0,5	0,10	20	4	1 January 2017
Over 150	1,00	0,6	0,15	30	4	

Table 8.4.

Ducks and geese

Where these minimum enclosures sizes cannot be provided for scientific reasons, the duration of the confinement shall be justified by the experimenter in consultation with veterinary staff. In such circumstances, birds can be housed in smaller enclosures containing appropriate enrichment and with a minimum floor area of 0,75 m^2. These can be used to house small groups of birds in accordance with the space allowances given in table 8.4.

Body mass (g)	Minimum enclosure size (m^2)	Area per bird (m^2) (*)	Minimum height (cm)	Minimum length of feed trough per bird (cm)	Date referred to in Article 33(2)
Ducks					1 January 2017
Up to 300	2,00	0,10	50	10	
Over 300 to 1 200 (**)	2,00	0,20	200	10	
Over 1 200 to 3 500	2,00	0,25	200	15	
Over 3 500	2,00	0,50	200	15	
Geese					
Up to 500	2,00	0,20	200	10	
Over 500 to 2 000	2,00	0,33	200	15	
Over 2 000	2,00	0,50	200	15	

(*) This shall include a pond of minimum area 0,5 m^2 per 2 m^2 enclosure with a minimum depth of 30 cm. The pond may contribute up to 50 % of the minimum enclosure size.
(**) Pre-fledged birds may be held in enclosures with a minimum height of 75 cm.

Table 8.5.

Ducks and geese: Minimum pond sizes (*)

	Area (m^2)	Depth (cm)
Ducks	0,5	30
Geese	0,5	from 10 to 30

(*) Pond sizes are per 2 m^2 enclosure. The pond may contribute up to 50 % of the minimum enclosure size.

Table 8.6.

Pigeons

Enclosures shall be long and narrow (for example 2 m by 1 m) rather than square to allow birds to perform short flights.

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum length of food trough per bird (cm)	Minimum length of perch per bird (cm)	Date referred to in Article 33(2)
Up to 6	2	200	5	30	1 January 2017

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum length of food trough per bird (cm)	Minimum length of perch per bird (cm)	Date referred to in Article 33(2)
from 7 to 12	3	200	5	30	
for each additional bird above 12	0,15		5	30	

Table 8.7.

Zebra finches

Enclosures shall be long and narrow (for example 2 m by 1 m) to enable birds to perform short flights. For breeding studies, pairs may be housed in smaller enclosures containing appropriate enrichment with a minimum floor area of 0,5 m^2 and a minimum height of 40 cm. The duration of the confinement shall be justified by the experimenter in consultation with veterinary staff.

Group size	Minimum enclosure size (m^2)	Minimum height (cm)	Minimum number of feeders	Date referred to in Article 33(2)
Up to 6	1,0	100	2	1 January 2017
7 to 12	1,5	200	2	
13 to 20	2,0	200	3	
for each additional bird above 20	0,05		1 per 6 birds	

9. Amphibians

Table 9.1.

Aquatic urodeles

Body length (*) (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group-holding (cm^2)	Minimum water depth (cm)	Date referred to in Article 33(2)
Up to 10	262,5	50	13	1 January 2017
over 10 to 15	525	110	13	
over 15 to 20	875	200	15	
over 20 to 30	1 837,5	440	15	
Over 30	3 150	800	20	

(*) Measured from snout to vent.

Table 9.2.

Aquatic anurans (*)

Body length (**) (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group-holding (cm^2)	Minimum water depth (cm)	Date referred to in Article 33(2)
Less than 6	160	40	6	1 January 2017
from 6 to 9	300	75	8	

Body length (**) (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group-holding (cm^2)	Minimum water depth (cm)	Date referred to in Article 33(2)
over 9 to 12	600	150	10	
over 12	920	230	12,5	

(*) These conditions apply to holding (i.e. husbandry) tanks but not to those tanks used for natural mating and super-ovulation for reasons of efficiency, as the latter procedures require smaller individual tanks. Space requirements determined for adults in the indicated size categories; juveniles and tadpoles shall either be excluded, or dimensions altered according to the scaling principle.
(**) Measured from snout to vent.

Table 9.3.

Semi-aquatic anurans

Body length (*) (cm)	Minimum enclosure size (**) (cm^2)	Minimum area for each additional animal in group holding (cm^2)	Minimum enclosure height (***) (cm)	Minimum water depth (cm)	Date referred to in Article 33(2)
up to 5,0	1 500	200	20	10	1 January 2017
over 5,0 to 7,5	3 500	500	30	10	
Over 7,5	4 000	700	30	15	

(*) Measured from snout to vent.
(**) One-third land division, two-thirds water division sufficient for animals to submerge.
(***) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design.

Table 9.4.

Semi-terrestrial anurans

Body length (*) (cm)	Minimum enclosure size (**) (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height (***) (cm)	Minimum water depth (cm)	Date referred to in Article 33(2)
Up to 5,0	1 500	200	20	10	1 January 2017
over 5,0 to 7,5	3 500	500	30	10	
over 7,5	4 000	700	30	15	

(*) Measured from snout to vent.
(**) Two-thirds land division, one-third water division sufficient for animals to submerge.
(***) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design.

Table 9.5.

Arboreal anurans

Body length (*) (cm)	Minimum enclosure size (**) (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height (***) (cm)	Date referred to in Article 33(2)
up to 3,0	900	100	30	1 January 2017
Over 3,0	1 500	200	30	

(*) Measured from snout to vent.
(**) Two-thirds land division, one-third pool division sufficient for animals to submerge.
(***) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosures shall be adapted to the interior design.

10. Reptiles

Table 10.1.

Aquatic chelonians

Body length (*) (cm)	Minimum water surface area (cm^2)	Minimum water surface area for each additional animal in group holding (cm^2)	Minimum water depth (cm)	Date referred to in Article 33(2)
up to 5	600	100	10	1 January 2017
Over 5 to 10	1 600	300	15	
Over 10 to 15	3 500	600	20	
Over 15 to 20	6 000	1 200	30	
Over 20 to 30	10 000	2 000	35	
Over 30	20 000	5 000	40	

(*) Measured in a straight line from the front edge to the back edge of the shell.

Table 10.2.

Terrestrial snakes

Body length (*) (cm)	Minimum floor area (cm^2)	Minimum area for each additional animal in group-holding (cm^2)	Minimum enclosure height (**) (cm)	Date referred to in Article 33(2)
up to 30	300	150	10	1 January 2017
Over 30 to 40	400	200	12	
Over 40 to 50	600	300	15	
Over 50 to 75	1 200	600	20	
Over 75	2 500	1 200	28	

(*) Measured from snout to tail.
(**) Measured from the surface of the land division up to the inner part of the top of the terrarium; furthermore, the height of the enclosure shall be adapted to the interior design.

11. Fish

11.1. Water supply and quality

Adequate water supply of suitable quality shall be provided at all times. Water flow in re-circulatory systems or filtration within tanks shall be sufficient to ensure that water quality parameters are maintained within acceptable levels. Water supply shall be filtered or treated to remove substances harmful to fish, where necessary. Water-quality parameters shall at all times be within the acceptable range that sustains normal activity and physiology for a given species and stage of development. The water flow shall be appropriate to enable fish to swim correctly and to maintain normal behaviour. Fish shall be given an appropriate time for acclimatisation and adaptation to changes in water-quality conditions.

11.2. Oxygen, nitrogen compounds, pH, and salinity

Oxygen concentration shall be appropriate to the species and to the context in which the fish are held. Where necessary, supplementary aeration of tank water shall be provided. The concentrations of nitrogen compounds shall be kept low.

The pH level shall be adapted to the species and kept as stable as possible. The salinity shall be adapted to the requirements of the fish species and to the life stage of the fish. Changes in salinity shall take place gradually.

11.3. Temperature, lighting, noise

Temperature shall be maintained within the optimal range for the fish species concerned and kept as stable as possible. Changes in temperature shall take place gradually. Fish shall be maintained on an appropriate photo-period. Noise levels shall be kept to a minimum and, where possible, equipment causing noise or vibration, such as power generators or filtration systems, shall be separate from the fish-holding tanks.

11.4. Stocking density and environmental complexity

The stocking density of fish shall be based on the total needs of the fish in respect of environmental conditions, health and welfare. Fish shall have sufficient water volume for normal swimming, taking account of their size, age, health and feeding method. Fish shall be provided with an appropriate environmental enrichment, such as hiding places or bottom substrate, unless behavioural traits suggest none is required.

11.5. Feeding and handling

Fish shall be fed a diet suitable for the fish at an appropriate feeding rate and frequency. Particular attention shall be given to feeding of larval fish during any transition from live to artificial diets. Handling of fish shall be kept to a minimum.

ANNEX IV

METHODS OF KILLING ANIMALS

1. In the process of killing animals, methods listed in the table below shall be used.

   Methods other than those listed in the table may be used:

   (a) on unconscious animals, providing the animal does not regain consciousness before death;

   (b) on animals used in agricultural research, when the aim of the project requires that the animals are kept under similar conditions to those under which commercial farm animals are kept; these animals may be killed in accordance with the requirements laid down in Annex I to Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing [1].

2. The killing of animals shall be completed by one of the following methods:

   (a) confirmation of permanent cessation of the circulation;

   (b) destruction of the brain;

   (c) dislocation of the neck;

   (d) exsanguination; or

   (e) confirmation of the onset of *rigor mortis*.

3. Table

Animals-remarks/ methods	Fish	Amphibians	Reptiles	Birds	Rodents	Rabbits	Dogs, cats, ferrets and foxes	Large mammals	Non-human primates
Anaesthetic overdose	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)
Captive bolt			(2)						
Carbon dioxide					(3)				
Cervical dislocation				(4)	(5)	(6)			
Concussion/ percussive blow to the head				(7)	(8)	(9)	(10)		
Decapitation				(11)	(12)				
Electrical stunning	(13)	(13)		(13)		(13)	(13)	(13)	
Inert gases (Ar, N_2)								(14)	
Shooting with a free bullet with appropriate rifles, guns and ammunition			(15)				(16)	(15)	

[1] OJ L 303, 18.11.2009, p. 1.

Requirements

1. Shall, where appropriate, be used with prior sedation.
2. Only to be used on large reptiles.
3. Only to be used in gradual fill. Not to be used for foetal and neonate rodents.
4. Only to be used for birds under 1 kg. Birds over 250 g shall be sedated.
5. Only to be used for rodents under 1 kg. Rodents over 150 g shall be sedated.
6. Only to be used for rabbits under 1 kg. Rabbits over 150 g shall be sedated.
7. Only to be used for birds under 5 kg.
8. Only to be used for rodents under 1 kg.
9. Only to be used for rabbits under 5 kg.
10. Only to be used on neonates.
11. Only to be used for birds under 250 g.
12. Only to be used if other methods are not possible.
13. Specialised equipment required.
14. Only to be used on pigs.
15. Only to be used in field conditions by experienced marksmen.
16. Only to be used in field conditions by experienced marksmen when other methods are not possible.

ANNEX V

LIST OF ELEMENTS REFERRED TO IN ARTICLE 23(3)

1. National legislation in force relevant to the acquisition, husbandry, care and use of animals for scientific purposes.
2. Ethics in relation to human-animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes.
3. Basic and appropriate species-specific biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration.
4. Animal behaviour, husbandry and enrichment.
5. Species-specific methods of handling and procedures, where appropriate.
6. Animal health management and hygiene.
7. Recognition of species-specific distress, pain and suffering of most common laboratory species.
8. Anaesthesia, pain relieving methods and killing.
9. Use of humane end-points.
10. Requirement of replacement, reduction and refinement.
11. Design of procedures and projects, where appropriate.

ANNEX VI

LIST OF ELEMENTS REFERRED TO IN ARTICLE 37(1)(c)

1. Relevance and justification of the following:

   (a) use of animals including their origin, estimated numbers, species and life stages;

   (b) procedures.

2. Application of methods to replace, reduce and refine the use of animals in procedures.

3. The planned use of anaesthesia, analgesia and other pain relieving methods.

4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate.

5. Use of humane end-points.

6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate.

7. Reuse of animals and the accumulative effect thereof on the animals.

8. The proposed severity classification of procedures.

9. Avoidance of unjustified duplication of procedures where appropriate.

10. Housing, husbandry and care conditions for the animals.

11. Methods of killing.

12. Competence of persons involved in the project.

ANNEX VII

DUTIES AND TASKS OF THE UNION REFERENCE LABORATORY

1. The Union Reference Laboratory referred to in Article 48 is the Commission's Joint Research Centre.

2. The Union Reference Laboratory shall be responsible, in particular, for:

   (a) coordinating and promoting the development and use of alternatives to procedures including in the areas of basic and applied research and regulatory testing;

   (b) coordinating the validation of alternative approaches at Union level;

   (c) acting as a focal point for the exchange of information on the development of alternative approaches;

   (d) setting up, maintaining and managing public databases and information systems on alternative approaches and their state of development;

   (e) promoting dialogue between legislators, regulators, and all relevant stakeholders, in particular, industry, biomedical scientists, consumer organisations and animal-welfare groups, with a view to the development, validation, regulatory acceptance, international recognition, and application of alternative approaches.

3. The Union Reference Laboratory shall participate in the validation of alternative approaches.

ANNEX VIII

SEVERITY CLASSIFICATION OF PROCEDURES

The severity of a procedure shall be determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure.

Section I: Severity categories

Non-recovery:

Procedures which are performed entirely under general anaesthesia from which the animal shall not recover consciousness shall be classified as 'non-recovery'.

Mild:

Procedures on animals as a result of which the animals are likely to experience short-term mild pain, suffering or distress, as well as procedures with no significant impairment of the well-being or general condition of the animals shall be classified as 'mild'.

Moderate:

Procedures on animals as a result of which the animals are likely to experience short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that are likely to cause moderate impairment of the well-being or general condition of the animals shall be classified as 'moderate'.

Severe:

Procedures on animals as a result of which the animals are likely to experience severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as procedures, that are likely to cause severe impairment of the well-being or general condition of the animals shall be classified as 'severe'.

Section II: Assignment criteria

The assignment of the severity category shall take into account any intervention or manipulation of an animal within a defined procedure. It shall be based on the most severe effects likely to be experienced by an individual animal after applying all appropriate refinement techniques.

When assigning a procedure to a particular category, the type of procedure and a number of other factors shall be taken into account. All these factors shall be considered on a case-by-case basis.

The factors related to the procedure shall include:

— type of manipulation, handling,

— nature of pain, suffering, distress or lasting harm caused by (all elements of) the procedure, and its intensity, the duration, frequency and multiplicity of techniques employed,

— cumulative suffering within a procedure,

— prevention from expressing natural behaviour including restrictions on the housing, husbandry and care standards.

Examples are given in Section III of procedures assigned to each of the severity categories on the basis of factors related to the type of the procedure alone. They shall provide the first indication as to what classification would be the most appropriate for a certain type of procedure.

However, for the purposes of the final severity classification of the procedure, the following additional factors, assessed on a case-by-case basis, shall also be taken into account:

— type of species and genotype,

— maturity, age and gender of the animal,

— training experience of the animal with respect to the procedure,

— if the animal is to be reused, the actual severity of the previous procedures,

— the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions,

— humane end-points.

Section III:

Examples of different types of procedure assigned to each of the severity categories on the basis of factors related to the type of the procedure

1. Mild:

   (a) administration of anaesthesia except for the sole purpose of killing;

   (b) pharmacokinetic study where a single dose is administered and a limited number of blood samples are taken (totalling < 10 % of circulating volume) and the substance is not expected to cause any detectable adverse effect;

   (c) non-invasive imaging of animals (e.g. MRI) with appropriate sedation or anaesthesia;

   (d) superficial procedures, e.g. ear and tail biopsies, non-surgical subcutaneous implantation of mini-pumps and transponders;

   (e) application of external telemetry devices that cause only minor impairment to the animals or minor interference with normal activity and behaviour;

   (f) administration of substances by subcutaneous, intramuscular, intraperitoneal routes, gavage and intravenously via superficial blood vessels, where the substance has no more than mild impact on the animal, and the volumes are within appropriate limits for the size and species of the animal;

   (g) induction of tumours, or spontaneous tumours, that cause no detectable clinical adverse effects (e.g. small, subcutaneous, non-invasive nodules);

   (h) breeding of genetically altered animals, which is expected to result in a phenotype with mild effects;

   (i) feeding of modified diets, that do not meet all of the animals' nutritional needs and are expected to cause mild clinical abnormality within the time-scale of the study;

   (j) short-term (< 24h) restraint in metabolic cages;

   (k) studies involving short-term deprivation of social partners, short-term solitary caging of adult rats or mice of sociable strains;

(l) models which expose animals to noxious stimuli which are briefly associated with mild pain, suffering or distress, and which the animals can successfully avoid;

(m) a combination or accumulation of the following examples may result in classification as 'mild':

(i) assessing body composition by non-invasive measures and with minimal restraint;

(ii) monitoring ECG with non-invasive techniques with minimal or no restraint of habituated animals;

(iii) application of external telemetry devices that are expected to cause no impairment to socially adapted animals and do not interfere with normal activity and behaviour;

(iv) breeding genetically altered animals which are expected to have no clinically detectable adverse phenotype;

(v) adding inert markers in the diet to follow passage of digesta;

(vi) withdrawal of food for < 24h in adult rats;

(vii) open field testing.

2. Moderate:

(a) frequent application of test substances which produce moderate clinical effects, and withdrawal of blood samples (> 10 % of circulating volume) in a conscious animal within a few days without volume replacement;

(b) acute dose-range finding studies, chronic toxicity/carcinogenicity tests, with non-lethal end-points;

(c) surgery under general anaesthesia and appropriate analgesia, associated with post surgical pain, suffering or impairment of general condition. Examples include: thoracotomy, craniotomy, laparotomy, orchidectomy, lymphadenectomy, thyroidectomy, orthopaedic surgery with effective stabilisation and wound management, organ transplantation with effective management of rejection, surgical implantation of catheters, or biomedical devices (e.g. telemetry transmitters, minipumps etc.);

(d) models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour;

(e) irradiation or chemotherapy with a sublethal dose, or with an otherwise lethal dose but with reconstitution of the immune system. Adverse effects would be expected to be mild or moderate and would be short-lived (< 5 days);

(f) breeding of genetically altered animals which are expected to result in a phenotype with moderate effects;

(g) creation of genetically altered animals through surgical procedures;

(h) use of metabolic cages involving moderate restriction of movement over a prolonged period (up to 5 days);

(i) studies with modified diets that do not meet all of the animals' nutritional needs and are expected to cause moderate clinical abnormality within the time-scale of the study;

(j) withdrawal of food for 48 hours in adult rats;

(k) evoking escape and avoidance reactions where the animal is unable to escape or avoid the stimulus, and are expected to result in moderate distress.

3. Severe:

(a) toxicity testing where death is the end-point, or fatalities are to be expected and severe pathophysiological states are induced. For example, single dose acute toxicity testing (see OECD testing guidelines);

(b) testing of device where failure may cause severe pain, distress or death of the animal (e.g. cardiac assist devices);

(c) vaccine potency testing characterised by persistent impairment of the animal's condition, progressive disease leading to death, associated with long-lasting moderate pain, distress or suffering;

(d) irradiation or chemotherapy with a lethal dose without reconstitution of the immune system, or reconstitution with production of graft versus host disease;

(e) models with induction of tumours, or with spontaneous tumours, that are expected to cause progressive lethal disease associated with long-lasting moderate pain, distress or suffering. For example tumours causing cachexia, invasive bone tumours, tumours resulting in metastatic spread, and tumours that are allowed to ulcerate;

(f) surgical and other interventions in animals under general anaesthesia which are expected to result in severe or persistent moderate postoperative pain, suffering or distress or severe and persistent impairment of the general condition of the animals. Production of unstable fractures, thoracotomy without adequate analgesia, or trauma to produce multiple organ failure;

(g) organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animals (e.g. xenotransplantation);

(h) breeding animals with genetic disorders that are expected to experience severe and persistent impairment of general condition, for example Huntington's disease, Muscular dystrophy, chronic relapsing neuritis models;

(i) use of metabolic cages involving severe restriction of movement over a prolonged period;

(j) inescapable electric shock (e.g. to produce learned helplessness);

(k) complete isolation for prolonged periods of social species e.g. dogs and non-human primates;

(l) immobilisation stress to induce gastric ulcers or cardiac failure in rats;

(m) forced swim or exercise tests with exhaustion as the end-point.

CORRIGENDA

Corrigendum to Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part One

(Official Journal of the European Union L 311 of 21 November 2008)

On page 29, Annex, point 5.6, paragraph 3 of the new Article 8 of Regulation (EC) No 808/2004:

for: '3. Implementing measures shall be adopted at least nine months before the start of a data collection period.',

read: '3. Implementing measures shall be drawn up at least nine months before the start of a data collection period.'.

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