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Contents

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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.

II *Non-legislative acts*

REGULATIONS

EN

[1] Text with EEA relevance

I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 576/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003

(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 43(2) and point (b) of Article 168(4) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

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) Regulation (EC) No 998/2003 of the European Parliament and of the Council [3] lays down the animal health requirements applicable to the non-commercial movement of pet animals into a Member State from another Member State or from third countries and the checks applicable to such movement. It aims to ensure a sufficient level of safety with regard to the public and animal health risks involved in such non-commercial movement and to remove any unjustified obstacles to such movement.

(2) In a statement annexed to Regulation (EU) No 438/2010 of the European Parliament and of the Council of 19 May 2010 amending Regulation (EC) No 998/2003 on the animal health requirements applicable to the non-commercial movement of pet animals [4], the Commission undertook to propose a revision of Regulation (EC) No 998/2003 in its entirety, in particular the aspects of delegated and implementing acts. Therefore, due to the entry into force of the Treaty on the Functioning of the European Union (TFEU), the powers conferred on the Commission under Regulation (EC) No 998/2003 need to be aligned with Articles 290 and 291 TFEU. Taking into account the number of amendments that need to be made to the animal health requirements laid down in Regulation (EC) No 998/2003 and in order to ensure that those requirements are sufficiently clear and accessible to the ordinary citizen, that Regulation should be repealed and replaced by this Regulation.

(3) This Regulation should establish a list of animal species to which harmonised animal health requirements should apply when animals of those species are kept as pet animals and are subject to non-commercial movement. When drawing up that list, account should be taken of their susceptibility to or role in the epidemiology of rabies.

(4) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC [5] establishes, inter alia, the animal health requirements

[1] OJ C 229, 31.7.2012, p. 119.
[2] Position of the European Parliament of 23 May 2013 (not yet published in the Official Journal) and decision of the Council of 10 June 2013.
[3] OJ L 146, 13.6.2003, p. 1.
[4] OJ L 132, 29.5.2010, p. 3.
[5] OJ L 268, 14.9.1992, p. 54.

applicable to trade in and imports of dogs, cats and ferrets, which are animals of species susceptible to rabies. Since those species are also kept as pet animals that frequently accompany their owner or an authorised person during non-commercial movement within and into the Union, this Regulation should lay down the animal health requirements applicable to the non-commercial movement of those species into Member States. Those species should be listed in Part A of Annex I to this Regulation.

(5) Similarly, a legal framework should be established for the animal health requirements applicable to the non-commercial movement of animals of species not affected by rabies or of no epidemiological significance as regards rabies, to which, if they were not kept as pet animals, other legal acts of the Union would apply, including legislation on food-producing animals. Those species should be listed in Part B of Annex I.

(6) The list in Part B of Annex I should include invertebrates, with the exception of bees and bumble bees covered by Directive 92/65/EEC, and molluscs and crustaceans covered by Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals ([1]). It should also include ornamental aquatic animals reared in non-commercial aquaria excluded from the scope of Directive 2006/88/EC, and amphibians and reptiles.

(7) The list in Part B of Annex I should further include all species of birds, other than those covered by Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs ([2]), and rodents and rabbits other than those intended for the production of food and defined in Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ([3]).

(8) However, in the interest of consistency of Union law, pending the establishment of Union rules governing the non-commercial movement into a Member State from another Member State or from a territory or a third country of pet animals of the species listed in Part B of Annex I, it should be possible for national rules to apply to such movement provided that they are not stricter than those applied to movement for commercial purposes.

(9) Since animals of the species listed in Part B of Annex I to this Regulation may belong to species that require particular protection, this Regulation should apply without prejudice 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 ([4]).

(10) In order to make a clear distinction between the rules that apply to non-commercial movement and to trade in and imports into the Union from third countries of dogs, cats and ferrets covered by the animal health requirements of Directive 92/65/EEC, this Regulation should not only define a pet animal, but also the non-commercial movement of a pet animal, during which such a pet animal accompanies its owner or an authorised person. Experience has shown that it is not always possible for the pet animal to be in the immediate vicinity of the owner or authorised person at all times during non-commercial movement. On duly justified and documented grounds, the pet animal should be considered as accompanying its owner or the authorised person even if the non-commercial movement of the pet animal takes place up to five days earlier or later than the movement of the owner or of the authorised person, or takes place in a different physical location than that occupied by the owner or by the authorised person.

(11) Experience with the application of the existing rules shows that trade in and imports into the Union from third countries of pet animals of the species listed in Part A of Annex I can be fraudulently disguised as non-commercial movement. In order to prevent such practices, since they might pose animal health risks, this Regulation should fix a maximum number of pet animals of the species listed in Part A of Annex I that may accompany their owner or an authorised person. However, it should be possible to exceed that maximum number under certain specified conditions. Further, it should be clarified that when the specified conditions are not fulfilled and the number of pet animals of the species listed in Part A of Annex I to this Regulation exceeds the established maximum number, the relevant provisions of Directive 92/65/EEC and of Directive 90/425/EEC ([5]) or Directive 91/496/EEC ([6]) apply to those pet animals.

([1]) OJ L 328, 24.11.2006, p. 14.
([2]) OJ L 343, 22.12.2009, p. 74.
([3]) OJ L 139, 30.4.2004, p. 55.
([4]) OJ L 61, 3.3.1997, p. 1.
([5]) Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29).
([6]) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries (OJ L 268, 24.9.1991, p. 56).

(12) Regulation (EC) No 998/2003 provides that, for a transitional period, pet animals of the species listed in Parts A and B of Annex I thereto are to be regarded as identified when they bear either a clear readable tattoo or an electronic identification system ('transponder'). This Regulation should therefore lay down rules for the marking of pet animals of the species listed in Part A of Annex I to this Regulation after expiry of the transitional period on 3 July 2011.

(13) The implantation of a transponder is an invasive intervention and certain qualifications are required to carry it out. Transponders should therefore be implanted only by a suitably qualified person. If a Member State allows a person other than veterinarians to implant transponders, it should lay down rules on the minimum qualifications required for such a person.

(14) Annex Ia to Regulation (EC) No 998/2003 sets out technical requirements for the identification of pet animals by transponders. Those technical requirements correspond to internationally accepted standards and should be set out, without any substantial amendments being made to them, in Annex II to this Regulation.

(15) In order to protect public health and the health of pet animals of the species listed in Annex I, this Regulation should provide for the possibility to adopt preventive health measures for diseases and infections other than rabies. Those measures should be based on validated scientific information and applied proportionately to the risk to public or animal health associated with the non-commercial movement of those pet animals likely to be affected by those diseases or infections. The measures should include rules for the categorisation of Member States or parts thereof, procedures under which Member States that require the application of preventive health measures should substantiate the rationale for such measures on a continuous basis, conditions for applying and documenting the preventive health measures and, where appropriate, conditions for derogating from the application of those measures. A list of Member States or parts thereof categorised pursuant to the relevant rules should therefore be set out in an implementing act to be adopted pursuant to this Regulation.

(16) It is possible that rabies vaccines administered to pet animals of the species listed in Part A of Annex I before the age of three months do not induce protective immunity due to competition with maternal antibodies. Consequently, vaccine manufacturers recommend not to vaccinate young pet animals before that age. Therefore, in order to authorise the non-commercial movement of young pet animals of the species listed in Part A of Annex I that have not been vaccinated, or that have been vaccinated, but have not yet acquired protective immunity against rabies, this Regulation should establish certain precautionary measures to be taken and give the Member States the possibility to authorise such movement into their territory when young pet animals comply with those measures.

(17) In order to simplify the conditions for the non-commercial movement of pet animals of the species listed in Part A of Annex I between Member States of equivalent favourable status with regard to rabies, this Regulation should also provide for the possibility to derogate from the anti-rabies vaccination requirement. Such a possibility should be available upon submission of a joint application by the Member States interested. Such a derogation should be based on validated scientific information and be applied proportionately to the risk to public or animal health associated with the non-commercial movement of those animals likely to be affected by rabies. Member States or parts thereof benefiting from such a derogation should be listed in an implementing act to be adopted pursuant to this Regulation.

(18) Countries and territories listed in Section 2 of Part B of Annex II to Regulation (EC) No 998/2003 apply rules equivalent to those applied by Member States while those listed in Part C of Annex II to that Regulation comply with the criteria laid down in Article 10 of that Regulation. Those lists should be set out, without any substantial amendments being made to them, in an implementing act to be adopted pursuant to this Regulation.

(19) Furthermore, a list of territories or third countries that apply rules the content and effect of which are the same as those laid down in this Regulation for pet animals of the species listed in Part B of Annex I should be set out in an implementing act to be adopted pursuant to this Regulation.

(20) Regulation (EC) No 998/2003 lays down certain requirements for the non-commercial movement of pet animals into Member States from other Member States and from countries or territories listed in Section 2 of Part B and in Part C of Annex II thereto. Those requirements include a valid anti-rabies vaccination carried out on the pet animals in question with vaccines complying with the minimum standards laid down in the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE), or for

which a marketing authorisation has been granted in accordance with either Directive 2001/82/EC [1] or Regulation (EC) No 726/2004 [2].Those vaccines have proven to be effective in protecting animals against rabies and form part of the validity requirements for the anti-rabies vaccination set out in Annex Ib to Regulation (EC) No 998/2003. Those requirements should be set out, without any substantial amendments being made to them, in Annex III to this Regulation.

(21) Regulation (EC) No 998/2003 lays down more stringent animal health requirements for pet animals moved into Member States from countries or territories other than those listed in Part C of Annex II thereto. Those requirements include checks on the effectiveness in individual animals of the anti-rabies vaccination by titration of antibodies in a laboratory approved in accordance with Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines [3]. That requirement should therefore be maintained in Annex IV to this Regulation and a condition should be included that the test should be performed in accordance with the methods laid down in the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE).

(22) Identification documents accompanying pet animals of the species listed in Part A of Annex I which are subject to non-commercial movement into Member States are necessary to attest compliance with this Regulation. This Regulation should therefore establish the conditions for issuing identification documents and the requirements for their content, validity, security features, format and layout.

(23) This Regulation should allow Member States to authorise the non-commercial movement into their territory of pet animals of the species listed in Part A of Annex I accompanied by an identification document issued in a territory or a third country which applies rules the content and effect of which are the same as those applied by Member States. It should also allow Member States to authorise the non-commercial movement into their territory after a movement to a territory or a third country of those pet animals accompanied by an identification document issued in a Member State provided that the conditions to return from those territories or third countries are met before the pet animal left the Union.

(24) This Regulation should also give Member States the possibility to authorise, where the need for the urgent departure of the owner arises, for example, in the event of a sudden natural disaster, political unrest or other force majeure relating to the owner, the direct entry into their territory of pet animals of the species listed in Annex I which do not comply with this Regulation provided that a permit is applied for in advance and granted by the Member State of destination, and a time-limited period of isolation under official supervision is carried out to fulfil the conditions of this Regulation. Despite the need for such urgent departure, such permits are indispensable due to the animal health risks arising from the introduction into the Union of a pet animal that does not comply with this Regulation.

(25) Directive 90/425/EEC and Directive 91/496/EEC do not apply to veterinary checks on pet animals accompanying travellers during non-commercial movement.

(26) Therefore, in order for the Member States to verify compliance with this Regulation and to take the necessary action, this Regulation should require the person accompanying the pet animal to present the required identification document at the time of any non-commercial movement into a Member State and should provide for appropriate documentary and identity checks on pet animals accompanying their owner during non-commercial movement into a Member State from another Member State or from certain territories or third countries.

(27) It should also require Member States to carry out systematic documentary and identity checks at designated entry points on pet animals accompanying their owner during non-commercial movement into a Member State from certain territories or third countries. Those checks should take account of the relevant principles of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules [4]. Where necessary for the purpose of further movement into other Member States, Member States should be required to document the checks in the identification document in order to be able to use the date of these checks to determine the period of validity of the identification document.

(28) In addition, this Regulation should provide for safeguard measures for the purpose of dealing with risks to public or animal health arising from the non-commercial movement of pet animals.

[1] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

[2] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[3] OJ L 79, 30.3.2000, p. 40.

[4] OJ L 165, 30.4.2004, p. 1.

(29) With a view to providing the citizen with clear and accessible information concerning the rules that apply to the non-commercial movement into the Union of pet animals of the species listed in Annex I, Member States should be required to make that information, in particular the relevant provisions of national law, available to the public.

(30) In order to ensure the proper application of this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of species-specific requirements for the marking of pet animals of the species listed in Part B of Annex I and species-specific preventive health measures against diseases or infections other than rabies affecting the species listed in Annex I, as well as to adopt rules for limiting the number of pet animals of the species listed in Part B of Annex I accompanying their owner during non-commercial movement and to amend Annexes II to IV. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(31) In addition, the power to adopt acts in accordance with the urgency procedure should be delegated to the Commission in duly justified cases of risks to public or animal health in respect of preventive health measures against diseases or infections other than rabies likely to affect pet animals of the species listed in Annex I.

(32) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission with respect to the list of Member States or parts thereof that have equivalent favourable status with regard to rabies and that are authorised to conclude mutual agreements to derogate from certain conditions applicable to the non-commercial movement of pet animals, the list of Member States categorised in accordance with the rules concerning preventive health measures against diseases and infections other than rabies, the lists of territories and third countries established for the purpose of derogating from certain conditions applicable to non-commercial movement, the model for the identification documents that are to accompany pet animals of the species listed in Annex I during non-commercial movement into a Member State from another Member State or from a territory or a third country, the rules on the format, layout and languages of the declarations to be signed, and the safeguard measures in the event of the occurrence or spread of rabies or of a disease or infection other than rabies. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [1].

(33) The Commission should adopt immediately applicable implementing acts updating the list of Member States or parts thereof, with equivalent favourable status with regard to rabies, that are authorised to conclude mutual agreements to derogate from certain conditions applicable to the non-commercial movement of pet animals and the list of territories or third countries established for the purpose of derogating from certain conditions applicable to non-commercial movement, and regarding safeguard measures in the event of the occurrence or spread of rabies or of a disease or infection other than rabies, where, in duly justified cases, related to animal and public health, imperative grounds of urgency so require.

(34) Certain failures to comply with the rules laid down in Regulation (EC) No 998/2003 have been revealed in a number of Member States. Accordingly, Member States should lay down rules on penalties applicable to infringements of this Regulation.

(35) Commission Decision 2003/803/EC of 26 November 2003 establishing a model passport for the intra-Community movement of dogs, cats and ferrets [2] establishes the model passport for the movement of pet animals of the species dogs, cats and ferrets between Member States under Regulation (EC) No 998/2003. Identification documents issued in accordance with that model passport should, subject to certain conditions, remain valid for the lifespan of a pet animal in order to limit the administrative and financial burden on owners.

(36) Commission Implementing Decision 2011/874/EU of 15 December 2011 laying down the list of third countries and territories authorised for imports of dogs, cats and ferrets and for non-commercial movements of more than five dogs, cats and ferrets into the Union and the model certificates for imports and non-commercial movement of those animals into the Union [3] establishes the model health certificate attesting compliance with the requirements of Regulation (EC) No 998/2003 for the non-commercial movement of five or fewer dogs, cats or ferrets into the Union. For the purpose of ensuring a smooth transition to the new rules laid down in this Regulation, that model certificate should remain valid subject to certain conditions.

[1] OJ L 55, 28.2.2011, p. 13.
[2] OJ L 312, 27.11.2003, p. 1.
[3] OJ L 343, 23.12.2011, p. 65.

(37) Since the objective of this Regulation, namely to lay down animal health requirements for the non-commercial movement of pet animals of the species listed in Annex I in order to prevent or minimise risks to public or animal health arising from such movement, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(38) In order to ensure the simultaneous publication of this Regulation and of the implementing acts regarding the lists of territories and third countries established for the purpose of derogating from certain conditions applicable to non-commercial movement, regarding the model for the identification documents that are to accompany pet animals of the species listed in Part A of Annex I during non-commercial movement into a Member State from another Member State or from a territory or a third country, and regarding the rules on the format, layout and languages of the declarations to be signed, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down the animal health requirements applicable to the non-commercial movement of pet animals and the rules for compliance checks on such movement.

Article 2

Scope

1. This Regulation shall apply to the non-commercial movement of pet animals into a Member State from another Member State or from a territory or a third country.

2. This Regulation shall apply without prejudice to:

(a) Regulation (EC) No 338/97;

(b) any national measures adopted, published and made available to the public by Member States to restrict the movement of certain species or breeds of pet animals on the basis of considerations other than those relating to animal health.

Article 3

Definitions

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

(a) 'non-commercial movement' means any movement which does not have as its aim either the sale of or the transfer of ownership of a pet animal;

(b) 'pet animal' means an animal of a species listed in Annex I accompanying its owner or an authorised person during non-commercial movement, and which remains for the duration of such non-commercial movement under the responsibility of the owner or the authorised person;

(c) 'owner' means a natural person indicated as the owner in the identification document;

(d) 'authorised person' means any natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the pet animal on behalf of the owner;

(e) 'transponder' means a read-only passive radio frequency identification device;

(f) 'identification document' means a document drawn up in accordance with the model set out in implementing acts to be adopted pursuant to this Regulation, that enables the pet animal to be clearly identified and its health status to be checked for compliance with this Regulation;

(g) 'authorised veterinarian' means any veterinarian who has been authorised by the competent authority to carry out specific tasks in accordance with this Regulation or with acts adopted pursuant to this Regulation;

(h) 'official veterinarian' means any veterinarian appointed by the competent authority;

(i) 'documentary check' means verification of the identification document accompanying the pet animal;

(j) 'identity check' means verification for consistency between the identification document and the pet animal and where appropriate, for the presence and conformity of the marking;

(k) 'travellers' point of entry' means any area designated by Member States for the purposes of the checks referred to in Article 34(1).

Article 4

General obligation

Non-commercial movement of pet animals that complies with the animal health requirements laid down in this Regulation shall not be prohibited, restricted or impeded on animal health grounds other than those resulting from the application of this Regulation.

Article 5

Maximum number of pet animals

1. The maximum number of pet animals of the species listed in Part A of Annex I which may accompany the owner or an authorised person during a single non-commercial movement shall not exceed five.

2. By way of derogation from paragraph 1, the maximum number of pet animals of the species listed in Part A of Annex I may exceed five if the following conditions are fulfilled:

(a) the non-commercial movement of pet animals is for the purpose of participating in competitions, exhibitions or sporting events or in training for such events;

(b) the owner or the authorised person submits written evidence that the pet animals are registered either to attend an event referred to in point (a), or with an association organising such events;

(c) the pet animals are more than six months old.

3. Member States may undertake standard spot checks to verify that the information submitted under point (b) of paragraph 2 is correct.

4. Where the maximum number of pet animals referred to in paragraph 1 is exceeded and the conditions referred to in paragraph 2 are not fulfilled, those pet animals shall comply with the animal health requirements laid down in Directive 92/65/EEC for the species concerned and Member States shall ensure that those animals are subject to the veterinary checks provided for in Directives 90/425/EEC or 91/496/EEC, as appropriate.

5. In order to prevent commercial movement of pet animals of the species listed in Part B of Annex I from being fraudulently disguised as non-commercial movement, the Commission shall be empowered to adopt delegated acts in accordance with Article 39 laying down rules setting the maximum number of pet animals of those species that may accompany the owner or an authorised person during a single non-commercial movement.

6. The Commission shall submit a report to the European Parliament and the Council on the implementation of this Article not later than 29 June 2018. The Commission shall, where necessary, propose amendments to this Regulation on the basis of its report.

CHAPTER II

CONDITIONS APPLICABLE TO THE NON-COMMERCIAL MOVEMENT OF PET ANIMALS INTO A MEMBER STATE FROM ANOTHER MEMBER STATE

SECTION 1

Pet animals of the species listed in Part A of Annex I

Article 6

Conditions applicable to the non-commercial movement of pet animals of the species listed in Part A of Annex I

Pet animals of the species listed in Part A of Annex I shall not be moved into a Member State from another Member State unless they fulfil the following conditions:

(a) they are marked in accordance with Article 17(1);

(b) they have received an anti-rabies vaccination that complies with the validity requirements set out in Annex III;

(c) they comply with any preventive health measures for diseases or infections other than rabies adopted pursuant to Article 19(1);

(d) they are accompanied by an identification document duly completed and issued in accordance with Article 22.

Article 7

Derogation from the anti-rabies vaccination condition for young pet animals of the species listed in Part A of Annex I

1. Subject to paragraph 2, Member States may, by way of derogation from point (b) of Article 6, authorise the non-commercial movement into their territory from another Member State of pet animals of the species listed in Part A of Annex I, which are:

(a) either less than 12 weeks old and have not received an anti-rabies vaccination; or

(b) between 12 and 16 weeks old and have received an anti-rabies vaccination, but do not yet meet the validity requirements referred to in point 2(e) of Annex III.

2. The authorisation referred to in paragraph 1 may be granted only if:

(a) either the owner or the authorised person provides a signed declaration that from birth until the time of the non-commercial movement the pet animals have had no contact with wild animals of species susceptible to rabies; or

(b) the pet animals are accompanied by their mother, on whom they still depend, and from the identification document accompanying their mother it can be established that, before their birth, the mother received an anti-rabies vaccination which complied with the validity requirements set out in Annex III.

3. The Commission may, by means of an implementing act, adopt rules on the format, layout and languages of the declarations referred to in point (a) of paragraph 2 of this Article. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 41(2).

Article 8

Derogation from the anti-rabies vaccination condition for pet animals of the species listed in Part A of Annex I

1. By way of derogation from point (b) of Article 6, the direct non-commercial movement between Member States or parts thereof, of pet animals of the species listed in Part A of Annex I that have not been vaccinated against rabies, may be authorised in accordance with the procedure referred to in paragraph 2 upon a joint application by the Member States concerned.

2. The Commission shall, by means of an implementing act, adopt a list of Member States that are authorised to conclude mutual agreements to derogate from point (b) of Article 6 in accordance with paragraph 1 of this Article. That list shall set out the parts of those Member States for which the derogation may apply.

3. In order to be included in the list referred to in paragraph 2, the Member States interested in such a mutual agreement shall submit a joint application to the Commission, including details of the draft agreement, by which they can demonstrate, taking into account the procedures in the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE) for self-declaration as to the freedom of a country or zone from rabies, that they fulfil at least the following conditions:

(a) the applicant Member States shall have in operation ongoing surveillance and reporting systems with regard to rabies;

(b) the applicant Member States, or the parts of their territory for which the application is made, shall have been free of rabies and rabies shall not be known to have been established in wild animals in the territory of the Member States concerned, or parts thereof, for at least the two years prior to the joint application on the basis of the systems referred to in point (a);

(c) the applicant Member States shall have in place efficient and effective control measures to prevent the introduction into and spread within their territory of rabies;

(d) the application of the derogation from point (b) of Article 6 shall be justified and proportionate to the risks to public or animal health associated with the direct non-commercial movement from one of the applicant Member States to the other or part of its territory of non-vaccinated pet animals of the species listed in Part A of Annex I.

The joint application shall contain adequate, reliable and scientifically validated information.

4. The Commission shall, by means of an implementing act, remove Member States from the list referred to in paragraph 2 for the whole or part of their territories should any change in the particulars specified in paragraph 3 no longer support the application of the derogation.

5. The implementing acts referred to in paragraphs 2 and 4 shall be adopted in accordance with the examination procedure referred to in Article 41(2).

6. On duly justified imperative grounds of urgency relating to risks to public or animal health, the Commission shall adopt immediately applicable implementing acts updating the list of Member States or parts thereof referred to in paragraph 2 of this Article in accordance with the procedure referred to in Article 41(3).

SECTION 2

Pet animals of the species listed in Part B of Annex I

Article 9

Conditions applicable to the non-commercial movement of pet animals of the species listed in Part B of Annex I

1. Insofar as the Commission has adopted a delegated act pursuant to Article 19(1) with regard to pet animals of one of the species listed in Part B of Annex I, the non-commercial movement of pet animals of that species into a Member State from another Member State shall be subject to compliance with the conditions laid down in paragraph 2 of this Article.

2. Pet animals of the species referred to in paragraph 1 may be moved into a Member State from another Member State only if they fulfil the following conditions:

(a) they are marked or described according to the requirements adopted pursuant to Article 17(2);

(b) they comply with any preventive health measures for diseases or infections other than rabies adopted pursuant to Article 19(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with Article 29.

3. Pending the adoption of the relevant delegated acts referred to in paragraph 1, Member States may apply national rules to the non-commercial movement of pet animals of the species listed in Part B of Annex I into their territory from another Member State, provided that such rules are:

(a) applied proportionately to the risk to public or animal health associated with the non-commercial movement of the pet animals of those species; and

(b) not stricter than those applied to trade in animals of those species in accordance with Directives 92/65/EEC or 2006/88/EC.

CHAPTER III

CONDITIONS APPLICABLE TO THE NON-COMMERCIAL MOVEMENT OF PET ANIMALS INTO A MEMBER STATE FROM A TERRITORY OR A THIRD COUNTRY

SECTION 1

Pet animals of the species listed in Part A of Annex I

Article 10

Conditions applicable to the non-commercial movement of pet animals of the species listed in Part A of Annex I

1. Pet animals of the species listed in Part A of Annex I shall not be moved into a Member State from a territory or a third country unless they fulfil the following conditions:

(a) they are marked in accordance with Article 17(1);

(b) they have received an anti-rabies vaccination that complies with the validity requirements set out in Annex III;

(c) they have undergone a rabies antibody titration test that complies with the validity requirements set out in Annex IV;

(d) they comply with any preventive health measures for diseases or infections other than rabies adopted pursuant to Article 19(1);

(e) they are accompanied by an identification document duly completed and issued in accordance with Article 26.

2. Pet animals of the species listed in Part A of Annex I may be moved into a Member State from a territory or a third country other than those listed pursuant to Article 13(1) only through a travellers' point of entry listed as required pursuant to Article 34(3).

3. By way of derogation from paragraph 2, Member States may authorise registered military or search-and-rescue dogs to move through a point of entry other than a travellers' point of entry provided that:

(a) the owner or the authorised person has applied in advance for a permit and the Member State has granted such a permit; and

(b) the dogs undergo compliance checks in accordance with Article 34(2) at a place designated by the competent authority for that purpose and in accordance with the arrangements set out in the permit referred to in point (a) of this paragraph.

Article 11

Derogation from the anti-rabies vaccination condition for young pet animals of the species listed in Part A of Annex I

1. Subject to paragraph 2, by way of derogation from point (b) of Article 10(1), Member States may authorise the non-commercial movement into their territory from territories or third countries listed pursuant to Article 13(1) or (2) of pet animals of the species listed in Part A of Annex I, which are:

(a) either less than 12 weeks old and have not received an anti-rabies vaccination; or

(b) between 12 and 16 weeks old and have received an anti-rabies vaccination, but do not yet meet the validity requirements referred to in point 2(e) of Annex III.

2. The authorisation referred to in paragraph 1 may be granted only if:

(a) either the owner or the authorised person provides a signed declaration that from birth until the time of the non-commercial movement the pet animals have had no contact with wild animals of species susceptible to rabies; or

(b) the pet animals are accompanied by their mother, on whom they still depend, and from the identification document accompanying their mother it can be established that, before their birth, the mother received an anti-rabies vaccination which complied with the validity requirements set out in Annex III.

3. The subsequent non-commercial movement into another Member State of pet animals referred to in paragraph 1 of this Article shall be prohibited, except where they are moved in accordance with the conditions laid down in Article 6 or where they have been authorised to be moved in accordance with Article 7 and the Member State of destination has also authorised the movement into its territory from territories or third countries in accordance with paragraph 1 of this Article.

4. The Commission may, by means of an implementing act, adopt rules on the format, layout and languages of the declarations referred to in point (a) of paragraph 2 of this Article. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 41(2).

Article 12

Derogation from the antibody titration test condition for pet animals of the species listed in Part A of Annex I

1. By way of derogation from point (c) of Article 10(1), the antibody titration test shall not be required for pet animals of the species listed in Part A of Annex I that are being moved into a Member State from a territory or a third country listed pursuant to Article 13(1) or (2):

(a) either directly;

(b) following residency exclusively in one or more of those territories or third countries; or

(c) after transit through a territory or a third country other than those listed pursuant to Article 13(1) or (2), provided that the owner or authorised person provides a signed declaration that during such transit the pet animals have had no contact with animals of species susceptible to rabies and remain secured within a means of transport or within the perimeter of an international airport.

2. The Commission may, by means of an implementing act, adopt rules on the format, layout and languages of the declarations referred to in point (c) of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(2).

Article 13

Establishment of a list of territories and third countries

1. The Commission shall, by means of an implementing act, adopt a list of territories and third countries which have made an application for entry on the list in which they demonstrate that for pet animals of the species listed in Part A of Annex I, they apply rules, the content and effect of which are the same as those laid down in Section 1 of Chapter II, this Section and Section 2 of Chapter VI and where applicable the rules adopted pursuant to those rules.

2. The Commission shall, by means of an implementing act, adopt a list of territories and third countries which have made an application for entry on the list in which they demonstrate that for pet animals of the species listed in Part A of Annex I, they fulfil at least the following criteria:

(a) the notification of cases of rabies to the competent authorities is obligatory;

(b) an effective surveillance system for rabies has been in place for at least two years prior to the application, a minimum requirement of which is an on-going early detection programme to ensure investigation and reporting of animals suspected of having rabies;

(c) the structure and organisation of their veterinary and control services, and the powers of such services, the supervision to which they are subject and the means at their disposal, including staff and laboratory capacity, are sufficient to:

(i) apply and enforce national legislation on the non-commercial movement of pet animals effectively; and

(ii) guarantee the validity of the identification documents in the format provided for in Article 25 and issued in accordance with Article 26;

(d) rules on the prevention and control of rabies are in force and implemented effectively to minimise the risk of infection of pet animals, including rules on imports of pet animals from other countries or territories, and where appropriate, on:

(i) the control of the stray dog and cat population;

(ii) the vaccination of domestic animals against rabies, in particular where rabies is present in vampire bats; and

(iii) the control and eradication of rabies in wildlife;

(e) rules are in force on the licensing and marketing of anti-rabies vaccines.

3. The implementing acts referred to in paragraphs 1 and 2 of this Article shall be adopted in accordance with the examination procedure referred to in Article 41(2).

On duly justified imperative grounds of urgency relating to risks to public or animal health, the Commission shall adopt immediately applicable implementing acts updating the list of territories or third countries referred to in paragraphs 1 and 2 of this Article in accordance with the procedure referred to in Article 41(3).

SECTION 2

Pet animals of the species listed in Part B of Annex I

Article 14

Conditions applicable to the non-commercial movement of pet animals of the species listed in Part B of Annex I

1. Insofar as the Commission has adopted a delegated act pursuant to Article 19(1) with regard to pet animals of one of the species listed in Part B of Annex I, the non-commercial movement of pet animals of that species into a Member State from a territory or a third country shall be subject to compliance with the conditions laid down in paragraph 2 of this Article.

2. Pet animals referred to in paragraph 1 may be moved into a Member State from a territory or a third country only if they fulfil the following conditions:

(a) they are marked or described according to the requirements adopted pursuant to Article 17(2);

(b) they comply with any preventive health measures for diseases or infections other than rabies adopted pursuant to Article 19(1);

(c) they are accompanied by an identification document duly completed and issued in accordance with Article 31;

(d) they enter through a travellers' point of entry when coming from a territory or a third country other than those listed pursuant to Article 15.

3. Pending the adoption of the relevant delegated acts referred to in paragraph 1, Member States may apply national rules to the non-commercial movement of pet animals of the species listed in Part B of Annex I into their territory from a territory or a third country, provided that such rules are:

(a) applied proportionately to the risk to public or animal health associated with the non-commercial movement of the pet animals of those species; and

(b) not stricter than those applied to imports of animals of those species in accordance with Directives 92/65/EEC or 2006/88/EC.

Article 15

Establishment of a list of territories and third countries

The Commission may, by means of an implementing act, adopt a list of territories and third countries which have demonstrated that for pet animals of the species listed in Part B of Annex I, they apply rules the content and effect of which are the same as those laid down in Section 2 of Chapter II, this Section and Section 2 of Chapter VI and where applicable the rules adopted pursuant to those rules.

SECTION 3

Derogation from the conditions on the non-commercial movement of pet animals

Article 16

Derogation from the conditions applicable to the non-commercial movement of pet animals between certain countries and territories

By way of derogation from Articles 10 and 14, the non-commercial movement of pet animals between the following countries and territories may continue under the conditions laid down by the national rules of those countries and territories:

(a) San Marino and Italy;

(b) the Vatican and Italy;

(c) Monaco and France;

(d) Andorra and France;

(e) Andorra and Spain;

(f) Norway and Sweden;

(g) Faeroe Islands and Denmark;

(h) Greenland and Denmark.

CHAPTER IV

MARKING AND PREVENTIVE HEALTH MEASURES

SECTION 1

Marking

Article 17

Marking of pet animals

1. Pet animals of the species listed in Part A of Annex I shall be marked by the implantation of a transponder or by a clearly readable tattoo applied before 3 July 2011.

Where the transponder referred to in the first subparagraph does not comply with the technical requirements set out in Annex II, the owner or the authorised person shall provide the means necessary for reading that transponder at the time of any verification of the marking provided for in Article 22(1) and (2), and Article 26, and the identity checks provided for in Article 33 and Article 34(1).

2. Pet animals of the species listed in Part B of Annex I shall be marked or described taking into account the specificities of each species, in such a manner that a link between the pet animal and its corresponding identification document is ensured.

In view of the diversity of species listed in Part B of Annex I, the Commission shall be empowered to adopt delegated acts in accordance with Article 39 concerning such species-specific requirements for marking or describing pet animals of those species, taking into account any relevant national requirements.

Article 18

Qualifications required for implanting transponders in pet animals

Where a Member State intends to allow the implantation of transponders by a person other than a veterinarian, it shall lay down rules on the minimum qualifications that such persons are required to have.

SECTION 2

Preventive health measures for diseases or infections other than rabies

Article 19

Preventive health measures and conditions for their application

1. Where preventive health measures are necessary for the protection of public health or the health of pet animals for controlling diseases or infections other than rabies that are likely to be spread due to the movement of those pet animals, the Commission shall be empowered to adopt delegated acts in accordance with Article 39 concerning species-specific preventive health measures for such diseases or infections.

Where, in the event of risks to public or animal health, imperative grounds of urgency so require, the procedure provided for in Article 40 shall apply to delegated acts adopted pursuant to this paragraph.

2. The species-specific preventive health measures authorised by a delegated act adopted pursuant to paragraph 1 shall be based on adequate, reliable and validated scientific information and applied proportionately to the risk to public or animal health associated with the non-commercial movement of pet animals likely to be affected by diseases or infections other than rabies.

3. The delegated acts provided for in paragraph 1 may also include:

(a) rules for the categorisation of Member States or parts thereof according to their animal health status and their surveillance and reporting systems with regard to certain diseases or infections other than rabies;

(b) the conditions that Member States are to fulfil in order to remain eligible for the application of the preventive health measures referred to in paragraph 2;

(c) the conditions for applying and documenting the preventive health measures referred to in paragraph 2 prior to the non-commercial movement of pet animals;

(d) the conditions for granting derogations in certain specified circumstances from the application of the preventive health measures referred to in paragraph 2.

Article 20

List of Member States or parts thereof referred to in point (a) of Article 19(3)

The Commission may, by means of an implementing act, adopt lists of Member States or parts of the territory of Member States that comply with the rules for the categorisation of Member States or parts thereof referred to in point (a) of Article 19(3). That implementing act shall be adopted in accordance with the examination procedure referred to in Article 41(2).

CHAPTER V

IDENTIFICATION DOCUMENTS

SECTION 1

Identification documents for the non-commercial movement into a Member State from another Member State of pet animals of the species listed in Part A of Annex I

Article 21

Format and content of the identification document referred to in point (d) of Article 6

1. The identification document referred to in point (d) of Article 6 shall be in the format of a passport in accordance with the model to be adopted pursuant to paragraph 2 of this Article and shall contain entries for the insertion of the following information:

(a) the location of the transponder or the tattoo and either the date of application or the date of reading of the transponder or the tattoo, as well as the alphanumeric code displayed by the transponder or the tattoo;

(b) the name, species, breed, sex, colour, date of birth as stated by the owner and any notable or discernable features or characteristics of the pet animal;

(c) the name and contact information of the owner;

(d) the name, contact information and signature of the authorised veterinarian issuing or completing the identification document;

(e) the signature of the owner;

(f) details of the anti-rabies vaccination;

(g) the date of blood sampling for the rabies antibody titration test;

(h) compliance with any preventive health measures for diseases or infections other than rabies;

(i) other relevant information regarding the health status of the pet animal.

2. The Commission shall adopt an implementing act laying down the model referred to in paragraph 1 of this Article as well as requirements concerning the languages, layout and security features of the passport referred to in that paragraph, and the rules necessary for the transition to the model of that passport. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 41(2).

3. The passport referred to in paragraph 1 shall bear a number consisting of the ISO code of the Member State of issue, followed by a unique alphanumeric code.

Article 22

Issuing and completing the identification document referred to in point (d) of Article 6

1. The identification document referred to in point (d) of Article 6 shall be issued by an authorised veterinarian after:

(a) he has verified that the pet animal is marked in accordance with Article 17(1);

(b) he has duly completed the relevant entries in the identification document with the information mentioned in points (a) to (d) of Article 21(1); and

(c) the owner has signed the identification document.

2. After verifying that the pet animal is marked in accordance with Article 17(1), an authorised veterinarian shall complete the relevant entries of the identification document with the information referred to in points (d), (f), (g) and (h) of Article 21(1), thus certifying compliance with the conditions set out in points (b) and (c) of Article 6 and, where applicable, in point (b)(ii) of Article 27.

Notwithstanding the first subparagraph, the entry on the information referred to in point (h) of Article 21(1) may be completed by a veterinarian other than an authorised veterinarian if so permitted by the delegated act adopted pursuant to Article 19(1).

3. The authorised veterinarian issuing the identification document shall keep records of the information referred to in points (a) to (c) of Article 21(1) and in Article 21(3) for a minimum period to be determined by the competent authority, but which shall not be less than three years.

4. Where necessary, compliance with the conditions referred to in paragraph 2 of this Article may be documented in more than one identification document in the format provided for in Article 21(1).

Article 23

Distribution of blank identification documents

1. Competent authorities shall ensure that blank identification documents are distributed only to authorised veterinarians and that their name and contact information are recorded with reference to the number referred to in Article 21(3).

2. The records referred to in paragraph 1 shall be kept for a minimum period to be determined by the competent authority, but which shall not be less than three years.

Article 24

Derogation from the format of the identification document provided for in Article 21(1)

1. By way of derogation from Article 21(1), Member States shall authorise the non-commercial movement into a Member State from another Member State of pet animals of the species listed in part A of Annex I accompanied by the identification document issued in accordance with Article 26.

2. Where necessary, compliance with the requirements referred to in point (c) of Article 6 shall be documented in the identification document referred to in paragraph 1, after completion of the checks provided for in Article 34(1).

SECTION 2

Identification documents for the non-commercial movement into a Member State from a territory or a third country of pet animals of the species listed in Part A of Annex I

Article 25

Format and content of the identification document referred to in point (e) of Article 10(1)

1. The identification document referred to in point (e) of Article 10(1) shall be in the format of an animal health certificate in accordance with the model to be adopted pursuant to paragraph 2 of this Article and shall contain entries for the insertion of the following information:

(a) the location of the transponder or the tattoo and either the date of application or the date of reading of the transponder or the tattoo, as well as the alphanumeric code displayed by the transponder or the tattoo;

(b) the species, breed, date of birth as stated by the owner, sex and colour of the pet animal;

(c) a unique certificate reference number;

(d) the name and contact information of the owner or the authorised person;

(e) the name, contact information and signature of the official or authorised veterinarian issuing the identification document;

(f) details of the anti-rabies vaccination;

(g) the date of blood sampling for the rabies antibody titration test;

(h) compliance with any preventive health measures for diseases or infections other than rabies;

(i) the name and the signature of the representative of the endorsing competent authority;

(j) the name, signature and contact information of the representative of the competent authority carrying out the checks referred to in Article 34 and the date of these checks;

(k) other relevant information regarding the health status of the pet animal.

2. The Commission shall adopt an implementing act laying down the model referred to in paragraph 1 of this Article as well as requirements concerning the languages, the layout and the validity of the animal health certificate referred to in that paragraph. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 41(2).

3. A written declaration signed by the owner or the authorised person confirming that the movement of the pet animal into the Union is a non-commercial movement shall be part of the identification document referred to in point (e) of Article 10(1).

Article 26

Issuing and completing the identification document referred to in point (e) of Article 10(1)

The identification document referred to in point (e) of Article 10(1) shall be issued either by an official veterinarian of the territory or third country of dispatch on the basis of supporting documentation, or by an authorised veterinarian and subsequently endorsed by the competent authority of the territory or third country of dispatch, after the issuing veterinarian:

(a) has verified that the pet animal is marked in accordance with Article 17(1); and

(b) has duly completed the relevant entries of the identification document with the information referred to in points (a) to (h) of Article 25(1), thus certifying compliance with the conditions set out in point (a) of Article 10(1), and where applicable points (b), (c) and (d) of Article 10(1).

Article 27

Derogation from the format of the identification document provided for in Article 25(1)

By way of derogation from Article 25(1), Member States shall authorise the non-commercial movement into their territory of pet animals of the species listed in Part A of Annex I accompanied by the identification document issued in accordance with Article 22 where:

(a) the identification document has been issued in one of the territories or third countries listed pursuant to Article 13(1); or

(b) such pet animals enter a Member State, after movement to or transit through a territory or a third country from a Member State, and the identification document was completed and issued by an authorised veterinarian certifying that, before leaving the Union, the pet animals:

(i) received the anti-rabies vaccination provided for in point (b) of Article 10(1); and

(ii) underwent the rabies antibody titration test provided for in point (c) of Article 10(1), except in the case of the derogation provided for in Article 12.

SECTION 3

Identification documents for the non-commercial movement into a Member State from another Member State of pet animals of the species listed in Part B of Annex I

Article 28

Format and content of the identification document referred to in point (c) of Article 9(2)

1. The Commission may, by means of an implementing act, adopt a model of the identification document referred to in point (c) of Article 9(2) which shall contain entries for the insertion of the following information:

(a) the characteristics of the mark or the description of the pet animal as provided for in Article 17(2);

(b) the species and, where relevant, the breed, the date of birth as stated by the owner, sex and colour of the pet animal;

(c) the name and contact information of the owner;

(d) the name, contact information and signature of the authorised veterinarian issuing or completing the identification document;

(e) the signature of the owner;

(f) details of any preventive health measures for diseases or infections other than rabies;

(g) other relevant information regarding the health status of the pet animal.

2. The implementing act referred to in paragraph 1 of this Article shall also lay down requirements concerning the languages, layout, validity or security features of the identification document referred to in that paragraph. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 41(2).

Article 29

Issuing and completing the identification document referred to in point (c) of Article 9(2)

1. The identification document referred to in point (c) of Article 9(2) shall be issued by an authorised veterinarian after:

(a) he has verified that the pet animal is marked or described in accordance with Article 17(2);

(b) he has duly completed the relevant entries with the information referred to in points (a) to (d) of Article 28(1); and

(c) the owner has signed the identification document.

2. After verifying that the pet animal is marked or described in accordance with Article 17(2), an authorised veterinarian shall complete the relevant entries of the identification document referred to in point (c) of Article 9(2) with the information referred to in points (d) and (f) of Article 28(1), thus certifying compliance with the conditions set out in point (b) of Article 9(2), where applicable.

SECTION 4

Identification documents for the non-commercial movement into a Member State from a territory or a third country of pet animals of the species listed in Part B of Annex I

Article 30

Format and content of the identification document referred to in point (c) of Article 14(2)

1. The Commission may, by means of an implementing act, adopt a model of the identification document referred to in point (c) of Article 14(2) which shall contain entries for the insertion of the following information:

(a) the characteristics of the mark or the description of the pet animal as provided for in Article 17(2);

(b) the species and, where relevant, the breed, date of birth as stated by the owner, sex and colour of the pet animal;

(c) the name and contact information of the owner or the authorised person;

(d) the name, contact information and signature of the issuing official or authorised veterinarian;

(e) a unique certificate reference number;

(f) details of any preventive health measures for diseases or infections other than rabies;

(g) the name and the signature of the representative of the endorsing competent authority;

(h) the name, signature and contact information of the representative of the competent authority carrying out the checks referred to in Article 34 and the date of these checks;

(i) other relevant information regarding the health status of the pet animal.

2. The implementing act referred to in paragraph 1 of this Article shall also lay down requirements concerning the languages, layout and validity of the identification document referred to in that paragraph. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 41(2).

3. A written declaration signed by the owner or the authorised person confirming that the movement of the pet animal into the Union is a non-commercial movement shall be part of the identification document referred to in point (c) of Article 14(2).

Article 31

Issuing and completing the identification document referred to in point (c) of Article 14(2)

The identification document referred to in point (c) of Article 14(2) shall be issued either by an official veterinarian of the territory or third country of dispatch on the basis of supporting documentation, or by an authorised veterinarian and subsequently endorsed by the competent authority of the territory or third country of dispatch after the issuing veterinarian:

(a) has verified that the pet animal is marked or described in accordance with Article 17(2); and

(b) has duly completed the relevant entries of the identification document with the information referred to in points (a) to (f) of Article 30(1), thus certifying compliance with the conditions set out in points (a) and (b) of Article 14(2) where applicable.

CHAPTER VI

COMMON PROVISIONS

SECTION 1

Derogation for the non-commercial movement of pet animals into Member States

Article 32

Derogation from the conditions of Articles 6, 9, 10 and 14

1. By way of derogation from the conditions provided for in Articles 6, 9, 10 and 14, Member States may, in exceptional situations, authorise the non-commercial movement into their territory of pet animals which do not comply with the conditions laid down in those Articles provided that:

(a) a prior application for a permit has been made by the owner and the Member State of destination has granted such a permit;

(b) the pet animals are isolated under official supervision for the time necessary for them to fulfil those conditions and not exceeding six months:

(i) at a place approved by the competent authority; and

(ii) in accordance with the arrangements set out in the permit.

2. The permit referred to in point (a) of paragraph 1 may include an authorisation for transiting through another Member State provided that the Member State of transit has given its prior agreement to the Member State of destination.

SECTION 2

General conditions regarding compliance

Article 33

Documentary and identity checks to be carried out in respect of non-commercial movement of pet animals into a Member State from another Member State or a territory or a third country listed pursuant to Article 13(1) and Article 15

1. Without prejudice to Article 16 and in order to verify compliance with Chapter II, Member States shall carry out documentary and identity checks in a non-discriminatory way on pet animals that are subject to non-commercial movement into their territory from another Member State or from a territory or a third country listed pursuant to Article 13(1) and, where applicable, Article 15.

2. At the time of any non-commercial movement into a Member State from another Member State or a territory or a third country listed pursuant to Article 13(1) and, where applicable, Article 15, the owner or the authorised person shall, at the request of the competent authority responsible for the checks provided for in paragraph 1 of this Article:

(a) present the identification document of the pet animal required under this Regulation which demonstrates compliance with the requirements for such movement; and

(b) make the pet animal available for those checks.

Article 34

Documentary and identity checks to be carried out in respect of non-commercial movement from a territory or a third country other than those listed pursuant to Article 13(1) or Article 15

1. In order to verify compliance with Chapter III, the competent authority of a Member State shall carry out documentary and identity checks at the travellers' point of entry on pet animals that are subject to non-commercial movement into that Member State from a territory or a third country other than those listed pursuant to Article 13(1) and, where applicable, Article 15.

2. The owner or the authorised person shall, at the time of entry into a Member State from a territory or a third country other than those listed pursuant to Article 13(1) and, where applicable, Article 15, contact the competent authority present at the point of entry for the purpose of the checks referred to in paragraph 1 and shall:

(a) present the identification document of the pet animal required under this Regulation which demonstrates compliance with the requirements for such movement; and

(b) make the pet animal available for those checks.

3. Member States shall draw up and keep up to date a list of travellers' points of entry.

4. Member States shall ensure that the competent authority that they have designated to carry out the checks provided for in paragraph 1:

(a) is fully informed of the rules laid down in Chapter III and the officials of the competent authority have the necessary training to implement them;

(b) keeps records of the total number of checks that have been carried out and of instances of non-compliance revealed during those checks; and

(c) documents the checks that have been carried out in the relevant entry of the identification document where such documentation is necessary for the purposes of non-commercial movement into other Member States as provided for in Article 24(1).

Article 35

Actions in case of non-compliance revealed during the checks provided for in Articles 33 and 34

1. Where the checks provided for in Articles 33 and 34 reveal that a pet animal does not comply with the conditions laid down in Chapters II or III, the competent authority shall decide, after consultation with the official veterinarian and, where necessary, with the owner or the authorised person, to:

(a) return the pet animal to its country or territory of dispatch;

(b) isolate the pet animal under official control for the time necessary for it to comply with the conditions laid down in Chapter II or III; or

(c) as a last resort where its return is not possible or isolation is not practical, put the pet animal down in accordance with applicable national rules relating to the protection of pet animals at the time of killing.

2. Where the non-commercial movement of pet animals into the Union is refused by the competent authority, the pet animals shall be isolated under official control pending:

(a) either their return to their country or territory of dispatch; or

(b) the adoption of any other administrative decision concerning those pet animals.

3. The measures referred to in paragraphs 1 and 2 shall be applied at the expense of the owner and without the possibility of any financial compensation for the owner or the authorised person.

Article 36

Safeguard measures

1. Where rabies or a disease or an infection other than rabies occurs or spreads in a Member State, a territory or a third country, and is liable to represent a serious threat to public or animal health, the Commission may, acting on its own initiative or at the request of a Member State, adopt one of the following measures, by means of an implementing act, without delay and depending on the gravity of the situation:

(a) suspend the non-commercial movement or transit of pet animals from all or part of the territory of the Member State or territory or third country concerned;

(b) lay down special conditions in respect of the non-commercial movement of pet animals from all or part of the Member State or territory or third country concerned.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(2).

2. On duly justified imperative grounds of urgency to contain or address a serious risk to public or animal health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 41(3).

Article 37

Information obligations

1. Member States shall provide the public with clear and easily accessible information concerning the animal health requirements applicable to the non-commercial movement of pet animals and the rules for compliance checks on such movement laid down in this Regulation.

2. The information referred to in paragraph 1 shall in particular include the following:

(a) the qualifications required for the persons carrying out the implantation of the transponder provided for in Article 18;

(b) the authorisation to derogate from the anti-rabies vaccination condition for young pet animals of the species listed in Part A of Annex I as provided for in Articles 7 and 11;

(c) the conditions applicable to the non-commercial movement into the Member States' territory of pet animals:

(i) which do not comply with Articles 6, 9, 10 or 14;

(ii) which come from certain countries and territories under conditions laid down by their national rules as provided for in Article 16;

(d) the list of travellers' points of entry drawn up pursuant to Article 34(3), including the competent authority designated to carry out the checks provided for in Article 34(4);

(e) the conditions applicable to the non-commercial movement into the Member States' territory of pet animals of the species listed in Part B of Annex I, laid down by their national rules as provided for in Article 9(3) and Article 14(3);

(f) information on anti-rabies vaccines for which the competent authority of the Member States has granted a marketing authorisation as provided for in point 1(b) of Annex III, and in particular on the corresponding vaccination protocol.

3. Member States shall establish internet-based pages providing the information referred to in paragraph 1 and communicate the internet address of those pages to the Commission.

4. The Commission shall assist the Member States in making that information available to the public by providing on its internet page:

a) the links to the internet-based information pages of the Member States; and

b) the information referred to in points (b), (d) and (e) of paragraph (2) of this Article, and the information made available to the public as referred to in point (b) of Article 2(2) in additional languages, as appropriate.

SECTION 3

Procedural provisions

Article 38

Amendments to Annexes

In order to take into account technical progress, scientific developments and the protection of public health or the health of pet animals, the Commission shall be empowered to adopt delegated acts in accordance with Article 39 to amend Annexes II to IV.

Article 39

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 5(5), the second subparagraph of Article 17(2), the first subparagraph of Article 19(1) and Article 38 shall be conferred on the Commission for a period of five years from 28 June 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 5(5), the second subparagraph of Article 17(2), the first subparagraph of Article 19(1) and Article 38 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Article 5(5), the second subparagraph of Article 17(2), the first subparagraph of Article 19(1) and Article 38 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Article 40

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 39(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 41

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 42

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

The Member States shall notify those provisions and any subsequent amendments affecting them to the Commission without delay.

[1] OJ L 31, 1.2.2002, p. 1.

CHAPTER VII

TRANSITIONAL AND FINAL PROVISIONS

Article 43

Repeal

1. Regulation (EC) No 998/2003 is hereby repealed, with the exception of Section 2 of Part B and Part C of Annex II, which remain in force until the entry into force of the implementing acts adopted pursuant to Article 13(1) and (2) of this Regulation respectively.

References in this Regulation to the list in the implementing acts adopted pursuant to Article 13(1) or (2) shall be construed as references to the list of third countries and territories set out in Section 2 of Part B and in Part C of Annex II to Regulation (EC) No 998/2003 respectively until the entry into force of those implementing acts.

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

3. The repeal of Regulation (EC) No 998/2003 shall be without prejudice to the maintenance in force of Commission Delegated Regulation (EU) No 1152/2011 of 14 July 2011 supplementing Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards preventive health measures for the control of *Echinococcus multilocularis* infection in dogs [2], which was adopted pursuant to the second subparagraph of Article 5(1) of that Regulation.

Article 44

Transitional measures regarding identification documents

1. By way of derogation from Article 21(1), the identification document referred to in point (d) of Article 6 shall be deemed to comply with this Regulation where it was:

(a) drawn up in accordance with the model passport established by Decision 2003/803/EC; and

(b) issued before 29 December 2014.

2. By way of derogation from Article 25(1) and Article 27(a), the identification document referred to in point (e) of Article 10(1) shall be deemed to comply with this Regulation where it was:

(a) drawn up in accordance with the model certificate set out in Annex II to Decision 2011/874/EU, or where relevant, the model passport established by Decision 2003/803/EC; and

(b) issued before 29 December 2014.

[2] OJ L 296, 15.11.2011, p. 6.

Article 45

Entry into force and applicability

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

It shall apply from 29 December 2014.

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

Done at Strasbourg, 12 June 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	L. CREIGHTON

ANNEX I

Species of pet animals

PART A

Dogs (*Canis lupus familiaris*)

Cats (*Felis silvestris catus*)

Ferrets (*Mustela putorius furo*)

PART B

Invertebrates (except bees and bumble bees covered by Article 8 of Directive 92/65/EEC and molluscs and crustaceans referred to respectively in points (e)(ii) and (e)(iii) of Article 3(1) of Directive 2006/88/EC).

Ornamental aquatic animals as defined in point (k) of Article 3 of Directive 2006/88/EC and excluded from the scope of that Directive by point (a) of Article 2(1) thereof.

Amphibia

Reptiles

Birds: specimens of avian species other than those referred to in Article 2 of Directive 2009/158/EC.

Mammals: rodents and rabbits other than those intended for food production and defined under 'lagomorphs' in Annex I to Regulation (EC) No 853/2004.

ANNEX II

Technical requirements for transponders

The transponders must:

(a) comply with ISO Standard 11784 and apply HDX or FDX-B technology; and

(b) be capable of being read by a reading device compatible with ISO Standard 11785.

ANNEX III

Validity requirements for anti-rabies vaccinations

1. The anti-rabies vaccine must:

   (a) be a vaccine other than a live modified vaccine and fall within one of the following categories:

      (i) an inactivated vaccine of at least one antigenic unit per dose (recommendation from the World Health Organisation); or

      (ii) a recombinant vaccine expressing the immunising glycoprotein of the rabies virus in a live virus vector;

   (b) where it is administered in a Member State, it must have been granted a marketing authorisation in accordance with:

      (i) Article 5 of Directive 2001/82/EC; or

      (ii) Article 3 of Regulation (EC) No 726/2004;

   (c) where it is administered in a territory or a third country, have been granted an approval or a licence by the competent authority and meet at least the requirements laid down in the relevant part of the Chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health.

2. An anti-rabies vaccination must fulfil the following conditions:

   (a) the vaccine was administered by an authorised veterinarian;

   (b) the pet animal was at least 12 weeks old at the date on which the vaccine was administered;

   (c) the date of administration of the vaccine is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document;

   (d) the date of administration referred to in point (c) does not precede the date of application of the transponder or tattoo or the date of reading of the transponder or the tattoo indicated in the appropriate section of the identification document;

   (e) the period of validity of the vaccination starts from the establishment of protective immunity, which shall not be less than 21 days from the completion of the vaccination protocol required by the manufacturer for the primary vaccination, and continues until the end of the period of protective immunity, as prescribed in the technical specification of the marketing authorisation referred to in point 1(b) or the approval or licence referred to in point 1(c) for the anti-rabies vaccine in the Member State or territory or third country where the vaccine is administered.

      The period of validity of the vaccination is indicated by an authorised veterinarian or an official veterinarian in the appropriate section of the identification document;

   (f) a revaccination must be considered a primary vaccination if it was not carried out within the period of validity referred to in point (e) of the previous vaccination.

ANNEX IV

Validity requirements for the rabies antibody titration test

1. The collection of the sample of blood necessary to carry out the rabies antibody titration test must be carried out and documented by an authorised veterinarian in the appropriate section of the identification document;

2. The rabies antibody titration test:

   (a) must be carried out on a sample collected at least 30 days after the date of vaccination and:

      (i) not less than three months before the date of:

         — the non-commercial movement from a territory or a third country other than those listed in the implementing acts adopted pursuant to Article 13(1) or (2), or

         — the transit through such a territory or third country, where the conditions laid down in point (c) of Article 12 are not fulfilled, or

      (ii) before the pet animal left the Union for movement to or transit through a territory or a third country other than those listed pursuant to Article 13(1) or (2); the identification document in the format provided for in Article 21(1) must confirm that a rabies antibody titration test was carried out with a favourable result before the date of movement;

   (b) must measure a level of neutralising antibody to rabies virus in serum equal to or greater than 0,5 IU/ml and using a method prescribed in the relevant part of the Chapter concerning rabies in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health;

   (c) must be performed in a laboratory approved in accordance with Article 3 of Decision 2000/258/EC;

   (d) does not have to be renewed following a satisfactory result described in point (b), provided that the pet animal is revaccinated within the period of validity referred to in point 2(e) of Annex III of the previous vaccination.

ANNEX V

Correlation table referred to in Article 43(2)

Regulation (EC) No 998/2003	This Regulation
Article 1	Article 1
First paragraph of Article 2	Article 2(1)
Second paragraph of Article 2	Point (a) of Article 2(2)
Third paragraph of Article 2	Point (b) of Article 2(2)
Point (a) of Article 3	Points (a) and (b) of Article 3
Point (b) of Article 3	Point (f) of Article 3
Point (c) of Article 3	Article 2(1)
First subparagraph of Article 4(1)	
	First subparagraph of Article 17(1)
Second subparagraph of Article 4(1)	Second subparagraph of Article 17(1)
Article 4(2)	—
Article 4(3)	—
Article 4(4)	—
Point (a) of Article 5(1)	Point (a) of Article 6
Point (b) of Article 5(1)	Point (d) of Article 6
Point (b)(i)Article 5(1)	Point (b) of Article 6
Point (b)(ii) of Article 5(1)	Point (c) of Article 6
Second subparagraph of Article 5(1)	Article 19
Article 5(2)	Article 7
Article 6	—
Article 7	Article 5(5), Articles 9, 14 and 28
Article 8(1)	Articles 10 and 12
Article 8(2)	Article 10(1)(e) and Article 27
Point (a) of Article 8(3)	Article 13(1)
Point (b) of Article 8(3)	Article 16
Point (c) of Article 8(3)	Article 11
Article 8(4)	Article 25(1) and (2)
Article 9	Article 14 and Article 30(1) and (2)
First subparagraph of Article 10	Article 13(2)
Second subparagraph of Article 10	Article 13(3)
First sentence of Article 11	Article 37(1)
Second sentence of Article 11	Point (a) of Article 34(4)
Introductory phrase and point (a) of the first subparagraph of Article 12	Article 10(2) and Article 34(1)

Regulation (EC) No 998/2003	This Regulation
Introductory phrase and point (b) of the first subparagraph of Article 12	Article 5(4)
Second subparagraph of Article 12	Article 34(3) and Article 37(2)(d)
Article 13	Article 34(3) and Article 37(2)(d)
First paragraph of Article 14	Point (a) of Article 34(2)
Second paragraph of Article 14	Second subparagraph of Article 17(1)
Third paragraph of Article 14	Article 35(1) and (3)
Fourth paragraph of Article 14	Article 35(2)
Article 15	Points 1 and 2(c) of Annex IV
Article 16	—
First paragraph of Article 17	—
Second paragraph of Article 17	Article 21(1)
First paragraph of Article 18	—
Second paragraph of Article 18	Article 36
Article 19	Article 13(3) and Article 5(5)
Article 19a(1) and (2)	Article 38
Article 19a(3)	—
Article 19b(1)	Article 39(2)
Article 19b(2)	Article 39(4)
Article 19b(3)	Article 39(1)
Article 19c(1) and (3)	Article 39(3)
Article 19c(2)	—
Article 19d(1) and Article 19d(2)	Article 39(5)
Article 19d(3)	—
Articles 20 to 23	—
Article 24(1), (2) and (3)	Article 41(1), (2) and (3)
Article 24(4) and (5)	—
Article 25	Article 45
Annex I	Annex I
Annex Ia	Annex II
Annex Ib	Annex III
Part A and Section 1 of Part B of Annex II	—
Section 2 of Part B of Annex II	Article 13(1)
Part C of Annex II	Article 13(2)

COMMISSION STATEMENT

Within the framework of the European Union Strategy for the Protection and Welfare of Animals [1], the Commission will study the welfare of dogs and cats involved in commercial practices.

If the outcome of that study indicates health risks arising from those commercial practices, the Commission will consider appropriate options for the protection of human and animal health, including proposing to the European Parliament and to the Council appropriate adaptations to current Union legislation on trade in dogs and cats, including the introduction of compatible systems for their registration accessible across Member States.

In light of the above, the Commission will assess the feasibility and appropriateness of an extension of such registration systems to dogs and cats marked and identified in accordance with Union legislation on non-commercial movements of pet animals.

[1] *COM(2012) 6 final/2 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the European Union Strategy for the Protection and Welfare of Animals 2012-2015.*

DIRECTIVES

DIRECTIVE 2013/29/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast)

(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,

After transmission of the draft legislative act to the national parliaments,

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

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

Whereas:

(1) Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles ([3]) has been substantially amended ([4]). Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products ([5]) lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products ([6]) lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2007/23/EC should be adapted to that Decision.

(4) The laws, regulations and administrative provisions in force in the Member States with regard to the making available on the market of pyrotechnic articles are divergent, in particular as regards aspects such as safety and performance characteristics.

(5) The laws, regulations and administrative provisions of Member States, being liable to cause barriers to trade within the Union, need to be harmonised in order to guarantee the free movement of pyrotechnic articles within the internal market while ensuring a high level of protection of human health and safety and the protection of consumers and professional end-users. Such high level of protection should include the relevant age limits associated with users of pyrotechnic articles being adhered to.

([1]) OJ C 181, 21.6.2012, p. 105.
([2]) Position of the European Parliament of 22 May 2013 (not yet published in the Official Journal) and decision of the Council of 10 June 2013.
([3]) OJ L 154, 14.6.2007, p. 1.
([4]) See Annex IV, Part A.
([5]) OJ L 218, 13.8.2008, p. 30.
([6]) OJ L 218, 13.8.2008, p. 82.

(6) Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses [1] excludes pyrotechnic articles from its scope.

(7) Safety during storage is governed by Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances [2] which sets out safety requirements for establishments where explosives, including pyrotechnic substances, are present.

(8) As regards safety in transportation, the rules concerning the transport of pyrotechnic articles are covered by international conventions and agreements, including the United Nations recommendations on the transport of dangerous goods. Those aspects should therefore not fall within the scope of this Directive.

(9) This Directive should apply to all forms of supply, including distance selling.

(10) This Directive should not apply to pyrotechnic articles to which Council Directive 96/98/EC of 20 December 1996 on marine equipment [3] and the relevant international conventions referred to therein apply. It should also not apply to percussion caps intended for toys falling within the scope of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys [4].

(11) Fireworks which are built by a manufacturer for his own use and approved for use exclusively on its territory by the Member State in which the manufacturer is established, and which remain on the territory of that Member State, should not be considered as having been made available on the market and should therefore not need to comply with this Directive.

(12) It should not be possible, where the requirements laid down in this Directive are satisfied, for Member States to prohibit, restrict or hinder the free movement of pyrotechnic articles. This Directive should apply without prejudice to national legislation on the licensing of manufacturers, distributors and importers by the Member States.

(13) Pyrotechnic articles should include fireworks, theatrical pyrotechnic articles and other pyrotechnic articles for technical purposes, such as gas generators used in airbags or in seatbelt pretensioners.

(14) In order to ensure appropriately high levels of protection, pyrotechnic articles should be categorised according to their level of hazard as regards their type of use, purpose or noise level.

(15) Given the dangers inherent in the use of pyrotechnic articles, it is appropriate to lay down age limits for their being made available to persons, and to ensure that their labelling displays sufficient and appropriate information on safe use, in order to protect human health and safety and the environment. Certain pyrotechnic articles should be made available only to persons with the necessary knowledge, skills and experience. With regard to pyrotechnic articles for vehicles, labelling requirements should take into account current practice and the fact that those articles are supplied exclusively to professional users.

(16) The use of pyrotechnic articles and, in particular, the use of fireworks, is subject to markedly divergent cultural customs and traditions in the respective Member States. It is therefore necessary to allow Member States to take national measures to limit the use or sale of certain categories of pyrotechnic articles to the general public for reasons, inter alia, of public security or health and safety.

(17) Economic operators should be responsible for the compliance of pyrotechnic articles with the requirements of this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety and the protection of consumers, and to guarantee fair competition on the Union market.

(18) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market pyrotechnic articles which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

(19) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.

(20) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

[1] OJ L 121, 15.5.1993, p. 20.
[2] OJ L 10, 14.1.1997, p. 13.
[3] OJ L 46, 17.2.1997, p. 25.
[4] OJ L 170, 30.6.2009, p. 1.

(21) It is necessary to ensure that pyrotechnic articles from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those pyrotechnic articles. Provision should therefore be made for importers to make sure that the pyrotechnic articles they place on the market comply with the requirements of this Directive and that they do not place on the market pyrotechnic articles which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of pyrotechnic articles and documentation drawn up by manufacturers are available for inspection by the competent national authorities.

(22) The distributor makes a pyrotechnic article available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that his handling of the pyrotechnic article does not adversely affect the compliance of the pyrotechnic article.

(23) Any economic operator who either places a pyrotechnic article on the market under his own name or trademark or modifies a pyrotechnic article in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(24) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the pyrotechnic article concerned.

(25) When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a pyrotechnic article or to whom they have supplied a pyrotechnic article.

(26) It is appropriate to establish essential safety requirements for pyrotechnic articles in order to protect consumers and to prevent accidents.

(27) Some pyrotechnic articles, particularly pyrotechnic articles for vehicles such as air bag gas generators, contain small amounts of commercial blasting agents and military explosives. Following the adoption of Directive 2007/23/EC it has become obvious that it will not be possible to replace these substances as additives in strictly combustive compositions, where they are used to enhance the energetic balance. The essential safety requirement, which restricts the use of commercial blasting agents and military explosives, should therefore be modified.

(28) In order to facilitate conformity assessment with the essential safety requirements provided for in this Directive, it is necessary to provide for a presumption of conformity for pyrotechnic articles which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council [1] for the purpose of expressing detailed technical specifications of those requirements.

(29) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.

(30) In order to enable economic operators to demonstrate and the competent authorities to ensure that pyrotechnic articles made available on the market comply with the essential safety requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure intersectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.

(31) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a pyrotechnic article with the requirements of this Directive and of other relevant Union harmonisation legislation.

(32) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

[1] OJ L 316, 14.11.2012, p. 12.

(33) The CE marking, indicating the conformity of a pyrotechnic article, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.

(34) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

(35) Experience has shown that the criteria set out in Directive 2007/23/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(36) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(37) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(38) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(39) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the pyrotechnic articles to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.

(40) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.

(41) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(42) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(43) Member States should take all appropriate measures to ensure that pyrotechnic articles may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Pyrotechnic articles should be considered as non-compliant with the essential safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

(44) In order to ensure legal certainty, it is necessary to clarify that the rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to pyrotechnic articles. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.

(45) Groups of pyrotechnic articles that are similar in design, function or behaviour should be assessed by the notified bodies as product families.

(46) A safeguard procedure is necessary to allow the possibility for contesting the conformity of a pyrotechnic article. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

(47) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to pyrotechnic articles presenting a risk to the health or safety of persons or to other aspects of public interest protection. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such pyrotechnic articles.

(48) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(49) It is in the interests of the manufacturer and the importer to supply safe pyrotechnic articles in order to avoid liability costs for defective products causing damage to individuals and private property. In this regard, Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1] complements this Directive, since Directive 85/374/EEC imposes a strict liability regime on manufacturers and importers and ensures an adequate level of protection for consumers. Furthermore, Directive 85/374/EEC provides that notified bodies should be adequately insured in respect of their professional activities, unless their liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.

(50) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [2].

(51) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

(52) The examination procedure should be used for the adoption of implementing acts determining a uniform numbering system for identification of pyrotechnic articles and the practical arrangements for a register with registration numbers of pyrotechnic articles as well as for the regular collection and updating of data on accidents related to pyrotechnic articles.

(53) The examination procedure should also be used for the adoption of implementing acts with respect to compliant pyrotechnic articles which present a risk to the health or safety of persons or to other aspects of public interest protection.

(54) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant pyrotechnic articles which present a risk to the health or safety of persons, imperative grounds of urgency so require.

(55) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

(56) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant pyrotechnic articles are justified or not.

(57) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

(58) Manufacturers and importers need to be given time to exercise any rights under national rules in force before the date of application of national measures transposing this Directive in order, for example, to sell their stocks of manufactured products. It is therefore necessary to provide for reasonable transitional arrangements that allow the making available on the market without the need to comply with further product requirements of pyrotechnic articles that have already been placed on the market in accordance with Directive 2007/23/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply pyrotechnic articles that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

[1] OJ L 210, 7.8.1985, p. 29.
[2] OJ L 55, 28.2.2011, p. 13.

(59) Pyrotechnic articles for vehicles are designed for vehicle life cycles and therefore require special transitional arrangements. It is necessary for such a pyrotechnic article to comply with the requirements of the law applicable at the time it is first made available on the market and for the period of the lifetime of the vehicle in which it is installed.

(60) In order to ensure the uninterrupted use of certain pyrotechnic articles, in particular in the automotive industry, it is necessary to apply point 4 of Annex I from 4 July 2013.

(61) Since the objective of this Directive, namely to ensure that pyrotechnic articles on the market fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market, 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.

(62) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arose under Directive 2007/23/EC.

(63) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directive set out in Annex IV, Part B,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER 1

GENERAL PROVISIONS

Article 1

Subject matter

1. This Directive establishes rules designed to achieve the free movement of pyrotechnic articles in the internal market while ensuring a high level of protection of human health and public security and the protection and safety of consumers and taking into account the relevant aspects related to environmental protection.

2. This Directive establishes the essential safety requirements which pyrotechnic articles are to fulfil with a view to their being made available on the market. Those requirements are set out in Annex I.

Article 2

Scope

1. This Directive shall apply to pyrotechnic articles.

2. This Directive shall not apply to:

(a) pyrotechnic articles intended for non-commercial use, in accordance with national law, by the armed forces, the police or fire departments;

(b) equipment falling within the scope of Directive 96/98/EC;

(c) pyrotechnic articles intended for use in the aerospace industry;

(d) percussion caps intended specifically for toys falling within the scope of Directive 2009/48/EC;

(e) explosives falling within the scope of Directive 93/15/EEC;

(f) ammunition;

(g) fireworks which are built by a manufacturer for his own use and approved for use exclusively on its territory by the Member State in which the manufacturer is established, and which remain on the territory of that Member State.

Article 3

Definitions

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

(1) 'pyrotechnic article' means any article containing explosive substances or an explosive mixture of substances designed to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions;

(2) 'firework' means a pyrotechnic article intended for entertainment purposes;

(3) 'theatrical pyrotechnic articles' means pyrotechnic articles designed for indoor or outdoor stage use, including film and television productions or similar use;

(4) 'pyrotechnic articles for vehicles' means components of safety devices in vehicles which contain pyrotechnic substances used to activate these or other devices;

(5) 'ammunition' means projectiles and propelling charges and blank ammunition used in portable firearms, other guns and artillery;

(6) 'person with specialist knowledge' means a person authorised by a Member State to handle and/or use on its territory category F4 fireworks, category T2 theatrical pyrotechnic articles and/or category P2 other pyrotechnic articles;

(7) 'making available on the market' means any supply of a pyrotechnic article for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(8) 'placing on the market' means the first making available of a pyrotechnic article on the Union market;

(9) 'manufacturer' means a natural or legal person who manufactures a pyrotechnic article, or has such an article designed or manufactured, and markets that pyrotechnic article under his name or trademark;

(10) 'importer' means any natural or legal person established within the Union who places a pyrotechnic article from a third country on the Union market;

(11) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a pyrotechnic article available on the market;

(12) 'economic operators' means the manufacturer, the importer and the distributor;

(13) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a pyrotechnic article;

(14) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

(15) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

(16) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

(17) 'conformity assessment' means the process demonstrating whether the essential safety requirements of this Directive relating to a pyrotechnic article have been fulfilled;

(18) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(19) 'recall' means any measure aimed at achieving the return of a pyrotechnic article that has already been made available to the end-user;

(20) 'withdrawal' means any measure aimed at preventing a pyrotechnic article in the supply chain from being made available on the market;

(21) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

(22) 'CE marking' means a marking by which the manufacturer indicates that the pyrotechnic article is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 4

Free movement

1. Member States shall not prohibit, restrict or hinder the making available on the market of pyrotechnic articles which satisfy the requirements of this Directive.

2. This Directive shall not preclude measures taken by a Member State to prohibit or restrict the possession, use and/or the sale to the general public of category F2 and F3 fireworks, theatrical pyrotechnic articles and other pyrotechnic articles, which are justified on grounds of public order, security, health and safety, or environmental protection.

3. At trade fairs, exhibitions and demonstrations for the marketing of pyrotechnic articles, Member States shall not prevent the showing and use of pyrotechnic articles not in conformity with this Directive, provided that a visible sign clearly indicates the name and date of the trade fair, exhibition or demonstration in question and the non-conformity and non-availability for sale of the pyrotechnic articles until brought into conformity. During such events, appropriate safety measures shall be taken in accordance with any requirements laid down by the competent authority of the Member State concerned.

4. Member States shall not prevent the free movement and use of pyrotechnic articles manufactured for the purpose of research, development and testing and which are not in conformity with this Directive, provided that a visible sign clearly indicates their non-conformity and non-availability for purposes other than research, development and testing.

Article 5

Making available on the market

Member States shall take all appropriate measures to ensure that pyrotechnic articles may be made available on the market only if they satisfy the requirements of this Directive.

Article 6

Categories of pyrotechnic articles

1. Pyrotechnic articles shall be categorised by the manufacturer according to their type of use, or their purpose and level of hazard, including their noise level. The notified bodies referred to in Article 21 shall confirm the categorisation as part of the conformity assessment procedures referred to in Article 17.

Categorisation shall be as follows:

(a) Fireworks:

(i) category F1: fireworks which present a very low hazard and negligible noise level and which are intended for use in confined areas, including fireworks which are intended for use inside domestic buildings;

(ii) category F2: fireworks which present a low hazard and low noise level and which are intended for outdoor use in confined areas;

(iii) category F3: fireworks which present a medium hazard, which are intended for outdoor use in large open areas and whose noise level is not harmful to human health;

(iv) category F4: fireworks which present a high hazard, which are intended for use only by persons with specialist knowledge (commonly known as fireworks for professional use) and whose noise level is not harmful to human health.

(b) Theatrical pyrotechnic articles:

(i) category T1: pyrotechnic articles for stage use which present a low hazard;

(ii) category T2: pyrotechnic articles for stage use which are intended for use only by persons with specialist knowledge.

(c) Other pyrotechnic articles:

(i) category P1: pyrotechnic articles, other than fireworks and theatrical pyrotechnic articles, which present a low hazard;

(ii) category P2: pyrotechnic articles, other than fireworks and theatrical pyrotechnic articles, which are intended for handling or use only by persons with specialist knowledge.

2. Member States shall inform the Commission of the procedures whereby they identify and authorise persons with specialist knowledge.

Article 7

Age limits and other limitations

1. Pyrotechnic articles shall not be made available on the market to persons below the following age limits:

(a) fireworks:

(i) category F1: 12 years;

(ii) category F2: 16 years;

(iii) category F3: 18 years;

(b) theatrical pyrotechnic articles of category T1 and other pyrotechnic articles of category P1: 18 years.

2. Member States may increase the age limits set out in paragraph 1 where justified on grounds of public order, security or health and safety. Member States may also lower the age limits for persons vocationally trained or undergoing such training.

3. Manufacturers, importers and distributors shall not make available on the market the following pyrotechnic articles except to persons with specialist knowledge:

(a) fireworks of category F4;

(b) theatrical pyrotechnic articles of category T2 and other pyrotechnic articles of category P2.

4. Other pyrotechnic articles of category P1 for vehicles, including airbag and seat belt pre-tensioner systems, shall not be made available to members of the general public unless those pyrotechnic articles for vehicles have been incorporated in a vehicle or a detachable vehicle part.

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of the manufacturers

1. When placing their pyrotechnic articles on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I.

2. Manufacturers shall draw up the technical documentation referred to in Annex II and have the relevant conformity assessment procedure referred to in Article 17 carried out.

Where compliance of a pyrotechnic article with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the pyrotechnic article has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in pyrotechnic article design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a pyrotechnic article is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a pyrotechnic article, manufacturers shall, to protect the health and safety of consumers, upon a duly justified request of the competent authorities, carry out sample testing of pyrotechnic articles made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming pyrotechnic articles and pyrotechnic article recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that pyrotechnic articles which they have placed on the market are labelled in accordance with Article 10 or Article 11.

6. Manufacturers shall indicate on the pyrotechnic article their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the pyrotechnic article. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the pyrotechnic article is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that a pyrotechnic article which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that pyrotechnic article into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the pyrotechnic article presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the pyrotechnic article available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the pyrotechnic article with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pyrotechnic articles which they have placed on the market.

Article 9

Traceability

1. In order to facilitate the traceability of pyrotechnic articles, manufacturers shall label them with a registration number assigned by the notified body carrying out the conformity assessment pursuant to Article 17. The numbering shall be done in accordance with a uniform system determined by the Commission.

2. Manufacturers and importers shall maintain records of the registration numbers of the pyrotechnic articles they make available on the market and shall make this information available to the relevant authorities upon request.

Article 10

Labelling of pyrotechnic articles other than pyrotechnic articles for vehicles

1. Manufacturers shall ensure that pyrotechnic articles other than pyrotechnic articles for vehicles are labelled visibly, legibly and indelibly in the official language(s) of the Member State in which the pyrotechnic article is made available to the consumer. Such labelling shall be clear, understandable and intelligible.

2. The labelling of pyrotechnic articles shall include as a minimum the information about the manufacturer set out in Article 8(6) and, where the manufacturer is not established in the Union, the information about the manufacturer and the importer set out in Article 8(6) and Article 12(3) respectively, the name and type of the pyrotechnic article, its registration number and its product, batch or serial number, the minimum age limits set out in Article 7(1) and (2), the relevant category and instructions for use, the year of production for category F3 and F4 fireworks and, where appropriate, a minimum safety distance. The labelling shall include the net explosive content (NEC).

3. Fireworks shall also display the following minimum information:

(a) category F1: where appropriate: 'for outdoor use only' and a minimum safety distance;

(b) category F2: 'for outdoor use only' and, where appropriate, minimum safety distance(s);

(c) category F3: 'for outdoor use only' and minimum safety distance(s);

(d) category F4: 'for use only by persons with specialist knowledge' and minimum safety distance(s).

4. Theatrical pyrotechnic articles shall also display the following minimum information:

(a) category T1: where appropriate: 'for outdoor use only' and minimum safety distance(s);

(b) category T2: 'for use only by persons with specialist knowledge' and minimum safety distance(s).

5. If the pyrotechnic article does not provide sufficient space for the labelling requirements referred to in paragraphs 2, 3 and 4, the information shall be provided on the smallest piece of packaging.

Article 11

Labelling of pyrotechnic articles for vehicles

1. The labelling of pyrotechnic articles for vehicles shall include the information about the manufacturer set out in Article 8(6), the name and type of the pyrotechnic article, its registration number and its product, batch or serial number and, where necessary, the safety instructions.

2. If the pyrotechnic article for vehicles does not provide sufficient space for the labelling requirements referred to in paragraph 1, the information shall be provided on the packaging.

3. A safety data sheet for the pyrotechnic article for vehicles, compiled in accordance with Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency [1] and which takes into account the specific needs of professional users, shall be supplied to those users in the language requested by them.

The safety data sheet may be supplied on paper or electronically, provided that the professional user has the necessary means of accessing it.

Article 12

Obligations of importers

1. Importers shall place only compliant pyrotechnic articles on the market.

2. Before placing a pyrotechnic article on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 17 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the pyrotechnic article bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that a pyrotechnic article is not in conformity with the essential safety requirements set out in Annex I, he shall not place the pyrotechnic article on the market until it has been brought into conformity. Furthermore, where the pyrotechnic article presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate on the pyrotechnic article their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the pyrotechnic article. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the pyrotechnic article is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a pyrotechnic article is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.

[1] OJ L 396, 30.12.2006, p. 1.

6. When deemed appropriate with regard to the risks presented by a pyrotechnic article, importers shall, to protect the health and safety of consumers, upon a duly justified request of the competent authorities, carry out sample testing of pyrotechnic articles made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming pyrotechnic articles and pyrotechnic articles recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a pyrotechnic article which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that pyrotechnic article into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the pyrotechnic article presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the pyrotechnic article available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for 10 years after the pyrotechnic article has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a pyrotechnic article in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pyrotechnic articles which they have placed on the market.

Article 13

Obligations of distributors

1. When making a pyrotechnic article available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making a pyrotechnic article available on the market distributors shall verify that the pyrotechnic article bears the CE marking, that it is accompanied by the required documents, and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the pyrotechnic article is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 12(3) respectively.

Where a distributor considers or has reason to believe that a pyrotechnic article is not in conformity with the essential safety requirements set out in Annex I, he shall not make the pyrotechnic article available on the market until it has been brought into conformity. Furthermore, where the pyrotechnic article presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a pyrotechnic article is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.

4. Distributors who consider or have reason to believe that a pyrotechnic article which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that pyrotechnic article into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the pyrotechnic article presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the pyrotechnic article available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a pyrotechnic article. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by pyrotechnic articles which they have made available on the market.

Article 14

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 8, where he places a pyrotechnic article on the market under his name or trademark or modifies a pyrotechnic article already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

Article 15

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with a pyrotechnic article;

(b) any economic operator to whom they have supplied a pyrotechnic article.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with the pyrotechnic article and for a period of 10 years after they have supplied the pyrotechnic article.

CHAPTER 3

CONFORMITY OF THE PYROTECHNIC ARTICLE

Article 16

Presumption of conformity of pyrotechnic articles

Pyrotechnic articles which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential safety requirements set out in Annex I covered by those standards or parts thereof.

Article 17

Conformity assessment procedures

For the assessment of conformity of pyrotechnic articles the manufacturer shall follow one of the following procedures referred to in Annex II:

(a) EU-type examination (Module B), and, at the choice of the manufacturer, one of the following procedures:

(i) conformity to type based on internal production control plus supervised product checks at random intervals (Module C2);

(ii) conformity to type based on quality assurance of the production process (Module D);

(iii) conformity to type based on product quality assurance (Module E);

(b) conformity based on unit verification (Module G);

(c) conformity based on full quality assurance (Module H), insofar as it concerns fireworks of category F4.

Article 18

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential safety requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex III, shall contain the elements specified in the relevant modules set out in Annex II and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the pyrotechnic article is placed or made available on the market.

3. Where a pyrotechnic article is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the pyrotechnic article with the requirements laid down in this Directive.

Article 19

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 20

Rules and conditions for affixing the CE marking and other markings

1. The CE marking shall be affixed visibly, legibly and indelibly to the pyrotechnic articles. Where that is not possible or not warranted on account of the nature of the pyrotechnic article, it shall be affixed to the packaging and to the accompanying documents.

2. The CE marking shall be affixed before the pyrotechnic article is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer.

4. The CE marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 21

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

Article 22

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 27.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

Article 23

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 24

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto. The Commission shall make that information publicly available.

Article 25

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the pyrotechnic article it assesses.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of pyrotechnic articles and/or explosive substances nor the representative of any of those parties. This shall not preclude the use of pyrotechnic articles and/or explosive substances that are necessary for the operations of the conformity assessment body or the use of pyrotechnic articles for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of pyrotechnic articles and/or explosive substances, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of pyrotechnic articles in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasksshall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 26

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 25 in so far as the applicable harmonised standards cover those requirements.

Article 27

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 25 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex II.

Article 28

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the pyrotechnic article or articles for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 25.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 25.

Article 29

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 25.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and pyrotechnic article or articles concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 28(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 25.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 30

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 31

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 25 or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 32

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

Article 33

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the pyrotechnic article with the requirements of this Directive.

3. Notified bodies carrying out conformity assessments shall assign registration numbers, identifying pyrotechnic articles which have been subject to a conformity assessment and their manufacturers, and shall maintain a register with the registration numbers of pyrotechnic articles for which they have issued certificates.

4. Where a notified body finds that essential safety requirements set out in Annex I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

5. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a pyrotechnic article no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

6. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 34

Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Article 35

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same pyrotechnic articles with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 36

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 37

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a forum of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that forum, directly or by means of designated representatives.

CHAPTER 5

UNION MARKET SURVEILLANCE, CONTROL OF PYROTECHNIC ARTICLES ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 38

Union market surveillance and control of pyrotechnic articles entering the Union market

1. Member States shall take all appropriate measures to ensure that pyrotechnic articles may be placed on the market only if, when properly stored and used for their intended purpose, they do not endanger the health and safety of persons.

2. Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to pyrotechnic articles.

3. Member States shall inform the Commission annually about their market surveillance activities.

Article 39

Procedure for dealing with pyrotechnic articles presenting a risk at national level

1. Where the market surveillance authorities of one Member State have sufficient reasons to believe that a pyrotechnic article presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the pyrotechnic article concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the pyrotechnic article does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the pyrotechnic article into compliance with those requirements, to withdraw the pyrotechnic article from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the pyrotechnic articles concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the pyrotechnic articles being made available on their national market, to withdraw the pyrotechnic article from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant pyrotechnic article, the origin of the pyrotechnic article, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the pyrotechnic article to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in this Directive; or

(b) shortcomings in the harmonised standards referred to in Article 16 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the pyrotechnic article concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the pyrotechnic article from the market, are taken in respect of the pyrotechnic article concerned without delay.

Article 40

Union safeguard procedure

1. Where on completion of the procedure set out in Article 39(3) and (4), objections are raised against measures taken by a Member State, or where the Commission considers that such measures are contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant pyrotechnic article is withdrawn from their national market and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the pyrotechnic article is attributed to a shortcoming in the harmonised standards referred to in point (b) of Article 39(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 41

Compliant pyrotechnic articles which present a risk to health or safety

1. Where, having carried out an evaluation under Article 39(1), a Member State finds that although a pyrotechnic article is in compliance with this Directive, it presents a risk to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the pyrotechnic article concerned, when placed on the market, no longer presents that risk, to withdraw the pyrotechnic article from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the pyrotechnic articles concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the pyrotechnic article concerned, the origin and the supply chain of the pyrotechnic article, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 42

Formal non-compliance

1. Without prejudice to Article 39, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Directive;

(b) the CE marking has not been affixed;

(c) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 20 or has not been affixed;

(d) the EU declaration of conformity has not been drawn up;

(e) the EU declaration of conformity has not been drawn up correctly;

(f) technical documentation is either not available or not complete;

(g) the information referred to in Article 8(6) or Article 12(3) is absent, false or incomplete;

(h) any other administrative requirement provided for in Article 8 or Article 12 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the pyrotechnic article being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER 6

IMPLEMENTING POWERS

Article 43

Implementing acts

The Commission shall, by means of implementing acts, determine:

(a) the uniform numbering system referred to in Article 9(1) and the practical arrangements for the register referred to in Article 33(3);

(b) the practical arrangements for the regular collection and updating of data on accidents related to pyrotechnic articles.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 44

Committee procedure

1. The Commission shall be assisted by the Committee on Pyrotechnic Articles. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

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

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

CHAPTER 7

TRANSITIONAL AND FINAL PROVISIONS

Article 45

Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all the measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

Article 46

Transitional provisions

1. Member States shall not impede the making available on the market of pyrotechnic articles which are in conformity with Directive 2007/23/EC and which were placed on the market before 1 July 2015.

2. National authorisations for fireworks of categories F1, F2 and F3 granted before 4 July 2010 shall continue to be valid on the territory of the Member State having granted the authorisation until their expiry date or until 4 July 2017, whichever is earlier.

3. National authorisations for other pyrotechnic articles, for fireworks of category F4 and for theatrical pyrotechnic articles granted before 4 July 2013 shall continue to be valid on the territory of the Member State having granted the authorisation until their expiry date or until 4 July 2017, whichever is earlier.

4. By way of derogation from paragraph 3, national authorisations for pyrotechnic articles for vehicles, including as spare parts, granted before 4 July 2013 shall continue to be valid until their expiry.

5. Certificates issued under Directive 2007/23/EC shall be valid under this Directive.

Article 47

Transposition

1. Member States shall adopt and publish, by 30 June 2015, the laws, regulations and administrative provisions necessary to comply with points 7, 12, 13 and 15 to 22 of Article 3, Article 4(1), Article 5, Article 7(4), Article 8(2) to (9), Article 9, Article 10(2), Article 11(1) and (3), Articles 12 to 16, Articles 18 to 29, Articles 31 to 35, Article 37, Article 38(1) and (2), Articles 39 to 42, Article 45, Article 46 and Annexes I, II and III. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 1 July 2015.

2. By way of derogation from paragraph 1, Member States shall adopt and publish by 3 October 2013 the laws, regulations and administrative provisions necessary to comply with point 4 of Annex I. They shall forthwith communicate the text of those measures to the Commission. They shall apply those measures from 4 July 2013.

3. When Member States adopt the measures referred to in paragraphs 1 and 2, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is formulated.

4. 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 48

Repeal

Directive 2007/23/EC, as amended by the act listed in Annex IV, Part A, is repealed with effect from 1 July 2015, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directive set out in Annex IV, Part B.

By way of derogation from the first paragraph of this Article, point 4 of Annex I to Directive 2007/23/EC is repealed with effect from 4 July 2013.

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

Article 49

Entry into force and application

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

Article 1, Article 2, points 1 to 6, 8 to 11 and 14 of Article 3, Article 4(2), (3) and (4), Article 6, Article 7(1), (2) and (3), Article 8(1), Article 10(1), (3) and (4), Article 11(2), Articles 17, 30 and 36, Article 38(3), Articles 43 and 44 and Annexes IV and V shall apply from 1 July 2015.

Article 50

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 12 June 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	L. CREIGHTON

ANNEX I

ESSENTIAL SAFETY REQUIREMENTS

1. Each pyrotechnic article must attain the performance characteristics specified by the manufacturer to the notified body in order to ensure maximum safety and reliability.

2. Each pyrotechnic article must be designed and manufactured in such a way that it can be disposed of safely by a suitable process with minimum effect on the environment.

3. Each pyrotechnic article must function correctly when used for its intended purpose.

   Each pyrotechnic article must be tested under realistic conditions. If this is not possible in a laboratory, the tests must be carried out in the conditions in which the pyrotechnic article is to be used.

   The following information and properties — where applicable — must be considered or tested:

   (a) design, construction and characteristic properties, including detailed chemical composition (mass and percentage of substances used) and dimensions;

   (b) the physical and chemical stability of the pyrotechnic article in all normal, foreseeable environmental conditions;

   (c) sensitivity to normal, foreseeable handling and transportation;

   (d) compatibility of all components as regards their chemical stability;

   (e) resistance of the pyrotechnic article to moisture where it is intended to be used in humid or wet conditions and where its safety or reliability may be adversely affected by moisture;

   (f) resistance to low and high temperatures, where the pyrotechnic article is intended to be kept or used at such temperatures and its safety or reliability may be adversely affected by cooling or heating of a component or of the pyrotechnic article as a whole;

   (g) safety features intended to prevent untimely or inadvertent initiation or ignition;

   (h) suitable instructions and, where necessary, markings in respect of safe handling, storage, use (including safety distances) and disposal;

   (i) the ability of the pyrotechnic article, its wrapping or other components to withstand deterioration under normal, foreseeable storage conditions;

   (j) specification of all devices and accessories needed and operating instructions for safe functioning of the pyrotechnic article.

   During transportation and normal handling, unless specified by the manufacturer's instructions, the pyrotechnic articles should contain the pyrotechnic composition.

4. Pyrotechnic articles must not contain detonative explosives other than black powder and flash composition, except for pyrotechnic articles of categories P1, P2, T2 and fireworks of category F4 meeting the following conditions:

   (a) the detonative explosive cannot be easily extracted from the pyrotechnic article;

   (b) for category P1, the pyrotechnic article cannot function in a detonative manner, or cannot, as designed and manufactured, initiate secondary explosives;

   (c) for categories F4, T2 and P2, the pyrotechnic article is designed and intended not to function in a detonative manner, or, if designed to detonate, it cannot as designed and manufactured initiate secondary explosives.

5. The various groups of pyrotechnic articles must at least also comply with the following requirements:

A. **Fireworks**

1. The manufacturer must assign fireworks to different categories according to Article 6 characterised by net explosive content, safety distances, noise level, or similar. The category must be clearly indicated on the label.

(a) For category F1 fireworks, the following conditions must be met:

(i) the safety distance must be at least 1 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance,

(iii) category F1 must not comprise bangers, banger batteries, flash bangers and flash banger batteries,

(iv) throwdowns in category F1 must not contain more than 2,5 mg silver fulminate.

(b) For category F2 fireworks, the following conditions must be met:

(i) the safety distance must be at least 8 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance.

(c) For category F3 fireworks, the following conditions must be met:

(i) the safety distance must be at least 15 m. However, where appropriate the safety distance may be less,

(ii) the maximum noise level must not exceed 120 dB (A, imp), or an equivalent noise level as measured by another appropriate method, at the safety distance.

2. Fireworks may only be constructed of materials which minimise risk to health, property and the environment from debris.

3. The method of ignition must be clearly visible or must be indicated by labelling or instructions.

4. Fireworks must not move in an erratic and unforeseeable manner.

5. Fireworks of categories F1, F2 and F3 must be protected against inadvertent ignition either by a protective cover, by the packaging, or by the construction of the pyrotechnic article. Fireworks of category F4 must be protected against inadvertent ignition by methods specified by the manufacturer.

B. **Other pyrotechnic articles**

1. Pyrotechnic articles must be designed in such a way as to minimise risk to health, property and the environment during normal use.

2. The method of ignition must be clearly visible or must be indicated by labelling or instructions.

3. The pyrotechnic article must be designed in such a way as to minimise risk to health, property and the environment from debris when initiated inadvertently.

4. Where appropriate, the pyrotechnic article must function properly until the 'use by' date specified by the manufacturer.

C. **Ignition devices**

1. Ignition devices must be capable of being reliably initiated and be of sufficient initiation capability under all normal, foreseeable conditions of use.

2. Ignition devices must be protected against electrostatic discharge under normal, foreseeable conditions of storage and use.

3. Electric igniters must be protected against electromagnetic fields under normal, foreseeable conditions of storage and use.

4. The covering of fuses must be of adequate mechanical strength and adequately protect the explosive filling when exposed to normal, foreseeable mechanical stress.

5. The parameters for the burning times of fuses must be provided with the pyrotechnic article.

6. The electrical characteristics (e.g. no-fire current, resistance, etc.) of electric igniters must be provided with the pyrotechnic article.

7. The wires of electric igniters must be sufficiently insulated and must be of sufficient mechanical strength, including the solidity of the link to the igniter, taking account of their intended use.

ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

MODULE B: **EU-type examination**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a pyrotechnic article and verifies and attests that the technical design of the pyrotechnic article meets the requirements of this Directive that apply to it.

2. EU-type examination shall be carried out as an assessment of the adequacy of the technical design of the pyrotechnic article through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete product (combination of production type and design type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

   The application shall include:

   (a) the name and address of the manufacturer;

   (b) a written declaration that the same application has not been lodged with any other notified body;

   (c) the technical documentation. The technical documentation shall make it possible to assess the pyrotechnic article's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pyrotechnic article. The technical documentation shall contain, wherever applicable, at least the following elements:

      (i) a general description of the pyrotechnic article;

      (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

      (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;

      (iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive including a list of other relevant technical specifications applied. In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

      (v) results of design calculations made, examinations carried out, etc.;

      (vi) test reports;

   (d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

   (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

   For the pyrotechnic article:

4.1. Examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the pyrotechnic article.

For the specimen(s):

4.2. Verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. Carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;

4.4. Carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer, including those in other relevant technical specifications applied, meet the corresponding essential safety requirements of this Directive;

4.5. Agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive that apply to the pyrotechnic article concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pyrotechnic articles with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the pyrotechnic article with the essential safety requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market.

MODULE C2: **Conformity to type based on internal production control plus supervised product checks at random intervals**

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pyrotechnic articles with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. Product checks

A notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the pyrotechnic article, taking into account, inter alia, the technological complexity of the pyrotechnic articles and the quantity of production. An adequate sample of the final products, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the pyrotechnic article with the type described in the EU-type examination certificate and with the relevant requirements of this Directive. Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pyrotechnic article performs within acceptable limits, with a view to ensuring conformity of the pyrotechnic article.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual pyrotechnic article that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

MODULE D: **Conformity to type based on quality assurance of the production process**

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pyrotechnic articles concerned.

The application shall include:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the pyrotechnic article category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2. The quality system shall ensure that the pyrotechnic articles are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; and

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e) to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body.

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

MODULE E: **Conformity to type based on product quality assurance**

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pyrotechnic articles concerned.

The application shall include the following information:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the pyrotechnic article category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2. The quality system shall ensure compliance of the pyrotechnic articles with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

(d) the means of monitoring the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e), in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

MODULE G: **Conformity based on unit verification**

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the pyrotechnic article concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the pyrotechnic article's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pyrotechnic article. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the pyrotechnic article;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;

(d) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pyrotechnic article has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pyrotechnic article with the applicable requirements of this Directive.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the pyrotechnic article with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved pyrotechnic article, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each pyrotechnic article that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

MODULE H: **Conformity based on full quality assurance**

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned satisfy the requirements of this Directive that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice for the pyrotechnic articles concerned.

The application shall include:

(a) the name and address of the manufacturer;

(b) the technical documentation for one model of each pyrotechnic article category intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the pyrotechnic article;

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;

— a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

— results of design calculations made, examinations carried out, etc.;

— test reports;

(c) the documentation concerning the quality system;

(d) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the pyrotechnic articles with the applicable requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential safety requirements of this Directive will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the pyrotechnic articles pertaining to the pyrotechnic article category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

The manufacturer shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records as provided for by the design part of the quality system such as the results of analyses, calculations, tests, etc.;

(c) the quality records as provided for by the manufacturing part of the quality system such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The EU declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

(a) the technical documentation referred to in point 3.1;

(b) the documentation concerning the quality system referred to in point 3.1;

(c) the information relating to the change referred to in point 3.5, as approved;

(d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

ANNEX III

EU DECLARATION OF CONFORMITY (No XXXX) [1]

1. Registration number in accordance with Article 9:

2. Product, batch or serial number:

3. Name and address of the manufacturer:

4. This declaration of conformity is issued under the sole responsibility of the manufacturer.

5. Object of the declaration (identification of product allowing traceability):

6. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

7. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

8. The notified body … (name, number) performed … (description of intervention) and issued the certificate:

9. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

[1] It is optional for the manufacturer to assign a number to the declaration of conformity.

ANNEX IV

PART A

Repealed Directive with the amendment thereto

(referred to in Article 48)

Directive 2007/23/EC of the European Parliament and of the Council (OJ L 154, 14.6.2007, p. 1).	
Regulation (EU) No 1025/2012 of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).	Only point (h) of Article 26(1)

PART B

Time-limits for transposition into national law and dates of application

(referred to in Article 48)

Directive	Time-limit for transposition	Date of application
2007/23/EC	4 January 2010	4 July 2010 (fireworks of categories F1, F2 and F3) 4 July 2013 (fireworks of category F4, other pyrotechnic articles and theatrical pyrotechnic articles)

ANNEX V

CORRELATION TABLE

Directive 2007/23/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)
Article 1(3)	Article 2(1)
Article 1(4)(a)	Article 2(2)(a)
Article 1(4)(b)	Article 2(2)(b)
Article 1(4)(c)	Article 2(2)(c)
Article 1(4)(d)	Article 2(2)(d)
Article 1(4)(e)	Article 2(2)(e)
Article 1(4)(f)	Article 2(2)(f) and Article 3(5)
Article 2(1)	Article 3(1)
Article 2(2), first sentence	Article 3(8)
Article 2(2), second sentence	Article 2(2)(g)
Article 2(3)	Article 3(2)
Article 2(4)	Article 3(3)
Article 2(5)	Article 3(4)
Article 2(6)	Article 3(9)
Article 2(7)	Article 3(10)
Article 2(8)	Article 3(11)
Article 2(9)	Article 3(14)
Article 2(10)	Article 3(6)
—	Article 3(7)
—	Article 3(12)
—	Article 3(13)
—	Article 3(15) to (22)
Article 3(1)	Article 6(1)
Article 3(2)	Article 6(2)
Article 4(1)	Article 8(1)
Article 4(2), first subparagraph	Article 12(1) to (9) and Article 14
Article 4(2), second subparagraph	Article 14
Article 4(3)	Article 13(1) and Article 13(2), first subparagraph
—	Article 13(2), second subparagraph
—	Article 13(3)

Directive 2007/23/EC	This Directive
—	Article 13(4)
—	Article 13(5)
Article 4(4)(a)	Article 8(2), first subparagraph
Article 4(4)(b)	Article 8(2), second subparagraph, and Article 8(5)
—	Article 8(3), (4) and (6) to (9)
—	Article 15
—	Article 9
Article 5(1)	Article 5
Article 5(2)	—
Article 6(1)	Article 4(1)
Article 6(2)	Article 4(2)
Article 6(3)	Article 4(3)
Article 6(4)	Article 4(4)
Article 7(1)	Article 7(1)
Article 7(2)	Article 7(2)
Article 7(3)	Article 7(3)
—	Article 7(4)
Article 8(1)	—
Article 8(2)	—
Article 8(3), first sentence	—
Article 8(3), second sentence	Article 16
Article 8(3), third sentence	—
Article 8(4)	—
Article 9	Article 17
—	Article 18
Article 10(1)	Article 21 and Article 30(1)
Article 10(2)	Article 30(2)
Article 10(3)	Articles 25 and 26
Article 10(4)	Article 31(1)
Article 10(5)	Article 31(2)
Article 10(6)	—
—	Articles 22 to 24
—	Articles 27 to 29
	Articles 32 to 37

Directive 2007/23/EC	This Directive
Article 11(1)	Article 20(1)
Article 11(2)	Article 19
Article 11(3)	Article 19
—	Article 20(2)
	Article 20(3)
—	Article 20(4)
—	Article 20(5)
Article 12(1)	Article 10(1)
Article 12(2)	Article 10(2)
Article 12(3)	Article 10(3)
Article 12(4)	Article 10(4)
Article 12(5)	Article 10(5)
Article 12(6)	—
Article 13(1)	Article 11(1)
Article 13(2)	Article 11(2)
Article 13(3)	Article 11(3)
Article 14(1)	Article 38(1)
Article 14(2)	Article 38(2)
Article 14(3)	Article 38(2)
Article 14(4)	Article 38(2)
Article 14(5)	Article 38(3)
Article 14(6)	Article 38(2)
Article 14(7)	Article 38(2)
Article 15	Article 39(1), first subparagraph
—	Article 39(1), second, third and fourth subparagraphs
—	Article 39(2) to (8)
Article 16(1)	Article 40(1), first subparagraph
Article 16(2)	Article 40(2) and (3)
Article 16(3)	Article 42(1)(a)
—	Article 40(1), second subparagraph
—	Article 41
—	Article 42(1)(b) to (h) and Article 42(2)
Article 17(1)	Article 38(2)
Article 17(2)	Article 38(2)

Directive 2007/23/EC	This Directive
Article 18(1)	—
Article 18(2)	Article 43
Article 19	Article 44
Article 20	Article 45
—	Article 46(1)
Article 21(1)	Article 47(1), first subparagraph
Article 21(2)	Article 47(1), second subparagraph
—	Article 47(2)
Article 21(3)	Article 47(3)
Article 21(4)	Article 47(4)
Article 21(5)	Article 46(2) and (3)
Article 21(6)	Article 46(4)
—	Article 46(5)
—	Article 48
Article 22	Article 49
Article 23	Article 50
Annex I(1)	Annex I, point 1
Annex I(2)	Annex I, point 2
Annex I(3)	Annex I, point 3
Annex I(4)(a)	Annex I, point 4
Annex I(4)(b)	Annex I, point 4
Annex I(5)	Annex I, point 5
Annex II(1)	Annex II, Module B
Annex II(2)	Annex II, Module C2
Annex II(3)	Annex II, Module D
Annex II(4)	Annex II, Module E
Annex II(5)	Annex II, Module G
Annex II(6)	Annex II, Module H
Annex III	Article 25
Annex IV	Article 19
—	Annex III
—	Annex IV
—	Annex V

DIRECTIVE 2013/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

on safety of offshore oil and gas operations and amending Directive 2004/35/EC

(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 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

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) Article 191 of the Treaty on the Functioning of the European Union establishes the objectives of preserving, protecting and improving the quality of the environment and the prudent and rational utilisation of natural resources. It creates an obligation for all Union action to be supported by a high level of protection based on the precautionary principle, and on the principles that preventive action needs to be taken, that environmental damage needs as a matter of priority to be rectified at source and that the polluter must pay.

(2) The objective of this Directive is to reduce as far as possible the occurrence of major accidents relating to offshore oil and gas operations and to limit their consequences, thus increasing the protection of the marine environment and coastal economies against pollution, establishing minimum conditions for safe offshore exploration and exploitation of oil and gas and limiting possible disruptions to Union indigenous energy production, and to improve the response mechanisms in case of an accident.

([1]) OJ C 143, 22.5.2012, p. 125.

([2]) Position of the European Parliament of 21 May 2013 (not yet published in the Official Journal) and decision of the Council of 10 June 2013.

(3) This Directive should apply not only to future offshore oil and gas installations and operations but, subject to transitional arrangements, also to existing installations.

(4) Major accidents relating to offshore oil and gas operations are likely to have devastating and irreversible consequences on the marine and coastal environment as well as significant negative impacts on coastal economies.

(5) Accidents relating to offshore oil and gas operations, in particular the accident in the Gulf of Mexico in 2010, have raised public awareness of the risks involved in offshore oil and gas operations and have prompted a review of policies aimed at ensuring the safety of such operations. The Commission launched a review of offshore oil and gas operations and expressed its initial views on the safety thereof in its Communication 'Facing the challenge of the safety of offshore oil and gas activities' on 13 October 2010. The European Parliament adopted resolutions on the topic on 7 October 2010 and 13 September 2011. Energy Ministers of the Member States expressed their views in the Conclusions of the Council of 3 December 2010.

(6) The risks relating to major offshore oil or gas accidents are significant. By reducing the risk of pollution of offshore waters, this Directive should therefore contribute to ensuring the protection of the marine environment and in particular to achieving or maintaining good environmental status by 2020 at the latest, an objective set out in Directive 2008/56/EC of the European Parliament and the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) ([3]).

(7) Directive 2008/56/EC aims to address, as one of its central purposes, the cumulative impacts from all activities on the marine environment, and is the environmental pillar of the Integrated Maritime Policy. That policy is relevant to offshore oil and gas operations as it requires the linking of particular concerns from each economic sector with the general aim of ensuring a comprehensive understanding of the oceans, seas and coastal areas, with the objective of developing a coherent approach to the seas taking into account all economic, environmental and social aspects through the use of maritime spatial planning and marine knowledge.

([3]) OJ L 164, 25.6.2008, p. 19.

(8) Offshore oil and gas industries are established in a number of regions of the Union, and there are prospects for new regional developments in offshore waters of Member States, with technological developments allowing for drilling in more challenging environments. Production of offshore oil and gas is a significant element in security of the Union's energy supply.

(9) The existing divergent and fragmented regulatory framework applying to safety of offshore oil and gas operations in the Union and current industry safety practices do not provide a fully adequate assurance that the risk of offshore accidents is minimised throughout the Union, and that in the event of an accident occurring in offshore waters of Member States, the most effective response would be deployed in a timely manner. Under existing liability regimes, the party responsible may not always be clearly identifiable and may not be able, or liable, to pay all the costs to remedy the damage it has caused. The party responsible should always be clearly identifiable before offshore oil and gas operations are commenced.

(10) Pursuant to Directive 94/22/EC of the European Parliament and of the Council of 30 May 1994 on the conditions for granting and using authorizations for the prospection, exploration and production of hydrocarbons [1] offshore oil and gas operations in the Union may be carried out subject to obtaining an authorisation. In this context the licensing authority is required to consider the technical and financial risks, and where appropriate, the previous record of responsibility, of applicants seeking exclusive exploration and production licences. There is the need to ensure that when examining the technical and financial capability of the licensee the licensing authority thoroughly examine also its capability for ensuring continued safe and effective operations under all foreseeable conditions. When assessing the financial capability of entities applying for authorisation pursuant to Directive 94/22/EC, Member States should verify that such entities have provided appropriate evidence that adequate provisions have been or are to be made to cover liabilities deriving from major accidents.

(11) There is a need to clarify that holders of authorisations for offshore oil and gas operations pursuant to Directive 94/22/EC are also the liable 'operators' within the meaning of Directive 2004/35/EC of the European Parliament and the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage [2], and should not delegate their responsibilities in this regard to third parties contracted by them.

(12) While general authorisations pursuant to Directive 94/22/EC guarantee to the licensees exclusive rights for exploring for or producing oil or gas within a given licensed area, offshore oil and gas operations within that area should be subject to continuous expert regulatory oversight by Member States in order to ensure there are effective controls in place for preventing major accidents, and limiting their impacts to persons, the environment, and security of energy supply.

(13) Offshore oil and gas operations should be conducted only by operators appointed by licensees or licensing authorities. The operator can be a third party or the licensee or one of the licensees depending on commercial arrangements or national administrative requirements. The operator should always be the entity with the primary responsibility for safety of operations and should be at all times competent to act in that regard. That role differs depending on the particular stage of activities covered by the licence. The operator's role is therefore to operate a well at the exploration stage and to operate a production installation at the production stage. It should be possible for the operator of a well at the exploration stage and the operator of a production installation to be the same entity for a given licensed area.

(14) Operators should reduce the risk of a major accident as low as reasonably practicable, to the point where the cost of further risk reduction would be grossly disproportionate to the benefits of such reduction. The reasonable practicability of risk reduction measures should be kept under review in the light of new knowledge and technology developments. In assessing whether the time, cost and effort would be grossly disproportionate to the benefits of further reducing the risk, regard should be had to best practice risk levels compatible with the operations being conducted.

(15) It is important to ensure that the public is given early and effective opportunity to participate in the decision-making relating to operations that can potentially have significant effects on the environment in the Union. This policy is in line with the Union's international commitments, such as the UN/ECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters [3] (the Aarhus Convention). Article 6 of the Aarhus Convention provides for public participation in decisions on the specific activities listed in Annex I thereto and on activities not listed there which may have a significant effect on the environment. Article 7 of the Aarhus Convention requires public participation concerning plans and programmes relating to the environment.

[1] OJ L 164, 30.6.1994, p. 3.
[2] OJ L 143, 30.4.2004, p. 56.
[3] OJ L 124, 17.5.2005, p. 4.

(16) Relevant requirements exist in Union legal acts in relation to the development of plans and projects, in particular in Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment ([1]), Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment ([2]), Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment ([3]) and Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances ([4]). However, not all exploratory offshore oil and gas operations are covered by existing Union requirements on public participation. This applies in particular to the decision-making that aims or could lead to exploration operations being commenced from a non-production installation. However, such exploration operations may in some circumstances potentially have significant effects on the environment and the decision-making should therefore be the subject of public participation as required under the Aarhus Convention.

(17) Within the Union, there are already examples of good standards in national regulatory practices relating to offshore oil and gas operations. However, these are inconsistently applied throughout the Union and no Member State has yet incorporated all of the best regulatory practices in its legislation for preventing major accidents or limiting the consequences for human life and health, and for the environment. Best regulatory practices are necessary to deliver effective regulation which secures the highest safety standards and protects the environment, and can be achieved, inter alia, by integrating related functions into a competent authority that may draw resources from one or more national bodies.

(18) In accordance with Council Directive 92/91/EEC of 3 November 1992 concerning the minimum requirements for improving the safety and health protection of workers in the mineral-extracting industries through drilling (eleventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ([5]), workers and/or their representatives should be consulted on matters relating to safety and health at work and be allowed to take part in discussions on all questions relating to safety and health at work. In addition, best practice in the Union is for consultation mechanisms to be formally established by Member States on a tripartite basis comprising the competent authority, operators and owners, and worker representatives. An example of such formal consultation is the International Labour Organisation Tripartite Consultation (International Labour Standards) Convention, 1976 (No 144).

(19) Member States should ensure that the competent authority is legally empowered and adequately resourced to be capable of taking effective, proportionate and transparent enforcement action, including where appropriate cessation of operations, in cases of unsatisfactory safety performance and environmental protection by operators and owners.

(20) The independence and objectivity of the competent authority should be ensured. In this regard, experience gained from major accidents shows clearly that the organisation of administrative competences within a Member State can prevent conflicts of interest by a clear separation between regulatory functions and associated decisions relating to offshore safety and the environment, and to the regulatory functions relating to the economic development of offshore natural resources including licensing and revenues management. Such conflicts of interest are best prevented by a complete separation of the competent authority from the functions relating to the economic development of offshore natural resources.

(21) However, complete separation of the competent authority from economic development of offshore natural resources may be disproportionate where there is a low level of offshore oil and gas operations in a Member State. In such a case, the Member State concerned would be expected to make the best alternative arrangements to secure the independence and objectivity of the competent authority.

(22) Specific legislation is needed to address the major hazards relating to the offshore oil and gas industry, specifically in process safety, safe containment of hydrocarbons, structural integrity, prevention of fire and explosion, evacuation, escape and rescue, and limiting environmental impact following a major accident.

(23) This Directive should apply without prejudice to any requirements under any other Union legal acts, especially in the field of safety and health of workers at work, in particular Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([6]) and Directive 92/91/EEC.

([1]) OJ L 197, 21.7.2001, p. 30.
([2]) OJ L 156, 25.6.2003, p. 17.
([3]) OJ L 26, 28.1.2012, p. 1.
([4]) OJ L 197, 24.7.2012, p. 1.
([5]) OJ L 348, 28.11.1992, p. 9.
([6]) OJ L 183, 29.6.1989, p. 1.

(24) An offshore regime needs to apply both to operations carried out on fixed installations and to those on mobile installations, and to the lifecycle of exploration and production activities from design to decommissioning and permanent abandonment.

(25) The best practices currently available for major accident prevention in offshore oil and gas operations are based on a goal-setting approach and on achieving desirable outcomes through thorough risk assessment and reliable management systems.

(26) According to the best practices in the Union, operators and owners are encouraged to establish effective corporate safety and environmental policies and to give effect to them in a comprehensive safety and environmental management system and emergency response plan. In order to make suitable arrangements for major accident prevention, operators and owners should comprehensively and systematically identify all major accident scenarios relating to all hazardous activities that may be carried out on that installation, including impacts on the environment arising from a major accident. Those best practices also require an assessment of the likelihood and consequences and therefore the risk of major accidents, and also the measures necessary to prevent them and the measures necessary for emergency response, should a major accident nonetheless occur. The risk assessments and arrangements for major accident prevention should be clearly described and compiled in the report on major hazards. The report on major hazards should be complementary to the safety and health document referred to in Directive 92/91/EEC. The workers should be consulted at the relevant stages of the preparation of the report on major hazards. The report on major hazards should have to be thoroughly assessed and accepted by the competent authority.

(27) In order to maintain the effectiveness of major hazard controls in offshore waters of Member States, the report on major hazards should be prepared and, as necessary, amended in respect of any significant aspect of the lifecycle of a production installation, including design, operation, operations when combined with other installations, relocation of such installation within the offshore waters of the Member State in question, major modifications, and final abandonment. Similarly, the report on major hazards should also be prepared in respect of non-production installations and amended as necessary to take into account significant changes to the installation. No installation should be operated in offshore waters of Member States unless the competent authority has accepted the report on major hazards submitted by the operator or owner. Acceptance by the competent authority of the report on major hazards should not imply any transfer of responsibility for control of major hazards from the operator or the owner to the competent authority.

(28) Well operations should be undertaken only by an installation which is technically capable of controlling all the foreseeable hazards at the well location, and in respect of which a report on major hazards has been accepted.

(29) In addition to using a suitable installation, the operator should prepare a detailed design plan and an operating plan pertinent to the particular circumstances and hazards of each well operation. In accordance with best practices in the Union, the operator should provide for independent expert examination of the well design. The operator should send a notification of well plans to the competent authority in sufficient time for the competent authority to take any necessary action in respect of the planned well operation. In this respect, Member States may introduce more stringent national requirements prior to the commencement of a well operation.

(30) To ensure safety in design and continuous safe operations, the industry is required to follow the best practices defined in authoritative standards and guidance. Such standards and guidance should be updated based on new knowledge and invention to ensure continuous improvement. Operators, owners and competent authorities should collaborate to establish priorities for the creation of new or improved standards and guidance in the light of the Deepwater Horizon accident experience and other major accidents. Having due regard to the established priorities the preparation of new or improved standards and guidance should be commissioned without delay.

(31) In view of the complexity of offshore oil and gas operations, the implementation of the best practices by the operators and owners requires a scheme of independent verification of safety and environmental critical elements throughout the lifecycle of the installation, including, in the case of production installations, the design stage.

(32) In so far as mobile offshore drilling units are in transit and are to be considered as ships, they are subject to international maritime conventions, in particular, SOLAS, MARPOL or the equivalent standards of the applicable version of the Code for the construction and equipment of mobile offshore drilling units (MODU Code). Such mobile offshore drilling units when in transit in offshore waters are also subject to Union law concerning port State control and compliance with flag State requirements. This Directive addresses such units when they are stationed in offshore waters for drilling, production or other activities associated with offshore oil and gas operations.

(33) The report on major hazards should, inter alia, take into account risks to the environment, including the impact of climatic conditions and climate change on the long term resilience of the installations. Given that offshore oil and gas operations in one Member State can have significant adverse environmental effects in another Member State, it is necessary to establish and apply specific provisions in accordance with the UN/ECE Convention on Environmental Impact Assessment in a Transboundary Context done at Espoo (Finland), on 25 February 1991. Member States with offshore waters that are inactive in offshore oil and gas operations should appoint contact points in order to facilitate effective cooperation in this regard.

(34) Operators should notify Member States without delay if a major accident occurs, or may be about to occur, so that the Member State can initiate a response as appropriate. Therefore, operators should include in the notification suitable and sufficient particulars concerning the location, magnitude and nature of the actual or imminent major accident, their own response, and the worst case escalation scenario including transboundary potential.

(35) In order to ensure effective response to emergencies, operators should prepare internal emergency response plans that are site specific and based on risks and hazard scenarios identified in the report on major hazards, submit them to their competent authority, and maintain such resources as are necessary for prompt execution of those plans when needed. In the case of mobile offshore drilling units, operators need to ensure that the owners' internal emergency response plans for the installation are amended as necessary to be applicable to the specific location and well operation hazards. Such amendments should be included in the notification of well operations. The adequate availability of emergency response resources should be assessed against the capacity to deploy them at the site of an accident. The readiness and effectiveness of emergency response resources should be assured and regularly tested by the operators. Where duly justified, response arrangements are allowed to be reliant on speedily transporting the response equipment such as capping devices, and other resources, from distant locations.

(36) Best global practice requires licensees, operators and owners to take primary responsibility for controlling the risks they create by their operations, including operations conducted by contractors on their behalf and therefore to establish within a corporate major accident prevention policy the mechanisms and highest level of corporate ownership to implement that policy consistently throughout the organisation in the Union and outside of the Union.

(37) Responsible operators and owners should be expected to conduct their operations worldwide in accordance with best practices and standards. Consistent application of such best practices and standards should become mandatory within the Union, and it would be desirable for operators and owners registered in the territory of a Member State to apply the corporate major accident prevention policy when operating outside offshore waters of Member States as far as possible within the applicable national legal framework.

(38) While recognising that it may not be possible to enforce application of the corporate major accident prevention policy outside of the Union, Member States should ensure that operators and owners include their offshore oil and gas operations outside of the Union in their corporate major accident prevention policy documents.

(39) Information on major accidents in offshore oil and gas operations outside the Union can help in further understanding their potential causes, in promoting learning of key lessons and in further developing the regulatory framework. Therefore, all Member States, including the landlocked Member States and the Member States with offshore waters which do not have offshore oil and gas operations or licensing activities, should require reports on major accidents occurring outside the Union which involve companies registered in their territory, and should share this information at Union level. The reporting requirement should not interfere with emergency response or the legal proceedings relating to an accident. Instead they should focus on the relevance of the accident for further developing the safety of offshore oil and gas operations in the Union.

(40) Member States should expect operators and owners, in following best practices, to establish effective cooperative relationships with the competent authority, supporting best regulatory practice by the competent authority and to proactively ensure the highest levels of safety, including, where necessary, suspending operations without the competent authority needing to intervene.

(41) To ensure that no relevant safety concerns are overlooked or ignored, it is important to establish and encourage adequate means for the confidential reporting of those concerns and the protection of whistleblowers. While Member States are not able to enforce rules outside the Union, those means should enable the reporting of concerns of persons involved in offshore oil and gas operations outside the Union.

(42) The sharing of comparable data between Member States is rendered difficult and unreliable due to the lack of a common data reporting format across all Member States. A common format for the reporting of data by operators

and owners to the Member State would provide transparency of the safety and environmental performance of operators and owners and would provide public access to relevant and Union-wide comparable information on safety of offshore oil and gas operations and would facilitate dissemination lessons learned from major accidents and near misses.

(43) In order to ensure uniform conditions for sharing information and encouraging transparency of performance of the offshore oil and gas sector, implementing powers should be conferred on the Commission regarding the format and details of information to be shared and to be made publicly available. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers ([1]).

(44) The advisory procedure should be used for the adoption of relevant implementing acts given that those acts are mainly of a mere practical nature. Therefore, the application of the examination procedure would not be justified.

(45) To facilitate public confidence in the authority and integrity of offshore oil and gas operations in the Union, Member States should provide periodic reports of activity and incidents to the Commission. The Commission should publish reports periodically on levels of Union activity and trends in the safety and environmental performance of the offshore oil and gas sector. Member States should, without delay, inform the Commission, and any other Member State whose territory or offshore waters are affected, as well as the public concerned, of a major accident.

(46) Experience shows that ensuring the confidentiality of sensitive data is necessary in order to foster an open dialogue between the competent authority and the operator and owner. To that effect the dialogue between operators and owners and all Member States should be based on relevant existing international legal instruments and Union law on access to environmentally relevant information subject to any overriding requirement for safety and environment protection.

(47) The value of collaboration between offshore authorities has been clearly established by the activities of the North Sea Offshore Authorities Forum and the International Regulators Forum. Similar collaboration has been established across the Union in an expert group, the European Union Offshore Oil and Gas Authorities Group (EUOAG) ([2]), whose task is to promote efficient collaboration between national representatives and the Commission, including disseminating best practices and operational intelligence, establishing priorities for raising standards, and for advising the Commission on regulatory reform.

(48) Emergency response and contingency planning for major accidents should be made more effective by systematic and planned cooperation between Member States and between Member States and the oil and gas industry, as well as by sharing compatible emergency response assets including expertise. Where appropriate, those responses and planning should also make use of the existing resources and assistance available from within the Union, in particular through the European Maritime Safety Agency ('the Agency'), established by Regulation (EC) No 1406/2002 ([3]), and the Union Civil Protection Mechanism, established by the Council Decision 2007/779/EC, Euratom ([4]). Member States should also be allowed to request additional assistance from the Agency through the Union Civil Protection Mechanism.

(49) Pursuant to Regulation (EC) No 1406/2002, the Agency was established for the purpose of ensuring a high, uniform and effective level of maritime safety and prevention of pollution by ships within the Union as well as ensuring a response to marine pollution caused by oil and gas installations.

(50) In implementing the obligations under this Directive, account should be taken of the fact that marine waters covered by the sovereignty or sovereign rights and jurisdiction of Member States form an integral part of the four marine regions identified in Article 4(1) of Directive 2008/56/EC, namely the Baltic Sea, the North-east Atlantic Ocean, the Mediterranean Sea and the Black Sea. For this reason, the Union should, as a matter of priority, strengthen coordination with third countries that have sovereignty or sovereign rights and jurisdiction over marine waters in such marine regions. Appropriate cooperation frameworks include regional sea conventions, as defined in point 10 of Article 3 of Directive 2008/56/EC.

(51) In relation to the Mediterranean Sea, in conjunction with this Directive, the necessary actions were undertaken for the Union to accede to the Protocol for the Protection of the Mediterranean Sea against Pollution Resulting from

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

([2]) Commission Decision of 19 January 2012 on setting up of the European Union Offshore Oil and Gas Authorities Group (OJ C 18, 21.1.2012, p. 8).

([3]) Regulation (EC) No 1406/2002 of the European Parliament and of the Council of 27 June 2002 establishing a European Maritime Safety Agency (OJ L 208, 5.8.2002, p. 1).

([4]) OJ L 314, 1.12.2007, p. 9.

Exploration and Exploitation of the Continental Shelf and the Seabed and its Subsoil [1] ('the Offshore Protocol') to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean ('the Barcelona Convention'), which was concluded by Council Decision 77/585/EEC [2].

(52) The Arctic waters are a neighbouring marine environment of particular importance for the Union, and play an important role in mitigating climate change. The serious environmental concerns relating to the Arctic waters require special attention to ensure the environmental protection of the Arctic in relation to any offshore oil and gas operation, including exploration, taking into account the risk of major accidents and the need for effective response. Member States who are members of the Arctic Council are encouraged to actively promote the highest standards with regard to environmental safety in this vulnerable and unique ecosystem, such as through the creation of international instruments on prevention, preparedness and response to Arctic marine oil pollution, and through building, inter alia, on the work of the Task Force established by the Arctic Council and the existing Arctic Council Offshore Oil and Gas Guidelines.

(53) National external emergency plans should be based on risk assessment, taking into account the reports on major hazards for the installations stationed in the offshore waters concerned. Member States should take into account the most up-to-date Risk Assessment and Mapping Guidelines for Disaster Management as prepared by the Commission.

(54) Effective response to emergencies requires immediate action by the operator and owner and close cooperation with Member States' emergency response organisations which coordinate the introduction of additional emergency response resources as the situation develops. Such response should also include a thorough investigation of the emergency which should commence without delay so as to ensure minimum loss of relevant information and evidence. Following an emergency, Member States should draw up appropriate conclusions and take any necessary measures.

(55) It is crucial that all relevant information, including the technical data and parameters, are available for the later investigation. Member States should ensure that relevant data are collected during the offshore oil and gas operations and that in the event of a major accident, relevant data are secured and data collection is intensified appropriately. In this context, Member States should encourage the use of suitable technical means in order to promote the reliability and recording of relevant data and to prevent possible manipulation thereof.

(56) In order to ensure effective implementation of the requirements of this Directive, effective, proportionate and dissuasive penalties for infringements should be put in place.

(57) In order to adapt certain Annexes to include additional information which may become necessary in light of technical progress, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the requirements in certain Annexes to this Directive. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(58) The definition of water damage in Directive 2004/35/EC should be amended to ensure that the liability of licensees under that Directive applies to marine waters of Member States as defined in Directive 2008/56/EC.

(59) Many provisions of this Directive are not relevant for the landlocked Member States, namely Austria, the Czech Republic, Hungary, Luxembourg and Slovakia. It is nonetheless desirable that those Member States promote the principles and high standards existing in Union law for the safety of offshore oil and gas operations in their bilateral contacts with third countries and with relevant international organisations.

(60) Not all Member States with offshore waters allow for offshore oil and gas operations under their jurisdiction. Those Member States are not engaged in the licensing and prevention of major accidents of such operations. It would therefore be a disproportionate and unnecessary obligation if those Member States had to transpose and implement all provisions of this Directive. However, accidents during offshore oil and gas operations may affect their shores. Therefore, those Member States should, inter alia, be prepared to respond to and investigate major accidents and should cooperate through contact points with other Member States concerned and with relevant third countries.

[1] Council Decision of 17 December 2012 on the accession of the European Union to the Protocol for the Protection of the Mediterranean Sea against pollution resulting from exploration and exploitation of the continental shelf and the seabed and its subsoil (OJ L 4, 9.1.2013, p. 13).

[2] OJ L 240, 19.9.1977, p. 1.

(61) Given their geographical location, landlocked Member States are neither engaged in the licensing of, and prevention of major accidents in, offshore oil and gas operations nor are they potentially affected by such accidents in offshore waters of other Member States. Therefore, they should not have to transpose the majority of provisions of this Directive. However, where a company that is active, itself or through subsidiaries, in offshore oil and gas operations outside the Union is registered in a landlocked Member State, that Member State should request that company to provide a report on accidents occurring in such operations, which can be shared at Union level, in order for all the interested parties in the Union to benefit from the experience gained from such accidents.

(62) Apart from the measures introduced by this Directive, the Commission should explore other appropriate means of improving the prevention of major accidents and limiting their consequences.

(63) Operators should ensure they have access to sufficient physical, human and financial resources to prevent major accidents and limit the consequences of such accidents. However, as no existing financial security instruments, including risk pooling arrangements, can accommodate all possible consequences of major accidents, the Commission should undertake further analysis and studies of the appropriate measures to ensure an adequately robust liability regime for damages relating to offshore oil and gas operations, requirements on financial capacity including availability of appropriated financial security instruments or other arrangements. This may include an examination of the feasibility of a mutual compensation scheme. The Commission should submit a report to the European Parliament and to the Council on its findings, accompanied if appropriate, by proposals.

(64) At Union level, it is important that technical standards are complemented by a corresponding legal framework of product safety legislation and that such standards apply to all offshore installations in offshore waters of Member States, and not just non-mobile production installations. The Commission should therefore undertake further analysis of the product safety standards applicable to offshore oil and gas operations.

(65) Since the objective of this Directive, namely establishing minimum requirements for preventing major accidents in offshore oil and gas operations and limiting the consequences of such accidents, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of the proposed 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 Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Subject and scope

1. This Directive establishes minimum requirements for preventing major accidents in offshore oil and gas operations and limiting the consequences of such accidents.

2. This Directive shall be without prejudice to Union law concerning safety and health of workers at work, in particular Directives 89/391/EEC and 92/91/EEC.

3. This Directive shall be without prejudice to Directives 94/22/EC, 2001/42/EC, 2003/4/EC [1], 2003/35/EC, 2010/75/EU [2] and 2011/92/EU.

Article 2

Definitions

For the purpose of this Directive:

(1) 'major accident' means, in relation to an installation or connected infrastructure:

(a) an incident involving an explosion, fire, loss of well control, or release of oil, gas or dangerous substances involving, or with a significant potential to cause, fatalities or serious personal injury;

(b) an incident leading to serious damage to the installation or connected infrastructure involving, or with a significant potential to cause, fatalities or serious personal injury;

(c) any other incident leading to fatalities or serious injury to five or more persons who are on the offshore installation where the source of danger occurs or who are engaged in an offshore oil and gas operation in connection with the installation or connected infrastructure; or

[1] Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information (OJ L 41, 14.2.2003, p. 26).

[2] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

(d) any major environmental incident resulting from incidents referred to in points (a), (b) and (c).

For the purposes of determining whether an incident constitutes a major accident under points (a), (b) or (d), an installation that is normally unattended shall be treated as if it were attended;

(2) 'offshore' means situated in the territorial sea, the Exclusive Economic Zone or the continental shelf of a Member State within the meaning of the United Nations Convention on the Law of the Sea;

(3) 'offshore oil and gas operations' means all activities associated with an installation or connected infrastructure, including design, planning, construction, operation and decommissioning thereof, relating to exploration and production of oil or gas, but excluding conveyance of oil and gas from one coast to another;

(4) 'risk' means the combination of the probability of an event and the consequences of that event;

(5) 'operator' means the entity appointed by the licensee or licensing authority to conduct offshore oil and gas operations, including planning and executing a well operation or managing and controlling the functions of a production installation;

(6) 'suitable' means right or fully appropriate, including consideration of proportionate effort and cost, for a given requirement or situation, based on objective evidence and demonstrated by an analysis, comparison with appropriate standards or other solutions used in comparable situations by other authorities or industry;

(7) 'entity' means any natural or legal person or any group of such persons;

(8) 'acceptable', in relation to a risk, means a level of risk for which the time, cost or effort of further reducing it would be grossly disproportionate to the benefits of such reduction. In assessing whether the time, cost or effort would be grossly disproportionate to the benefits of further reducing the risk, regard shall be had to best practice risk levels compatible with the undertaking;

(9) 'licence' means an authorisation for offshore oil and gas operations pursuant to Directive 94/22/EC;

(10) 'licensed area' means the geographical area covered by the licence;

(11) 'licensee' means the holder or joint holders of a licence;

(12) 'contractor' means any entity contracted by the operator or owner to perform specific tasks on behalf of the operator or owner;

(13) 'licensing authority' means the public authority which is responsible for granting authorisations or for monitoring the use of authorisations as provided for in Directive 94/22/EC;

(14) 'competent authority' means the public authority, appointed pursuant to this Directive and responsible for the duties assigned to it in this Directive. The competent authority may be comprised of one or more public bodies;

(15) 'exploration' means drilling into a prospect and all related offshore oil and gas operations necessary prior to production-related operations;

(16) 'production' means offshore extraction of oil and gas from the underground strata of the licensed area including offshore processing of oil and gas and its conveyance through connected infrastructure;

(17) 'non-production installation' means an installation other than an installation used for production of oil and gas;

(18) 'the public' means one or more entities and, in accordance with national legislation or practice, their associations, organisations or groups;

(19) 'installation' means a stationary, fixed or mobile facility, or a combination of facilities permanently inter-connected by bridges or other structures, used for offshore oil and gas operations or in connection with such operations. Installations include mobile offshore drilling units only when they are stationed in offshore waters for drilling, production or other activities associated with offshore oil and gas operations;

(20) 'production installation' means an installation used for production;

(21) 'connected infrastructure' means, within the safety zone or within a nearby zone of a greater distance from the installation at the discretion of the Member State:

(a) any well and associated structures, supplementary units and devices connected to the installation;

(b) any apparatus or works on or fixed to the main structure of the installation;

(c) any attached pipeline apparatus or works;

(22) 'acceptance', in relation to the report on major hazards, means the communication in writing by the competent authority to the operator or the owner that the report, if implemented as set out therein, meets the requirements of this Directive. Acceptance does not imply any transfer of responsibility for control of major hazards to the competent authority;

(23) 'major hazard' means a situation with the potential to result in a major accident;

(24) 'well operation' means any operation concerning a well that could result in the accidental release of materials that has the potential to lead to a major accident, including the drilling of a well, the repair or modification of a well, the suspension of well operations and the permanent abandonment of a well;

(25) 'combined operation' means an operation carried out from an installation with another installation or installations for purposes related to the other installation(s) which thereby materially affects the risks to the safety of persons or the protection of the environment on any or all of the installations;

(26) 'safety zone' means the area within a distance of 500 metres from any part of the installation, established by the Member State;

(27) 'owner' means an entity legally entitled to control the operation of a non-production installation;

(28) 'internal emergency response plan' means a plan prepared by the operator or owner pursuant to the requirements of this Directive concerning the measures to prevent escalation or limit the consequences of a major accident relating to offshore oil and gas operations;

(29) 'independent verification' means an assessment and confirmation of the validity of particular written statements by an entity or an organisational part of the operator or the owner that is not under the control of or influenced by, the entity or the organisational part using those statements;

(30) 'material change' means:

(a) in the case of a report on major hazards, a change to the basis on which the original report was accepted including, inter alia, physical modifications, availability of new knowledge or technology and operational management changes;

(b) in the case of a notification of well operations or combined operations, a change to the basis on which the original notification was submitted including, inter alia, physical modifications, replacement of one installation with another, availability of new knowledge or technology and operational management changes;

(31) 'commencement of operations' means the point in time when the installation or connected infrastructure is involved for the first time in the operations for which it is designed;

(32) 'oil spill response effectiveness' means the effectiveness of spill response systems in responding to an oil spill, on the basis of an analysis of the frequency, duration, and timing of environmental conditions that would preclude a response. The assessment of oil spill response effectiveness is to be expressed as a percentage of time that such conditions are not present and is to include a description of the operating limitations placed on the installations concerned as a result of that assessment;

(33) 'safety and environmental critical elements' means parts of an installation, including computer programmes, the purpose of which is to prevent or limit the consequences of a major accident, or the failure of which could cause or contribute substantially to a major accident;

(34) 'tripartite consultation' means a formal arrangement to enable dialogue and cooperation between the competent authority, operators and owners, and workers' representatives;

(35) 'industry' means entities that are directly involved in offshore oil and gas operations covered by this Directive or whose activities are closely related to those operations;

(36) 'external emergency response plan' means a local, national or regional strategy to prevent escalation or limit the consequences of a major accident relating to offshore oil and gas operations using all resources available to the operator as described in the relevant internal emergency response plan, and any supplementary resources made available by the Member States;

(37) 'major environmental incident' means an incident which results, or is likely to result, in significant adverse effects on the environment in accordance with Directive 2004/35/EC.

CHAPTER II

PREVENTION OF MAJOR ACCIDENTS RELATING TO OFFSHORE OIL AND GAS OPERATIONS

Article 3

General principles of risk management in offshore oil and gas operations

1. Member States shall require operators to ensure that all suitable measures are taken to prevent major accidents in offshore oil and gas operations.

2. Member States shall ensure that operators are not relieved of their duties under this Directive by the fact that actions or omissions leading or contributing to major accidents were carried out by contractors.

3. In the case of a major accident, Member States shall ensure that operators take all suitable measures to limit its consequences for human health and for the environment.

4. Member States shall require operators to ensure that offshore oil and gas operations are carried out on the basis of systematic risk management so that the residual risks of major accidents to persons, the environment and offshore installations are acceptable.

Article 4

Safety and environmental considerations relating to licences

1. Member States shall ensure that decisions on granting or transferring licences to carry out offshore oil and gas operations take into account the capability of an applicant for such a licence to meet the requirements for operations within the framework of the licence as required by the relevant provisions of Union law, in particular this Directive.

2. In particular, when assessing the technical and financial capability of the applicant for a licence, due account shall be taken of the following:

(a) the risk, the hazards and any other relevant information relating to the licensed area concerned, including, where appropriate, the cost of degradation of the marine environment referred to in point (c) of Article 8(1) of Directive 2008/56/EC;

(b) the particular stage of offshore oil and gas operations;

(c) the applicant's financial capabilities, including any financial security, to cover liabilities potentially deriving from the offshore oil and gas operations in question including liability for potential economic damages where such liability is provided for by national law;

(d) the available information relating to the safety and environmental performance of the applicant, including in relation to major accidents, as may be appropriate to the operations for which the licence was requested.

Before granting or transferring a licence for offshore oil and gas operations, the licensing authority shall consult, where appropriate, the competent authority.

3. Member States shall ensure that the licensing authority does not grant a licence unless it is satisfied with evidence from the applicant that the applicant has made or will make adequate provision, on the basis of arrangements to be decided by Member States, to cover liabilities potentially deriving from the applicant's offshore oil and gas operations. Such provision shall be valid and effective from the start of offshore oil and gas operations. Member State shall require applicants to provide, in an appropriate manner, evidence of technical and financial capacity and any other relevant information relating to the area covered by the licence and the particular stage of offshore oil and gas operations.

Member States shall assess the adequacy of provisions referred to in the first subparagraph in order to establish whether the applicant has sufficient financial resources for the immediate launch and uninterrupted continuation of all measures necessary for effective emergency response and subsequent remediation.

Member States shall facilitate the deployment of sustainable financial instruments and other arrangements to assist applicants for licences in demonstrating their financial capacity pursuant to the first subparagraph.

Member States shall, as a minimum, establish procedures for ensuring prompt and adequate handling of compensation claims including in respect of compensation payments for transboundary incidents.

The Member States shall require the licensee to maintain sufficient capacity to meet their financial obligations resulting from liabilities for offshore oil and gas operations.

4. The licensing authority or the licensee shall appoint the operator. Where the operator is to be appointed by the licensee, the licensing authority shall be notified of the appointment in advance. In such cases, the licensing authority, if necessary in consultation with the competent authority, may object to the appointment of the operator. Where such an objection is raised, the Member States shall require the licensee to appoint a suitable alternative operator or assume the responsibilities of the operator under this Directive.

5. The licensing procedures for offshore oil and gas operations relating to a given licensed area shall be organised in such a way that information collected as a result of exploration can be considered by the Member State prior to production commencing.

6. When assessing the technical and financial capabilities of an applicant for a licence, special attention shall be paid to any environmentally sensitive marine and coastal environments, in particular ecosystems which play an important role in mitigation and adaptation to climate change, such as salt marshes and sea grass beds, and marine protected areas, such as special areas of conservation pursuant to the Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora [1], special protection areas pursuant to the Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds [2], and marine protected areas as agreed by the Union or Member States concerned within the framework of any international or regional agreements to which they are a party.

Article 5

Public participation relating to the effects of planned offshore oil and gas exploration operations on the environment

1. The drilling of an exploration well from a non-production installation shall not be commenced unless the relevant authorities of the Member State have previously ensured that early and effective public participation on the possible effects of planned offshore oil and gas operations on the environment pursuant to other Union legal acts, in particular Directive 2001/42/EC or 2011/92/EU as appropriate, has been undertaken.

2. Where public participation has not been undertaken pursuant to paragraph 1, Member States shall ensure that the following arrangements are made:

(a) the public is informed, whether by public notices or other appropriate means such as electronic media, where it is planned to allow exploration operations;

(b) the public concerned is identified, including the public affected or likely to be affected by, or having an interest in, the decision to allow exploration operations, including relevant non-governmental organisations such as those promoting environmental protection, and other relevant organisations;

(c) relevant information about such planned operations is made available to the public including, inter alia, information about the right to participate in decision-making, and to whom comments or questions may be submitted;

(d) the public is entitled to express comments and opinions at a time when all options are open before decisions to allow exploration are taken;

(e) when decisions under point (d) are taken, due account is taken of the results of the public participation; and

(f) the Member State in question promptly informs the public, after examining the comments and opinions expressed by them, about the decisions taken and the reasons therefor and considerations upon which those decisions are based, including information about the public participation process.

Reasonable time-frames shall be provided allowing sufficient time for each of the different stages of public participation.

3. This Article does not apply in respect of areas licensed before 18 July 2013.

Article 6

Offshore oil and gas operations within licensed areas

1. Member States shall ensure that production installations and connected infrastructure are operated only in licensed areas and only by operators appointed for that purpose pursuant to Article 4(4).

2. Member States shall require the licensee to ensure that the operator has the capacity to meet the requirements for specific operations within the framework of the licence.

3. Throughout all offshore oil and gas operations, Member States shall require the licensee to take all reasonable steps to ensure that the operator meets the requirements, carries out its functions and discharges its duties under this Directive.

[1] OJ L 206, 22.7.1992, p. 7.
[2] OJ L 20, 26.1.2010, p. 7.

4. Where the competent authority determines that the operator no longer has the capacity to meet the relevant requirements under this Directive, the licensing authority shall be informed. The licensing authority shall then notify the licensee thereof and the licensee shall assume responsibility for the discharge of the duties concerned and shall, without delay, propose a replacement operator to the licensing authority.

5. Member States shall ensure that operations relating to production and non-production installations are not commenced or continued until the report on major hazards has been accepted by the competent authority in accordance with this Directive.

6. Member States shall ensure that well operations or combined operations are not commenced or continued until the report on major hazards for the installations involved has been accepted in accordance with this Directive. Furthermore, such operations shall not be commenced or continued where a notification of well operations or a notification of combined operations has not been submitted pursuant to point (h) or (i) of Article 11(1) respectively to the competent authority or where the competent authority expresses objections to the content of a notification.

7. Member States shall ensure that a safety zone is established around an installation and that vessels are prohibited from entering or remaining in that safety zone.

However, that prohibition shall not apply to a vessel entering or remaining in the safety zone:

(a) in connection with the laying, inspection, testing, repair, maintenance, alteration, renewal or removal of any submarine cable or pipeline in or near that safety zone;

(b) to provide services for or to transport persons or goods to or from any installation in that safety zone;

(c) to inspect any installation or connected infrastructure in that safety zone under the authority of the Member State;

(d) in connection with saving or attempting to save life or property;

(e) owing to stress of weather;

(f) when in distress; or

(g) if there is consent from the operator, owner or the Member State in which the safety zone is located.

8. Member States shall establish a mechanism for effective participation in tripartite consultation between the competent authority, operators and owners, and worker representatives in the formulation of standards and policies dealing with major accident prevention.

Article 7

Liability for environmental damage

Without prejudice to the existing scope of liability relating to the prevention and remediation of environmental damage pursuant to Directive 2004/35/EC, Member States shall ensure that the licensee is financially liable for the prevention and remediation of environmental damage as defined in that Directive, caused by offshore oil and gas operations carried out by, or on behalf of, the licensee or the operator.

Article 8

Appointment of the competent authority

1. Member States shall appoint a competent authority responsible for the following regulatory functions:

(a) assessing and accepting reports on major hazards, assessing design notifications, and assessing notifications of well operations or combined operations, and other similar documents that are submitted to it;

(b) overseeing compliance by operators and owners with this Directive, including inspections, investigations and enforcement actions;

(c) advising other authorities or bodies, including the licensing authority;

(d) making annual plans pursuant to Article 21;

(e) producing reports;

(f) cooperating with the competent authorities or contact points pursuant to Article 27.

2. Member States shall at all times ensure the independence and objectivity of the competent authority in carrying out its regulatory functions and particularly in respect of points (a), (b) and (c) of paragraph 1. Accordingly, conflicts of interest shall be prevented between, on the one hand, the regulatory functions of the competent authority and, on the other hand, the regulatory functions relating to the economic development of the offshore natural resources and licensing of offshore oil and gas operations within the Member State and the collection and management of revenues from those operations.

3. In order to achieve the objectives set out in paragraph 2, Member States shall require the regulatory functions of the competent authority to be carried out within an authority that is independent of any of the functions of the Member State relating to the economic development of the offshore natural resources and licensing of offshore oil and gas operations within the Member State and the collection and management of revenues from those operations.

However, where the total number of normally attended installations is below six, the Member State concerned may decide not to apply the first subparagraph. Such a decision shall be without prejudice to its obligations under paragraph 2.

4. Member States shall make available to the public a description of how the competent authority is organised, including why they have established the competent authority in such a way, and how they have ensured that the regulatory functions set out in paragraph 1 are carried out and that the obligations set out in paragraph 2 are complied with.

5. Member States shall ensure that the competent authority has adequate human and financial resources to carry out its duties under this Directive. Those resources shall be commensurate with the extent of offshore oil and gas operations of the Member States.

6. Member States may enter into formal agreements with appropriate Union agencies or other suitable bodies where available for the provision of specialist expertise to support the competent authority in carrying out its regulatory functions. For the purposes of this paragraph a body shall not be deemed suitable where its objectivity may be compromised by conflicts of interest.

7. Member States may establish mechanisms according to which the financial costs to the competent authority in carrying out its duties under this Directive may be recovered from licensees, operators or owners.

8. Where the competent authority is comprised of more than one body, Member States shall make every effort to avoid duplication of regulatory functions between the bodies. Member States may designate one of the constituent bodies as the lead body with responsibility for the coordination of the regulatory functions under this Directive and for reporting to the Commission.

9. Member States shall review the activities of the competent authority and shall take any necessary measures to improve its effectiveness in carrying out the regulatory functions set out in paragraph 1.

Article 9

Functioning of the competent authority

Member States shall ensure that the competent authority:

(a) acts independently of policies, regulatory decisions or other considerations unrelated to its duties under this Directive;

(b) makes clear the extent of its responsibilities and the responsibilities of the operator and the owner for the control of major accident risks under this Directive;

(c) establishes a policy, process and procedures for thorough assessment of reports on major hazards and notifications submitted pursuant to Article 11 as well as for overseeing compliance with this Directive within the jurisdiction of the Member State, including inspection, investigation and enforcement actions;

(d) makes the policy, process and procedures pursuant to point (c) available to operators and owners and makes summaries thereof available to the public;

(e) where necessary, prepares and implements coordinated or joint procedures with other authorities in the Member State to undertake the duties under this Directive; and

(f) bases its policy, organisation and operational procedures on the principles set out in Annex III.

Article 10

Tasks of the European Maritime Safety Agency

1. The European Maritime Safety Agency (EMSA, hereinafter 'Agency') shall provide the Member States and Commission with technical and scientific assistance in accordance with its mandate under Regulation (EC) No 1406/2002.

2. Within the framework of its mandate, the Agency shall:

(a) assist the Commission and the affected Member State, on its request, in detecting and monitoring the extent of an oil or gas spill;

(b) assist Member States, at their request, with the preparation and execution of external emergency response plans, especially when there are transboundary impacts within and beyond offshore waters of Member States;

(c) on the basis of the Member States' external and internal emergency response plans, develop with Member States and operators a catalogue of emergency equipment and services available.

3. The Agency may, if requested:

(a) assist the Commission in assessing the external emergency response plans of Member States to check whether the plans are in conformity with this Directive;

(b) review exercises that focus on testing transboundary and Union emergency mechanisms.

CHAPTER III

PREPARING AND CARRYING OUT OFFSHORE OIL AND GAS OPERATIONS

Article 11

Documents to be submitted for carrying out offshore oil and gas operations

1. Member States shall ensure that the operator or the owner submit to the competent authority the following documents:

(a) the corporate major accident prevention policy or an adequate description thereof, in accordance with Article 19(1) and (5);

(b) the safety and environmental management system applicable to the installation, or an adequate description thereof, in accordance with Article 19(3) and (5);

(c) in the case of a planned production installation, a design notification in accordance with the requirements of Annex I, Part 1;

(d) a description of the scheme of independent verification in accordance with Article 17;

(e) a report on major hazards, in accordance with Articles 12 and 13;

(f) in the event of a material change or dismantling of an installation, an amended report on major hazards in accordance with Articles 12 and 13;

(g) the internal emergency response plan or an adequate description thereof, in accordance with Articles 14 and 28;

(h) in the case of a well operation, a notification of that well operation and information on that well operation in accordance with Article 15;

(i) in the case of a combined operation, a notification of combined operations in accordance with Article 16;

(j) in the case of an existing production installation which is to be moved to a new production location where it is to be operated, a relocation notification in accordance with Annex I, Part 1;

(k) any other relevant document requested by the competent authority.

2. The documents to be submitted under points (a), (b), (d) and (g) of paragraph 1 shall be included with the report on major hazards required under point (e) of paragraph 1. The corporate major accident prevention policy of an operator of a well shall, where not previously submitted, be included with the notification of well operations to be submitted under point (h) of paragraph 1.

3. The design notification required pursuant to point (c) of paragraph 1 shall be submitted to the competent authority by a deadline set by the competent authority before the intended submission of the report on major hazards for the planned operation. The competent authority shall respond to the design notification with comments to be taken into account in the report on major hazards.

4. Where an existing production installation is to enter or leave the offshore waters of a Member State, the operator shall notify the competent authority in writing prior to the date on which the production installation is due to enter or leave the offshore waters of the Member State.

5. The relocation notification required pursuant to point (j) of paragraph 1 shall be submitted to the competent authority at a stage that is sufficiently early in the proposed development to enable the operator to take into account any matters raised by the competent authority during the preparation of the report on major hazards.

6. Where there is a material change affecting the design notification or the relocation notification prior to the submission of the report on major hazards, the competent authority shall be notified of that change as soon as possible.

7. The report on major hazards required pursuant to point (e) of paragraph 1 shall be submitted to the competent authority by a deadline set by the competent authority that is before the planned commencement of the operations.

Article 12

Report on major hazards for a production installation

1. Member States shall ensure that the operator prepares a report on major hazards for a production installation, to be submitted pursuant to point (e) of Article 11(1). That report shall contain the information specified in Annex I, Parts 2 and 5 and shall be updated whenever appropriate or when so required by the competent authority.

2. Member States shall ensure that workers' representatives are consulted at the relevant stages in the preparation of the report on major hazards for a production installation, and that evidence is provided to this effect in accordance with Annex I, Part 2, point 3.

3. The report on major hazards for a production installation may be prepared in relation to a group of installations, subject to the agreement of the competent authority.

4. Where further information is necessary before a report on major hazards can be accepted, Member States shall ensure that the operator provides, at the request of the competent authority, such information and makes any necessary changes to the submitted report on major hazards.

5. Where modifications are to be made to the production installation that entail a material change, or it is intended to dismantle a fixed production installation, the operator shall prepare an amended report on major hazards, to be submitted pursuant to point (f) of Article 11(1) by a deadline specified by the competent authority, in accordance with Annex I, Part 6.

6. Member States shall ensure that the planned modifications are not brought into use nor any dismantlement commenced until the competent authority has accepted the amended report on major hazards for the production installation.

7. The report on major hazards for a production installation shall be subject to a thorough periodic review by the operator at least every five years or earlier when so required by the competent authority. The results of the review shall be notified to the competent authority.

Article 13

Report on major hazards for a non-production installation

1. Member States shall ensure that the owner prepares a report on major hazards for a non-production installation, to be submitted pursuant to point (e) of Article 11(1). That report shall contain the information specified in Annex I, Parts 3 and 5 and shall be updated whenever appropriate or when so required by the competent authority.

2. Member States shall ensure that workers' representatives are consulted at the relevant stages in the preparation of the report on major hazards for a non-production installation, and that evidence is provided to this effect in accordance with Annex I, Part 3, point 2.

3. Where further information is necessary before a report on major hazards for a non-production installation can be accepted, Member States shall require the owner to provide, at the request of the competent authority, such information and to make any necessary changes to the submitted report on major hazards.

4. Where modifications are to be made to the non-production installation that entail a material change, or it is intended to dismantle a fixed non-production installation, the owner shall prepare an amended report on major hazards, to be submitted pursuant to point (f) of Article 11(1) by a deadline specified by the competent authority, in accordance with Annex I, Part 6, points 1, 2 and 3.

5. For a fixed non-production installation, Member States shall ensure that the planned modifications are not brought into use nor any dismantlement commenced until the competent authority has accepted the amended report on major hazards for the fixed non-production installation.

6. For a mobile non-production installation, Member States shall ensure that the planned modifications are not brought into use until the competent authority has accepted the amended report on major hazards for the mobile non-production installation.

7. The report on major hazards for a non-production installation shall be subject to a thorough periodic review by the owner at least every five years or earlier when so required by the competent authority. The results of the review shall be notified to the competent authority.

Article 14

Internal emergency response plans

1. Member States shall ensure that operators or owners, as appropriate, prepare internal emergency response plans to be submitted pursuant to point (g) of Article 11(1). The plans shall be prepared in accordance with Article 28 taking into account the major accident risk assessment undertaken during preparation of the most recent report on major hazards. The plan shall include an analysis of the oil spill response effectiveness.

2. In the event that a mobile non-production installation is to be used for carrying out well operations, the internal emergency response plan for the installation shall take into account the risk assessment undertaken during the preparation of the notification of well operations to be submitted pursuant to point (h) of Article 11(1). Where the internal emergency response plan has to be amended due to the particular nature or location of the well, Member States shall ensure that the operator of the well submits the amended internal emergency response plan, or an adequate description thereof, to the competent authority to complement the relevant notification of well operations.

3. In the event that a non-production installation is to be used for carrying out combined operations, the internal emergency response plan shall be amended to cover the combined operations and shall be submitted to the competent authority to complement the relevant notification of the combined operations.

Article 15

Notification of and information on well operations

1. Member States shall ensure that the operator of a well prepares the notification to be submitted pursuant to point (h) of Article 11(1) to the competent authority. It shall be submitted by a deadline set by the competent authority that is before the commencement of the well operation. That notification of well operations shall contain details of the design of the well and the proposed well operations in accordance with Annex I, Part 4. This shall include an analysis of the oil spill response effectiveness.

2. The competent authority shall consider the notification and, if deemed necessary, take appropriate action before the well operations are commenced, which may include prohibiting the operation from being commenced.

3. Member States shall ensure that the operator of the well involves the independent verifier in planning and preparation of a material change to the submitted notification of well operations pursuant to point (b) of Article 17(4) and that it immediately informs the competent authority of any material change to the submitted notification of well operations. The competent authority shall consider those changes and, if deemed necessary, take appropriate action.

4. Member States shall ensure that the operator of the well submits reports of well operations to the competent authority in accordance with the requirements of Annex II. The reports shall be submitted at weekly intervals, starting on the day of commencement of the well operations, or at intervals specified by the competent authority.

Article 16

Notification of combined operations

1. Member States shall ensure that operators and owners involved in a combined operation jointly prepare the notification to be submitted pursuant to point (i) of Article 11(1). The notification shall contain the information specified in Annex I, Part 7. Member States shall ensure that one of the operators concerned submits the notification of combined operations to the competent authority. The notification shall be submitted by a deadline set by the competent authority before combined operations are commenced.

2. The competent authority shall consider the notification and, if deemed necessary, take appropriate action before the combined operations are commenced, which may include prohibiting the operation from being commenced.

3. Member States shall ensure that the operator who submitted the notification informs, without delay, the competent authority of any material change to the submitted notification. The competent authority shall consider those changes and, if deemed necessary, take appropriate action.

Article 17

Independent verification

1. Member States shall ensure that operators and owners establish schemes for independent verification and that they prepare a description of such schemes, to be submitted pursuant to point (d) of Article 11(1) and included within the safety and environmental management system submitted pursuant to point (b) of Article 11(1). The description shall contain the information specified in Annex I, Part 5.

2. The results of the independent verification shall be without prejudice to the responsibility of the operator or the owner for the correct and safe functioning of the equipment and systems under verification.

3. The selection of the independent verifier and the design of schemes for independent verification shall meet the criteria of Annex V.

4. The schemes for independent verification shall be established:

(a) in respect of installations, to give independent assurance that the safety and environmental critical elements identified in the risk assessment for the installation, as described in the report on major hazards, are suitable and that the schedule of examination and testing of the safety and environmental critical elements is suitable, up-to-date and operating as intended;

(b) in respect of notifications of well operations, to give independent assurance that the well design and well control measures are suitable for the anticipated well conditions at all times.

5. Member States shall ensure that operators and owners respond to and take appropriate action based on the advice of the independent verifier.

6. Member States shall require operators and owners to ensure that advice received from the independent verifier pursuant to point (a) of paragraph 4 and records of action taken on the basis of such advice are made available to the competent authority and retained by the operator or the owner for a period of six months after completion of the offshore oil and gas operations to which they relate.

7. Member States shall require operators of wells to ensure that the findings and comments of the independent verifier pursuant to point (b) of paragraph 4 of this Article and their actions in response to those findings and comments are presented in the notification of well operations prepared in accordance with Article 15.

8. For a production installation, the verification scheme shall be in place prior to the completion of the design. For a non-production installation, the scheme shall be in place prior to the commencement of operations in the offshore waters of Member States.

Article 18

Power of the competent authority in relation to operations on installations

Member States shall ensure that the competent authority:

(a) prohibits the operation or commencement of operations on any installation or any connected infrastructure where the measures proposed in the report on major hazards for the prevention or limiting the consequences of major accidents or notifications of well operations or combined operations submitted pursuant to points (h) or (i) of Article 11(1) respectively are considered insufficient to fulfil the requirements set out in this Directive;

(b) in exceptional situations and where it considers that safety and environmental protection are not compromised, shortens the time interval required between the submission of the report on major hazards or other documents to be submitted pursuant to Article 11 and the commencement of operations;

(c) requires the operator to take such proportionate measures as the competent authority considers necessary to ensure compliance with Article 3(1);

(d) where Article 6(4) applies, takes adequate measures to ensure the continuing safety of operations;

(e) is empowered to require improvements and, if necessary, prohibit the continued operation of any installation or any part thereof or any connected infrastructure where it is shown by the outcome of an inspection, a determination pursuant to Article 6(4), a periodic review of the report on major hazards submitted pursuant to point (e) of Article 11(1) or by changes to notifications submitted pursuant to Article 11, that the requirements of this Directive are not being fulfilled or there are reasonable concerns about the safety of offshore oil and gas operations or installations.

CHAPTER IV

PREVENTION POLICY

Article 19

Major accident prevention by operators and owners

1. Member States shall require operators and owners to prepare a document setting out their corporate major accident prevention policy which is to be submitted pursuant to point (a) of Article 11(1), and to ensure that it is implemented throughout their offshore oil and gas operations, including by setting up appropriate monitoring arrangements to assure effectiveness of the policy. The document shall contain the information specified in Annex I, Part 8.

2. The corporate major accident prevention policy shall take account of the operators' primary responsibility for, inter alia, the control of risks of a major accident that are a result of its operations and for continuously improving control of those risks so as to ensure a high level of protection at all times.

3. Member States shall ensure that operators and owners prepare a document setting out their safety and environmental management system which is to be submitted pursuant to point (b) of Article 11(1). That document shall include a description of the:

(a) organisational arrangements for control of major hazards;

(b) arrangements for preparing and submitting reports on major hazards, and other documents as appropriate, pursuant to this Directive; and

(c) schemes for independent verification established pursuant to Article 17.

4. Member States shall create opportunities for operators and owners to contribute to mechanisms for effective tripartite consultation established pursuant to Article 6(8). When appropriate, an operator's and owner's commitment to such mechanisms may be outlined in the corporate major accident prevention policy.

5. The corporate major accident prevention policy and the safety and environmental management systems shall be prepared in accordance with Annex I, Parts 8 and 9 and Annex IV. The following conditions shall apply:

(a) the corporate major accident prevention policy shall be in writing and shall establish the overall aims and arrangements for controlling the risk of a major accident, and how those aims are to be achieved and arrangements put into effect at corporate level;

(b) the safety and environmental management system shall be integrated within the overall management system of the operator or owner and shall include organisational structure, responsibilities, practices, procedures, processes and resources for determining and implementing the corporate major accident prevention policy.

6. Member States shall ensure that operators and owners prepare and maintain a complete inventory of emergency response equipment pertinent to their offshore oil and gas operation.

7. Member States shall ensure that operators and, owners in consultation with the competent authority and making use of the exchanges of knowledge, information and experience provided for in Article 27(1), prepare and revise standards and guidance on best practice in relation to the control of major hazards throughout the design and operational lifecycle of offshore oil and gas operations, and that as a minimum they follow the outline in Annex VI.

8. Member States shall require operators and owners to ensure that their corporate major accident prevention policy document referred to in paragraph 1 also covers their production and non-production installations outside of the Union.

9. Where an activity carried out by an operator or an owner poses an immediate danger to human health or significantly increases the risk of a major accident, Member States shall ensure that the operator or the owner takes suitable measures which may include, if deemed necessary, suspending the relevant activity until the danger or risk is adequately controlled. Member States shall ensure that where such measures are taken, the operator or the owner notifies the competent authority accordingly without delay and no later than 24 hours after taking those measures.

10. Member States shall ensure that, where appropriate, operators and owners take suitable measures to use suitable technical means or procedures in order to promote the reliability of the collection and recording of relevant data and to prevent possible manipulation thereof.

Article 20

Offshore oil and gas operations conducted outside the Union

1. Member States shall require companies registered in their territory and conducting, themselves or through subsidiaries, offshore oil and gas operations outside the Union as licence holders or operators to report to them, on request, the circumstances of any major accident in which they have been involved.

2. In the request for a report pursuant to paragraph 1 of this Article, the relevant Member State shall specify the details of the information required. Such reports shall be exchanged in accordance with Article 27(1). Member States which have neither a competent authority nor a contact point shall submit the reports received to the Commission.

Article 21

Securing compliance with the regulatory framework for major accident prevention

1. Member States shall ensure that operators and owners comply with the measures established in the report on major hazards and in the plans referred to in the notification of well operations and notification of combined operations, submitted pursuant to points (e), (h) and (i) of Article 11(1) respectively.

2. Member States shall ensure that operators and owners provide the competent authority, or any other persons acting under the direction of the competent authority, with transport to or from an installation or vessel associated with oil and gas operations, including the conveyance of their equipment, at any reasonable time, and with accommodation, meals and other subsistence in connection with the visits to the installations, for the purpose of facilitating competent authority oversight, including inspections, investigations and enforcement of compliance with this Directive.

3. Member States shall ensure that the competent authority develops annual plans for effective oversight, including inspections, of major hazards based on risk management and with particular regard to compliance with the report on major hazards and other documents submitted pursuant to Article 11. The effectiveness of the plans shall be regularly reviewed and the competent authority shall take any necessary measures to improve them.

Article 22

Confidential reporting of safety concerns

1. Member States shall ensure that the competent authority establishes mechanisms:

(a) for confidential reporting of safety and environmental concerns relating to offshore oil and gas operations from any source; and

(b) for investigation of such reports while maintaining the anonymity of the individuals concerned.

2. Member States shall require operators and owners to communicate details of the national arrangements for the mechanisms referred to in paragraph 1 to their employees and contractors connected with the operation and their employees, and to ensure that reference to confidential reporting is included in relevant training and notices.

CHAPTER V

TRANSPARENCY AND SHARING OF INFORMATION

Article 23

Sharing of information

1. Member States shall ensure that operators and owners provide the competent authority, as a minimum, with the information described in Annex IX.

2. The Commission shall by means of an implementing act determine a common data reporting format and the details of information to be shared. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 37(2).

Article 24

Transparency

1. Member States shall make the information referred to in Annex IX publicly available.

2. The Commission shall by means of an implementing act determine a common publication format that enables easy cross-border comparison of data. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 37(2). The common publication format shall allow for a reliable comparison of national practices under this Article and Article 25.

Article 25

Reporting on safety and environmental impact

1. Member States shall submit an annual report to the Commission containing the information specified in Annex IX, point 3.

2. Member States shall designate an authority to be responsible for exchanging information pursuant to Article 23 and for publication of information pursuant to Article 24.

3. The Commission shall publish an annual report based on the information reported to it by Member States pursuant to paragraph 1.

Article 26

Investigation following a major accident

1. Member States shall initiate thorough investigations of major accidents occurring in their jurisdiction.

2. A summary of the findings pursuant to paragraph 1 shall be made available to the Commission either at the conclusion of the investigation or at the conclusion of legal proceedings as appropriate. The Member States shall make a non-confidential version of the findings publicly available.

3. Member States shall ensure that, following the investigations pursuant to paragraph 1, the competent authority implements any recommendations of the investigation that are within its powers to act.

CHAPTER VI

COOPERATION

Article 27

Cooperation between Member States

1. Each Member State shall ensure that its competent authority regularly exchanges knowledge, information and experience with other competent authorities, inter alia, through the European Union Offshore Oil and Gas Authorities Group (EUOAG), and that it engages in consultations on the application of relevant national and Union law with the industry, other stakeholders and the Commission.

For Member States without offshore oil and gas operations under their jurisdiction, the information referred to in the first subparagraph shall be received by the contact points appointed pursuant to Article 32(1).

2. Knowledge, information and experience exchanged pursuant to paragraph 1 shall concern, in particular, the functioning of the measures for risk management, major accident prevention, verification of compliance and emergency response relating to offshore oil and gas operations within the Union, as well as outside of the Union where appropriate.

3. Each Member State shall ensure that its competent authority participates in establishing clear joint priorities for the preparation and updating of standards and guidance in order to identify and facilitate the implementation and consistent application of best practices in offshore oil and gas operations.

4. By 19 July 2014, the Commission shall present to the Member States a report on the adequacy of national expert resources for complying with the regulatory functions pursuant to this Directive which, if necessary, shall include proposals for ensuring all Member States have access to adequate expert resources.

5. By 19 July 2016, the Member States shall notify the Commission of the national measures they have in place regarding access to knowledge, assets and expert resources, including formal agreements pursuant to Article 8(6).

CHAPTER VII

EMERGENCY PREPAREDNESS AND RESPONSE

Article 28

Requirements for internal emergency response plans

1. Member States shall ensure that the internal emergency response plans to be prepared by the operator or the owner in accordance with Article 14 and submitted pursuant to point (g) of Article 11(1) are:

(a) put into action without delay to respond to any major accident or a situation where there is an immediate risk of a major accident; and

(b) consistent with the external emergency response plan referred to in Article 29.

2. Member States shall ensure that the operator and the owner maintain equipment and expertise relevant to the internal emergency response plan in order for that equipment and expertise to be available at all times and to be made available as necessary to the authorities responsible for the execution of the external emergency response plan of the Member State where the internal emergency response plan applies.

3. The internal emergency response plan shall be prepared in accordance with Annex I, Part 10, and updated as a consequence of any material change to the report on major hazards or notifications submitted pursuant to Article 11 Any such updates shall be submitted to the competent authority pursuant to point (g) of Article 11(1) and notified to the relevant authority or authorities responsible for preparing the external emergency response plans for the area concerned.

4. The internal emergency response plan shall be integrated with other measures relating to protection and rescue of personnel from the stricken installation so as to secure a good prospect of personal safety and survival.

Article 29

External emergency response plans and emergency preparedness

1. Member States shall prepare external emergency response plans covering all offshore oil and gas installations or connected infrastructure and potentially affected areas within their jurisdiction. Member States shall specify the role and financial obligation of licensees and operators in the external emergency response plans.

2. External emergency response plans shall be prepared by the Member State in cooperation with relevant operators and owners and, as appropriate, licensees and the competent authority, and shall take into account the most up to date version of the internal emergency response plans of the existing or planned installations or connected infrastructure in the area covered by the external emergency response plan.

3. External emergency response plans shall be prepared in accordance with Annex VII, and shall be made available to the Commission, other potentially affected Member States and the public. When making available their external emergency response plans, the Member States shall ensure that disclosed information does not pose risks to the safety and security of offshore oil and gas installations and their operation and does not harm the economic interests of the Member States or the personal safety and well-being of officials of Member States.

4. Member States shall take suitable measures to achieve a high level of compatibility and interoperability of response equipment and expertise between all Member States in a geographical region, and further afield where appropriate. Member States shall encourage industry to develop response equipment and contracted services that are compatible and interoperable throughout the geographical region.

5. Member States shall keep records of emergency response equipment and services in accordance with Annex VIII, point 1. Those records shall be available to the other potentially affected Member States and the Commission and, on a reciprocal basis, to neighbouring third countries.

6. Member States shall ensure that operators and owners regularly test their preparedness to respond effectively to major accidents in close cooperation with the relevant authorities of the Member States.

7. Member States shall ensure that competent authorities or, where appropriate, contact points develop cooperation scenarios for emergencies. Such scenarios shall be regularly assessed and updated as necessary.

Article 30

Emergency response

1. Member States shall ensure that the operator or, if appropriate, the owner notifies without delay the relevant authorities of a major accident or of a situation where there is an immediate risk of a major accident. That notification shall describe the circumstances, including, where possible, the origin, the potential impacts on the environment and the potential major consequences.

2. Member States shall ensure that in the event of a major accident, the operator or the owner takes all suitable measures to prevent its escalation and to limit its consequences. The relevant authorities of the Member States may assist the operator or owner, including with the supply of additional resources.

3. In the course of the emergency response, the Member State shall collect the information necessary for thorough investigation pursuant to Article 26(1).

CHAPTER VIII

TRANSBOUNDARY EFFECTS

Article 31

Transboundary emergency preparedness and response of Member States with offshore oil and gas operations under their jurisdiction

1. Where a Member State considers that a major hazard relating to offshore oil and gas operations that are to take place under its jurisdiction is likely to have significant effects on the environment in another Member State, it shall, prior to the commencement of operations, forward the relevant information to the potentially affected Member State and shall endeavour, jointly with that Member State, to adopt measures to prevent damage.

Member States that consider themselves to be potentially affected may request the Member State in whose jurisdiction the offshore oil and gas operation is to take place, to forward all relevant information to them. Those Member States may jointly assess the effectiveness of the measures, without prejudice to the regulatory functions of the competent authority with jurisdiction for the operation concerned under points (a), (b) and (c) of Article 8(1).

2. The major hazards identified pursuant to paragraph 1 shall be taken into account in internal and external emergency response plans to facilitate joint effective response to a major accident.

3. Where there is a risk of the foreseeable transboundary effects of major accidents affecting third countries, Member States shall, on a reciprocal basis, make information available to the third countries.

4. Member States shall coordinate between themselves measures relating to areas outside of the Union in order to prevent potential negative effects of offshore oil and gas operations.

5. Member States shall regularly test their preparedness to respond effectively to major accidents in cooperation with potentially affected Member States, relevant Union agencies and, on a reciprocal basis, potentially affected third countries. The Commission may contribute to exercises focused on testing transboundary emergency mechanisms.

6. In the event of a major accident, or of an imminent threat thereof, which has or is capable of having transboundary effects, the Member State under whose jurisdiction the situation occurs shall, without delay, notify the Commission and those Member States or third countries which may be affected by the situation and shall continuously provide information relevant for an effective emergency response.

Article 32

Transboundary emergency preparedness and response of Member States without offshore oil and gas operations under their jurisdiction

1. Member States without offshore oil and gas operations under their jurisdiction shall appoint a contact point in order to exchange information with relevant adjacent Member States.

2. Member States without offshore oil and gas operations under their jurisdiction shall apply Article 29(4) and (7) so as to ensure that adequate response capacity is in place in the event that they are affected by a major accident.

3. Member States without offshore oil and gas operations under their jurisdiction shall coordinate their national contingency planning in the marine environment with other relevant Member States to the extent necessary to ensure the most effective response to a major accident.

4. Where a Member State without offshore oil and gas operations under its jurisdiction is affected by a major accident, it shall:

(a) take all suitable measures, in line with the national contingency planning referred to in paragraph 3;

(b) ensure that any information which is under its control and available within its jurisdiction and which may be relevant for a full investigation of the major accident is provided or made accessible on request to the Member State conducting the investigation pursuant to Article 26.

Article 33

Coordinated approach towards the safety of offshore oil and gas operations at international level

1. The Commission shall, in close cooperation with the Member State and without prejudice to relevant international agreements, promote cooperation with third countries that undertake offshore oil and gas operations in the same marine regions as Member States.

2. The Commission shall facilitate the exchange of information between Member States with offshore oil and gas operations and adjacent third countries with similar operations in order to promote preventive measures and regional emergency response plans.

3. The Commission shall promote high safety standards for offshore oil and gas operations at international level in relevant global and regional fora, including those relating to Arctic waters.

CHAPTER IX

FINAL PROVISIONS

Article 34

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 shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 19 July 2015 and shall notify it without delay of any subsequent amendment affecting them.

Article 35

Delegated powers of the Commission

The Commission shall be empowered to adopt delegated acts in accordance with Article 36 in order to adapt Annexes I, II, VI and VII to include additional information which may become necessary in light of technical progress. Such adaptations shall not result in substantial changes in the obligations laid down in this Directive.

Article 36

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 35 shall be conferred on the Commission for a period of five years from 18 July 2013. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than four months before the end of each period.

3. The delegation of power referred to in Article 35 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Article 35 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 37

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Article 38

Amendment to Directive 2004/35/EC

1. In Article 2(1) of Directive 2004/35/EC, point (b) shall be replaced by the following:

'(b) "water damage", which is any damage that significantly adversely affects:

(i) the ecological, chemical or quantitative status or the ecological potential, as defined in Directive 2000/60/EC, of the waters concerned, with the exception of adverse effects where Article 4(7) of that Directive applies; or

(ii) the environmental status of the marine waters concerned, as defined in Directive 2008/56/EC, in so far as particular aspects of the environmental status of the marine environment are not already addressed through Directive 2000/60/EC;'.

2. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with paragraph 1 by 19 July 2015. They shall forthwith inform the Commission thereof.

Article 39

Reports to the European Parliament and to the Council

1. The Commission shall, by 31 December 2014, submit to the European Parliament and to the Council a report on the availability of financial security instruments, and on the handling of compensation claims, where appropriate, accompanied by proposals.

2. The Commission shall, by 19 July 2015, submit to the European Parliament and to the Council a report on its assessment of the effectiveness of the liability regimes in the Union in respect of the damage caused by offshore oil and gas operations. That report shall include an assessment of the appropriateness of broadening liability provisions. The report shall be accompanied, where appropriate, by proposals.

3. The Commission shall examine the appropriateness of bringing certain conduct leading to a major accident within the scope of Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law [1]. The Commission shall, by 31 December 2014, submit a report on its findings to the European Parliament and the Council, accompanied, where appropriate, by legislative proposals, subject to appropriate information being made available by Member States.

Article 40

Report and review

1. No later than 19 July 2019, the Commission shall, taking due account of the efforts and experiences of competent authorities, assess the experience of implementing this Directive.

2. The Commission shall submit a report to the European Parliament and to the Council with the result of that assessment. That report shall include any appropriate proposals for amending this Directive.

Article 41

Transposition

1. Member States shall bring into force the laws, regulations, and administrative provisions necessary to comply with this Directive by 19 July 2015.

They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

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

3. By way of derogation from the first subparagraph of paragraph 1 and subject to paragraph 5, Member States with offshore waters that do not have offshore oil and gas operations under their jurisdiction, and which do not plan to license such operations, shall inform the Commission thereof and shall be obliged to bring into force, by 19 July 2015, only those measures which are necessary to ensure compliance with Articles 20, 32 and 34. Such Member States may not license such operations until they have transposed and implemented the remaining provisions of this Directive and have informed the Commission thereof.

4. By way of derogation from the first subparagraph of paragraph 1 and subject to paragraph 5, landlocked Member States shall be obliged to bring into force, by 19 July 2015, only those measures which are necessary to ensure compliance with Article 20.

5. Where, on 18 July 2013, no company conducting operations covered by Article 20 is registered in a Member State falling within paragraph 3 or 4, that Member State shall be obliged to bring into force those measures which are necessary to ensure compliance with Article 20 only as from 12 months following any later registration of such a company in that Member State or by 19 July 2015, whichever is the later.

Article 42

Transitional provisions

1. In relation to owners, operators of planned production installations and operators planning or executing well operations, Member States shall apply the laws, regulations and administrative provisions adopted pursuant to Article 41 by 19 July 2016.

2. In relation to existing installations, Member States shall apply the laws, regulations and administrative provisions adopted pursuant to Article 41 from the date of scheduled regulatory review of risk assessment documentation and no later than by 19 July 2018.

Article 43

Entry into force

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

Article 44

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 12 June 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	L. CREIGHTON

[1] OJ L 328, 6.12.2008, p. 28.

ANNEX I

Information to be included in documents submitted to the competent authority pursuant to Article 11

1. INFORMATION TO BE SUBMITTED IN A DESIGN OR RELOCATION NOTIFICATION FOR A PRODUCTION INSTALLATION

The design notification and the relocation notification for a production installation to be submitted pursuant to points (c) and (j) of Article 11(1) respectively shall contain at least the following information:

(1) the name and address of the operator of the installation;

(2) a description of the design process for the production operations and systems, from an initial concept to the submitted design or selection of an existing installation, the relevant standards used, and the design concepts included in the process;

(3) a description of the selected design concept in relation to the major hazard scenarios for the particular installation and its location, and the primary risk control features;

(4) a demonstration that the concept contributes to reducing major hazard risks to an acceptable level;

(5) a description of the installation and the conditions at its intended location;

(6) a description of any environmental, meteorological and seabed limitations on safe operations, and the arrangements for identifying risks from seabed and marine hazards such as pipelines and the moorings of adjacent installations;

(7) a description of the types of major hazard operations to be carried out;

(8) a general description of the safety and environmental management system by which the intended major accident risk control measures are to be maintained in good effect;

(9) a description of the independent verification schemes and an initial list of safety and environmental critical elements and their required performance;

(10) where an existing production installation is to be moved to a new location to serve a different production operation, a demonstration that the installation is suitable for the proposed production operation;

(11) where a non-production installation is to be converted for use as a production installation, a justification demonstrating that the installation is suitable for such conversion.

2. INFORMATION TO BE SUBMITTED IN A REPORT ON MAJOR HAZARDS FOR OPERATION OF A PRODUCTION INSTALLATION

Reports on major hazards for a production installation to be prepared in accordance with Article 12 and submitted pursuant to point (e) of Article 11(1) shall contain at least the following information:

(1) a description of the account taken of the competent authority's response to the design notification;

(2) the name and address of the operator of the installation;

(3) a summary of any worker involvement in the preparation of the report on major hazards;

(4) a description of the installation and any association with other installations or connected infrastructure, including wells;

(5) demonstration that all the major hazards have been identified, their likelihood and consequences assessed, including any environmental, meteorological and seabed limitations on safe operations, and that their control measures including associated safety and environmental critical elements are suitable so as to reduce the risk of a major accident to an acceptable level; this demonstration shall include an assessment of oil spill response effectiveness;

(6) a description of the types of operations with major hazard potential to be carried out, and the maximum number of persons that can be on the installation at any time;

(7) a description of equipment and arrangements to ensure well control, process safety, containment of hazardous substances, prevention of fire and explosion, protection of the workers from hazardous substances, and protection of the environment from an incipient major accident;

(8) a description of the arrangements to protect persons on the installation from major hazards, and to ensure their safe escape, evacuation and rescue, and arrangements for the maintenance of control systems to prevent damage to the installation and the environment in the event that all personnel are evacuated;

(9) relevant codes, standards and guidance used in the construction and commissioning of the installation;

(10) information, regarding the operator's safety and environmental management system, that is relevant to the production installation;

(11) an internal emergency response plan or an adequate description thereof;

(12) a description of the independent verification scheme;

(13) any other relevant details, for example where two or more installations operate in combination in a way which affects the major hazard potential of either or all installations;

(14) the information relevant to other requirements under this Directive obtained pursuant to the major accident prevention requirements of Directive 92/91/EEC;

(15) in respect of operations to be conducted from the installation, any information relating to the prevention of major accidents resulting in significant or serious damage to the environment relevant to other requirements under this Directive, obtained pursuant to Directive 2011/92/EU;

(16) an assessment of the identified potential environmental effects resulting from the loss of containment of pollutants arising from a major accident, and a description of the technical and non-technical measures envisaged to prevent, reduce or offset them, including monitoring.

3. INFORMATION TO BE SUBMITTED IN A REPORT ON MAJOR HAZARDS FOR A NON-PRODUCTION INSTALLATION

Reports on major hazards for a non-production installation to be prepared in accordance with Article 13 and submitted pursuant to point (e) of Article 11(1) shall contain at least the following information:

(1) the name and address of the owner;

(2) a summary of any worker involvement in the preparation of the report on major hazards;

(3) a description of the installation and, in the case of a mobile installation, a description of its means of transfer between locations, and its stationing system;

(4) a description of the types of operations with major hazard potential that the installation is capable of performing, and the maximum number of persons that can be on the installation at any time;

(5) demonstration that all the major hazards have been identified, their likelihood and consequences assessed, including any environmental, meteorological and seabed limitations on safe operations and that their control measures including associated safety and environmental critical elements are suitable so as to reduce the risk of a major accident to an acceptable level; this demonstration shall include an assessment of any oil spill response effectiveness;

(6) a description of the plant and arrangements to ensure well control, process safety, containment of hazardous substances, prevention of fire and explosion, protection of the workers from hazardous substances, and protection of the environment from a major accident;

(7) a description of the arrangements to protect persons on the installation from major hazards, and to ensure their safe escape, evacuation and rescue, and arrangements for the maintenance of control systems to prevent damage to the installation and the environment in the event that all personnel are evacuated;

(8) relevant codes, standards and guidance used in the construction and commissioning of the installation;

(9) demonstration that all the major hazards have been identified for all operations the installation is capable of performing, and that the risk of a major accident is reduced to an acceptable level;

(10) a description of any environmental, meteorological and seabed limitations on safe operations, and the arrangements for identifying risks from seabed and marine hazards such as pipelines and the moorings of adjacent installations;

(11) information, regarding the safety and environmental management system, that is relevant to the non-production installation;

(12) an internal emergency response plan or an adequate description thereof;

(13) a description of the independent verification scheme;

(14) any other relevant details, for example where two or more installations operate in combination in a way which affects the major hazard potential of either or all installations;

(15) in respect of operations to be conducted from the installation, any information obtained pursuant to Directive 2011/92/EU relating to the prevention of major accidents resulting in significant or serious damage to the environment relevant to other requirements under this Directive;

(16) an assessment of the identified potential environmental effects resulting from the loss of containment of pollutants arising from a major accident, and a description of the technical and non-technical measures envisaged to prevent, reduce or offset them, including monitoring.

4. INFORMATION TO BE SUBMITTED IN A NOTIFICATION OF WELL OPERATIONS

Notifications of well operations to be prepared in accordance with Article 15 and submitted pursuant to point (h) of Article 11(1) shall contain at least the following information:

(1) the name and address of the operator of the well;

(2) the name of the installation to be used and the name and address of the owner or, in the case of a production installation, the contractor undertaking drilling activities;

(3) details that identify the well and any association with installations and connected infrastructure;

(4) information on the well work programme, including the period of its operation, details and verification of barriers against loss of well control (equipment, drilling fluids and cement etc.), directional control of the well path, and limitations on safe operations in keeping with the risk management;

(5) in the case of an existing well, information regarding its history and condition;

(6) any details concerning safety equipment to be deployed that are not described in the current report on major hazards for the installation;

(7) a risk assessment incorporating a description of:

(a) the particular hazards associated with the well operation including any environmental, meteorological and seabed limitations on safe operations;

(b) the subsurface hazards;

(c) any surface or subsea operations which introduce simultaneous major hazard potential;

(d) suitable control measures;

(8) a description of the well configuration at the end of operations – i.e. permanently or temporarily abandoned; and whether production equipment has been placed into the well for future use;

(9) in the case of a modification to a previously submitted notification of well operations, sufficient details to fully update the notification;

(10) where a well is to be constructed, modified or maintained by means of a non-production installation, additional information as follows:

(a) a description of any environmental, meteorological and seabed limitations on safe operations, and arrangements for identifying risks from seabed and marine hazards such as pipelines and the moorings of adjacent installations;

(b) a description of environmental conditions that have been taken into account within the internal emergency response plan for the installation;

(c) a description of emergency response arrangements including arrangements for responding in cases of environmental incidents that are not described in the report on major hazards; and

(d) a description of how the management systems of the operator of the well and the owner are to be coordinated to ensure effective control of major hazards at all times;

(11) a report with findings of the independent well examination, including a statement by the operator of the well that, after considering the report and findings of independent well examination by the independent verifier, the risk management relating to well design and its barriers to loss of control are suitable for all anticipated conditions and circumstances;

(12) the information relevant to this Directive obtained pursuant to the major accident prevention requirements of Directive 92/91/EEC;

(13) in respect of the well operations to be conducted, any information relevant to other requirements under this Directive obtained pursuant to Directive 2011/92/EU relating to the prevention of major accidents resulting in significant or serious damage to the environment.

5. INFORMATION TO BE SUBMITTED RELATING TO A VERIFICATION SCHEME

Descriptions to be submitted pursuant to point (d) of Article 11(1) in relation to schemes of independent verification to be established pursuant to Article 17(1) shall include:

(a) a statement by the operator or owner, made after considering the report of the independent verifier, that the record of safety critical elements and their scheme of maintenance as specified in the report on major hazards are or will be suitable;

(b) a description of the verification scheme including the selection of independent verifiers, the means of verification that safety and environmental critical elements and any specified plant in the scheme remain in good repair and condition;

(c) a description of the means of verification referred to in point (b) that shall include details of the principles that will be applied to carry out the functions under the scheme and to keep the scheme under review throughout the lifecycle of the installation including:

(i) the examination and testing of the safety and environmental critical elements by independent and competent verifiers;

(ii) verification of the design, standard, certification or other system of conformity of the safety and environmental critical elements;

(iii) examination of work in progress;

(iv) the reporting of any instances of non-compliance;

(v) remedial actions taken by the operator or owner.

6. INFORMATION TO BE PROVIDED IN RESPECT OF A MATERIAL CHANGE TO AN INSTALLATION, INCLUDING REMOVAL OF A FIXED INSTALLATION

Where material changes are to be made to the installation as referred to in Article 12(5) and Article 13(4), the amended report on major hazards incorporating the material changes to be submitted pursuant to point (f) of Article 11(1) shall contain at least the following information:

(1) the name and address of the operator or the owner;

(2) a summary of any worker involvement in the preparation of the revised report on major hazards;

(3) sufficient details to fully update the earlier report on major hazards and associated internal emergency response plan for the installation and to demonstrate major hazard risks are reduced to an acceptable level;

(4) in the case of taking a fixed production installation out of use:

(a) means of isolating all hazardous substances and in the case of wells connected to the installation, the permanent sealing of the wells from the installation and the environment;

(b) a description of major hazard risks associated with the decommissioning of the installation to workers and the environment, the total exposed population, and the risk control measures;

(c) emergency response arrangements to secure safe evacuation and rescue of personnel and to maintain control systems for preventing a major accident to the environment.

7. INFORMATION TO BE SUBMITTED IN A NOTIFICATION OF COMBINED OPERATIONS

The notification of combined operations to be prepared pursuant to Article 16 and submitted pursuant to point (i) of Article 11(1) shall contain at least the following information:

(1) the name and address of the operator submitting the notification;

(2) in the event that other operators or owners are involved in the combined operations their names and addresses, including a confirmation that they agree with the contents of the notification;

(3) a description, in the form of a bridging document authorised by all parties to the document, of how the management systems for the installations involved in the combined operation will be coordinated so as to reduce the risk of a major accident to an acceptable level;

(4) a description of any equipment to be used in connection with the combined operation but which is not described in the current report on major hazards for any of the installations involved in the combined operations;

(5) a summary of the risk assessment carried out by all operators and owners involved in the combined operations, which shall include:

(a) a description of any operation during the combined operation which may involve hazards with the potential to cause a major accident on or in connection with an installation;

(b) a description of any risk control measures introduced as a result of the risk assessment;

(6) a description of the combined operation and a programme of work.

8. INFORMATION TO BE SUBMITTED IN RESPECT OF A CORPORATE MAJOR ACCIDENT PREVENTION POLICY

The corporate major accident prevention policy to be prepared in accordance with Article 19(1) and submitted pursuant to point (a) of Article 11(1) shall include but not be limited to:

(1) the responsibility at corporate board level for ensuring, on a continuous basis, that the corporate major accident prevention policy is suitable, implemented, and operating as intended;

(2) measures for building and maintaining a strong safety culture with a high likelihood of continuous safe operation;

(3) the extent and intensity of process auditing;

(4) measures for rewarding and recognising desired behaviours;

(5) the evaluation of the company's capabilities and goals;

(6) measures for maintenance of safety and environmental protection standards as a corporate core value;

(7) formal command and control systems that include board members and senior management of the company;

(8) the approach to competency at all levels of the company;

(9) the extent to which particulars (1)-(8) are applied in the company's offshore oil and gas operations conducted outside the Union.

9. INFORMATION TO BE PROVIDED IN RESPECT OF A SAFETY AND ENVIRONMENTAL MANAGEMENT SYSTEM

The safety and environmental management system to be prepared pursuant to Article 19(3) and submitted pursuant to point (b) of Article 11(1) shall include but not be limited to:

(1) organisation structure and personnel roles and responsibilities;

(2) identification and evaluation of major hazards as well as their likelihood and potential consequences;

(3) integration of environmental impact into major accident risk assessments in the report on major hazards;

(4) controls of the major hazards during normal operations;

(5) management of change;

(6) emergency planning and response;

(7) limitation of damage to the environment;

(8) monitoring of performance;

(9) audit and review arrangements; and

(10) the measures in place for participating in tripartite consultations and how actions resulting from those consultations are put into effect.

10. INFORMATION TO BE PROVIDED IN AN INTERNAL EMERGENCY RESPONSE PLAN

Internal emergency response plans to be prepared pursuant to Article 14 and submitted pursuant to point (g) of Article 11(1) shall include but not be limited to:

(1) names and positions of persons authorised to initiate emergency response procedures and the person directing the internal emergency response;

(2) name or position of the person with responsibility for liaising with the authority or authorities responsible for the external emergency response plan;

(3) a description of all foreseeable conditions or events which could cause a major accident, as described in the report on major hazards to which the plan is attached;

(4) a description of the actions that will be taken to control conditions or events which could cause a major accident and to limit their consequences;

(5) a description of the equipment and the resources available, including for capping any potential spill;

(6) arrangements for limiting the risks to persons on the installation and the environment, including how warnings are to be given and the actions persons are expected to take on receipt of a warning;

(7) in the case of combined operation, arrangements for coordinating escape, evacuation and rescue between the installations concerned, to secure a good prospect of survival for persons on the installations during a major accident;

(8) an estimate of oil spill response effectiveness. Environmental conditions to be considered in this response analysis shall include:

(i) weather, including wind, visibility, precipitation and temperature;

(ii) states, tides, and currents;

(iii) presence of ice and debris;

(iv) hours of daylight; and

(v) other known environmental conditions that might influence the efficiency of the response equipment or the overall effectiveness of a response effort;

(9) arrangements for providing early warning of a major accident to the authority or authorities responsible for initiating the external emergency response plan, the type of information which shall be contained in an initial warning and the arrangements for the provision of more detailed information as it becomes available;

(10) arrangements for training personnel in the duties they will be expected to carry out, and where necessary coordinating this with external emergency responders;

(11) arrangements for coordinating internal emergency response with external emergency response;

(12) evidence of prior assessments of any chemicals used as dispersants that have been carried out to minimise public health implications and any further environmental damage.

ANNEX II

Reports of well operations to be submitted pursuant to Article 15(4)

The reports to be submitted to the competent authority pursuant to Article 15(4) shall contain at least the following information:

(1) the name and address of the operator of the well;

(2) the name of the installation and the name and address of the operator or owner;

(3) details that identify the well and any association with installations or connected infrastructure;

(4) a summary of the operations undertaken since the commencement of operations or since the previous report;

(5) the diameter and true vertical and measured depths of:

(a) any hole drilled; and

(b) any casing installed;

(6) the drilling fluid density at the time of making the report; and

(7) in the case of operations relating to an existing well, its current operational state.

ANNEX III

Provisions relating to the appointment and functioning of the competent authority pursuant to Articles 8 and 9

1. PROVISIONS RELATING TO MEMBER STATES

(1) For the purposes of appointing a competent authority responsible for the duties set out in Article 8, Member States shall as a minimum undertake the following:

(a) make organisational arrangements which allow for the duties assigned to the competent authority in this Directive to be effectively discharged, including arrangements for regulating safety and environmental protection in an equitable manner;

(b) prepare a policy statement describing the aims of oversight and enforcement, and the obligations on the competent authority to achieve transparency, consistency, proportionality and objectivity in its regulation of offshore oil and gas operations.

(2) Member States shall make the necessary provisions to bring the arrangements in point 1 into effect, including:

(a) funding sufficient specialist expertise available internally or by formal agreements with third parties or both in order that the competent authority may inspect and investigate operations, take enforcement action, and to handle reports on major hazards and notifications;

(b) where there is reliance on external sources of expertise, funding the preparation of sufficient written guidance and oversight to maintain consistency of approach and to ensure the legally appointed competent authority retains full responsibility under this Directive;

(c) funding essential training, communication, access to technology, travel and subsistence of competent authority personnel for the carrying out of their duties, and to facilitate the active cooperation between competent authorities pursuant to Article 27;

(d) where appropriate, requiring operators or owners to reimburse the competent authority for the cost of carrying out its duties pursuant to this Directive;

(e) funding and encouraging research pursuant to the competent authority's duties under this Directive;

(f) providing funding for reports by the competent authority.

2. PROVISIONS RELATING TO THE FUNCTIONING OF THE COMPETENT AUTHORITY

(1) For the purposes of carrying out its duties pursuant to Article 9 effectively, the competent authority shall prepare:

(a) a written strategy that describes its duties, priorities for action i.e. in design and operation of installations, integrity management and in emergency preparedness and response, and how it is organised;

(b) operating procedures that describe how it will inspect and enforce the execution of the duties of operators and owners under this Directive, including how it will handle, assess and accept reports on major hazards, handle notifications of well operations and how the intervals between inspection of major hazard risk control measures, including to the environment, for a given installation or activity are to be determined;

(c) procedures for carrying out its duties without prejudice to other responsibilities, for example onshore oil and gas operations, and arrangements pursuant to Directive 92/91/EEC;

(d) where the competent authority is comprised of more than one body, a formal agreement establishing the necessary mechanisms for joint operation of the competent authority, including senior management oversight and monitoring and reviews, joint planning and inspection, division of responsibilities for handling reports on major hazards, joint investigation, internal communications, and reports to be published jointly externally.

(2) The detailed procedures for assessment of reports on major hazards shall require all factual information and other particulars required under this Directive to be provided by the operator or the owner. As a minimum the competent authority shall ensure that the requirements for the following information are clearly specified in guidance to operators and owners:

(a) all foreseeable hazards with the potential to cause a major accident, including to the environment, have been identified, their risks evaluated and measures identified, including emergency responses, to control the risks;

(b) the safety and environmental management system is adequately described to demonstrate compliance with this Directive;

(c) adequate arrangements have been described for independent verification, and for audit by the operator or owner.

(3) In undertaking a thorough assessment of reports on major hazards, the competent authority shall ensure that:

(a) all factual information required is provided;

(b) the operator or the owner has identified all reasonably foreseeable major accident hazards that apply to the installation and its functions, together with potential initiating events, and that the methodology and evaluation criteria adopted for major accident risk management are clearly explained, including factors for uncertainty in the analysis;

(c) the risk management have taken into consideration all relevant stages in the lifecycle of the installation and have anticipated all foreseeable situations including:

(i) how the design decisions described in the design notification have taken account of risk management so as to ensure inherent safety and environmental principles are incorporated;

(ii) how well operations are to be conducted from the installation when operating;

(iii) how well operations are to be undertaken and temporarily suspended before production is commenced from a production installation;

(iv) how combined operations are to be undertaken with other installation;

(v) how the decommissioning of the installation will be undertaken;

(d) how risk reduction measures identified as part of the risk management are intended to be implemented if necessary to reduce risks to an acceptable level;

(e) whether, in determining the necessary measures to achieve acceptable levels of risk, the operator or owner has clearly demonstrated how relevant good practice and judgment based on sound engineering, best management practice, and human and organisational factors principles have been taken into account;

(f) whether the measures and arrangements for the detection of, and the rapid and effective response to, an emergency are clearly identified and justified;

(g) how escape, evacuation and rescue arrangements and measures to limit escalation of an emergency and reduce its impact on the environment are integrated in a logical and systematic manner, taking account of the likely emergency conditions in which they will be operated;

(h) how the requirements are incorporated in the internal emergency response plans and whether a copy or an adequate description of the internal emergency response plan has been submitted to the competent authority;

(i) whether the safety and environmental management system described in the report on major hazards is adequate to ensure control of the major hazard risks at each stage of the installation lifecycle, and ensures compliance with all relevant legal provisions, and provides for auditing and implementing audit recommendations;

(j) whether the scheme for independent verification is clearly explained.

ANNEX IV

Provisions by operators and owners for prevention of major accidents pursuant to Article 19

1. Member States shall ensure that operators and owners:

   (a) pay particular attention to evaluation of the reliability and integrity requirements of all safety and environmental critical systems and base their inspection and maintenance systems on achieving the required level of safety and environmental integrity;

   (b) take appropriate measures to ensure as far as reasonably practicable that there is no unplanned escape of hazardous substances from pipelines, vessels and systems intended for their safe confinement. In addition, operators and owners shall ensure that no single failure of a containment barrier can lead to a major accident;

   (c) prepare an inventory of available equipment, its ownership, location, transport to and mode of deployment at the installation and any entities relevant to the implementation of the internal emergency response plan. The inventory shall identify measures in place to ensure equipment and procedures are maintained in operable condition;

   (d) ensure they have a suitable framework for monitoring compliance with all relevant statutory provisions by incorporating their statutory duties in respect of major hazards control and environmental protection into their standard operating procedures; and

   (e) pay particular attention to building and maintaining a strong safety culture with a high likelihood of continuous safe operation, including with regard to securing cooperation of the workers through, inter alia:

      (i) visible commitment to tripartite consultations and actions arising therefrom;

      (ii) encouraging and rewarding reporting of accidents and near-misses;

      (iii) working effectively with elected safety representatives;

      (iv) protecting whistleblowers.

2. Member States shall ensure that industry cooperates with competent authorities to establish and implement a priority plan for the development of standards, guidance and rules which will give effect to best practice in major accident prevention, and limitation of consequences of major accidents should they nonetheless occur.

ANNEX V

Selection of the independent verifier and the design of schemes for independent verification pursuant to Article 17(3)

1. Member States shall require the operator or owner to ensure the following conditions are fulfilled with regard to the verifier's independence from the operator and the owner:

   (a) the function does not require the independent verifier to consider any aspect of a safety and environmental critical element or any part of an installation or a well or a well design in which the verifier was previously involved prior to the verification activity or where his or her objectivity might be compromised;

   (b) the independent verifier is sufficiently independent of a management system which has, or has had, any responsibility for any aspect of a component covered by the scheme for independent verification or well examination so as to ensure objectivity in carrying out his or her functions under the scheme.

2. Member States shall require the operator or the owner to ensure that, in respect of the scheme for independent verification relating to an installation or a well, the following conditions are fulfilled:

   (a) the independent verifier has suitable technical competence, including where necessary, suitably qualified and experienced personnel in adequate numbers who fulfil the requirements of point 1 of this Annex;

   (b) tasks under the scheme for independent verification are appropriately allocated by the independent verifier to personnel qualified to undertake them;

   (c) suitable arrangements are in place for the flow of information between the operator or owner and the independent verifier;

   (d) the independent verifier is given suitable authority to be able to carry out the functions effectively.

3. Material changes shall be referred to the independent verifier for further verification in accordance with the scheme for independent verification, and the outcomes of such further verification shall be communicated to the competent authority, if requested.

ANNEX VI

Information relating to priorities for cooperation between operators and owners and competent authorities pursuant to Article 19(7)

The matters to be considered for establishing priorities for the development of standards and guidance shall give practical effect to major accident prevention and limitation of their consequences. The matters shall include:

(a) improving well integrity, well control equipment and barriers and monitoring their effectiveness;

(b) improving primary containment;

(c) improving secondary containment that restricts escalation of an incipient major accident, including well blow-outs;

(d) reliable decision making;

(e) management and supervision of major hazard operations;

(f) competency of key post holders;

(g) effective risk management;

(h) reliability assessment for safety and environmental critical systems;

(i) key performance indicators;

(j) effectively integrating safety and environmental management systems between operators and owners and other entities involved in oil and gas operations.

ANNEX VII

Information to be provided in external emergency response plans pursuant to Article 29

External emergency response plans prepared pursuant to Article 29 shall include but not be limited to:

(a) names and positions of persons authorised to initiate emergency procedures, and of persons authorised to direct the external emergency response;

(b) arrangements for receiving early warning of major accidents, and the associated alert and emergency response procedures;

(c) arrangements for coordinating resources necessary to implement the external emergency response plan;

(d) arrangements for providing assistance to the internal emergency response;

(e) a detailed description of the external emergency response arrangements;

(f) arrangements for providing persons and organisations that may be affected by the major accident with suitable information and advice relating to it;

(g) arrangements for the provision of information to the emergency services of other Member States and the Commission in the event of a major accident with possible transboundary consequences;

(h) arrangements for the mitigation of the negative impacts on wildlife both onshore and offshore including the situations where oiled animals reach shore earlier than the actual spill.

ANNEX VIII

Particulars to be included in the preparation of external emergency response plans pursuant to Article 29

1. The authority or authorities responsible for coordinating emergency response shall make the following available:

   (a) an inventory of available equipment, its ownership, location, means of transport to and mode of deployment at the site of the major accident;

   (b) a description of the measures in place to ensure equipment and procedures are maintained in operable condition;

   (c) an inventory of industry-owned equipment that can be made available in an emergency;

   (d) a description of the general arrangements for responding to major accidents, including competencies and responsibilities of all involved parties and the bodies responsible for maintaining such arrangements;

   (e) measures to ensure that equipment, personnel and procedures are available and up to date and sufficient members of trained personnel are available at all times;

   (f) evidence of prior environment and health assessments of any chemicals foreseen for use as dispersants.

2. External emergency response plans shall clearly explain the role of the authorities, emergency responders, coordinators and other subjects active in emergency response, so that cooperation is ensured in responding to major accidents.

3. Arrangements shall include provisions for responding to a major accident that potentially overwhelms the Member State or exceeds its boundaries by:

   (a) sharing external emergency response plans with adjacent Member States and the Commission;

   (b) compiling at cross-border level the inventories of response assets, both industry and publicly owned and all necessary adaptations to make equipment and procedures compatible between adjacent countries and Member States;

   (c) procedures for invoking the Union Civil Protection Mechanism;

   (d) arranging transboundary exercises of external emergency response.

ANNEX IX

Sharing of information and transparency

1. The common data reporting format for major hazard indicators shall make it possible to compare information from competent authorities and to compare information from individual operators and owners.

2. The information to be shared by the competent authority and operators and owners shall include information relating to:

   (a) unintended release of oil, gas or other hazardous substances, whether or not ignited;

   (b) loss of well control requiring actuation of well control equipment, or failure of a well barrier requiring its replacement or repair;

   (c) failure of a safety and environmental critical element;

   (d) significant loss of structural integrity, or loss of protection against the effects of fire or explosion, or loss of station keeping in relation to a mobile installation;

   (e) vessels on collision course and actual vessel collisions with an offshore installation;

   (f) helicopter accidents, on or near offshore installations;

   (g) any fatal accident;

   (h) any serious injuries to 5 or more persons in the same accident;

   (i) any evacuation of personnel;

   (j) a major environmental incident.

3. The annual reports to be submitted by Member States pursuant to Article 25 shall contain as a minimum the following information:

   (a) the number, age and location of installations;

   (b) the number and type of inspections and investigations carried out, any enforcement actions or convictions;

   (c) incident data pursuant to the common reporting system required in Article 23;

   (d) any major change in the offshore regulatory framework;

   (e) the performance of offshore oil and gas operations in relation to prevention of major accidents and the limiting of consequences of major accidents that do occur.

4. The information referred to in point 2 shall consist of both factual information and analytical data regarding oil and gas operations, and shall be unambiguous. The information and data provided shall be such that the performance of individual operators and owners can be compared within the Member State and the performance of the industry as a whole can be compared between Member States.

5. The information collected and assembled referred to in point 2 shall enable Member States to provide advanced warning of potential deterioration of safety and environmentally critical barriers, and shall enable them to take preventive action. The information shall also demonstrate the overall effectiveness of measures and controls implemented by individual operators and owners, and industry as a whole, in particular to prevent major accidents and to minimise risks for the environment.

6. In order to meet the requirements of Article 24, a simplified format shall be developed to facilitate publication of relevant data pursuant to point 2 of this Annex and preparation of reports pursuant to Article 25 in a way that is easily accessible to the public and facilitates transboundary comparison of data.

STATEMENT BY THE COMMISSION

1. The Commission regrets that under paragraphs 3 and 5 of Article 41 some Member States are partially exempted from the obligation to transpose the Directive and considers that such derogations shall not be regarded as a precedent in order not to affect the integrity of EU law.

2. The Commission notes that Member States may use the option not to transpose and apply Article 20 of the Directive because of the current absence of any company registered in their jurisdiction which has offshore activities outside the territory of the Union.

In order to ensure effective enforcement of this Directive, the Commission underlines that it is incumbent on these Member States to ensure that companies already registered with them do not circumvent the aims of the Directive by extending their business objects to include offshore activities without notification of this extension to the competent national authorities so that they can take the necessary steps to ensure full application of Article 20.

The Commission will take all necessary measures against any circumvention which may be brought to its attention.

DIRECTIVE 2013/31/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 June 2013

amending Council Directive 92/65/EEC as regards the animal health requirements governing intra-Union trade in and imports into the Union of dogs, cats and ferrets

(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 43(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

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

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

Whereas:

(1) The animal health requirements governing trade in and imports into the Union of dogs, cats and ferrets are laid down in Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC [3].

(2) Those requirements refer to the relevant animal health requirements applicable to the non-commercial movement of dogs, cats and ferrets into a Member State from another Member State or from third countries or territories laid down in Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals [4].

(3) The repeal of Regulation (EC) No 998/2003 by Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals [5] makes it necessary to amend Directive 92/65/EEC in order to delete and replace the references to Regulation (EC) No 998/2003 by references to Regulation (EU) No 576/2013.

(4) Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations [6] applies, inter alia, to the transport of dogs, cats and ferrets carried out within the Union. Reference to that Regulation should therefore be inserted in Directive 92/65/EEC which establishes the animal health requirements applicable to trade in those animals.

(5) Moreover, experience in the application of Directive 92/65/EEC has shown that carrying out the clinical examination of an animal within 24 hours before dispatch is in most cases impracticable. It is therefore appropriate to extend the time limit laid down in Directive 92/65/EEC to 48 hours, as recommended by the World Organisation for Animal Health.

(6) The Commission considers that in this particular case it is not justified to ask Member States to communicate explanatory documents to the Commission in order to explain the relationship between the provisions of this Directive and the corresponding parts of national transposition documents. This Directive provides for a very limited number of amendments to Directive 92/65/EEC, which should make it possible for the Commission to obtain the information regarding transposition without devoting significant resources to that task. Member States should, in any event, transmit the text of the transposed measures to the Commission.

(7) Directive 92/65/EEC should therefore be amended accordingly,

[1] OJ C 229, 31.7.2012, p. 119.
[2] Position of the European Parliament of 23 May 2013 (not yet published in the Official Journal) and decision of the Council of 10 June 2013.
[3] OJ L 268, 14.9.1992, p. 54.
[4] OJ L 146, 13.6.2003, p. 1.
[5] See page 1 of this Official Journal.
[6] OJ L 3, 5.1.2005, p. 1.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments

Directive 92/65/EEC is hereby amended as follows:

(1) Article 10 is hereby amended as follows:

(a) paragraph 2 is replaced by the following:

'2. To be the subject of trade, dogs, cats and ferrets shall:

(a) satisfy the conditions set out in Article 6 and, where applicable, in Article 7 of Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals (*);

(b) undergo a clinical examination carried out within 48 hours prior to the time of dispatch of the animals by a veterinarian authorised by the competent authority; and

(c) be accompanied during transport to the place of destination by a health certificate which:

(i) corresponds to the specimen in Part 1 of Annex E; and

(ii) is signed by an official veterinarian who shall attest that the veterinarian authorised by the competent authority has documented in the relevant section of the identification document in the format provided for in Article 21(1) of Regulation (EU) No 576/2013 the clinical examination carried out in accordance with point (b) showing, at the time of the clinical examination, that the animals are fit to be transported for the intended journey in accordance with Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations (**).

(*) OJ L 178, 28.6.2013, p. 1.
(**) OJ L 3, 5.1.2005, p. 1.';

(b) paragraph 3 is deleted;

(2) in Article 16, the second and third paragraphs are replaced by the following:

'With respect to cats, dogs and ferrets, import conditions must be at least equivalent to those provided for in points (a) to (d) of Article 10(1) and point (a) of Article 12 of Regulation (EU) No 576/2013.

In addition to the conditions referred to in the second subparagraph, dogs, cats and ferrets shall, during transport to the place of destination, be accompanied by a health certificate, which is completed and signed by an official veterinarian who shall attest that a clinical examination was carried out within 48 hours prior to the time of dispatch of the animals by a veterinarian authorised by the competent authority who has verified that at the time of the clinical examination, the animals were fit to be transported for the intended journey.'.

Article 2

Transposition

1. Member States shall adopt and publish, by 28 December 2014, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof.

They shall apply those provisions from 29 December 2014.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such a 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 3

Entry into force

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

Article 4

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 12 June 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	L. CREIGHTON

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 577/2013

of 28 June 2013

on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations attesting compliance with certain conditions provided for in Regulation (EU) No 576/2013 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 [1], and in particular Article 7(3), Article 11(4), Article 13(1) and (2), Article 21(2) and Article 25(2) thereof,

Whereas:

(1) Regulation (EU) No 576/2013 lays down the animal health requirements applicable to the non-commercial movement of pet animals into a Member State from another Member State or from a territory or a third country and the rules for compliance checks on such movements. That Regulation repealed and replaced Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC [2].

(2) Dogs, cats and ferrets are listed in Part A of Annex I to Regulation (EU) No 576/2013, as species of animals covered by that Regulation.

(3) Regulation (EU) No 576/2013 provides that dogs, cats and ferrets are not to be moved into a Member State from another Member State or from territories or third countries unless they have received an anti-rabies vaccination that complies with the validity requirements set out in Annex III thereto. However, the movement of young dogs, cats and ferrets which are not vaccinated or do not meet the validity requirements set out in Annex III thereto may be authorised from Member States or from territories or third countries listed pursuant to Article 13 of Regulation (EU) No 576/2013, where, inter alia, the owner or the authorised person provides a signed declaration that from birth until the time of the non-commercial movement the pet animals have had no contact with wild animals of species susceptible to rabies. It is therefore appropriate to set out the format, layout and language requirements for that declaration in this Regulation.

(4) In addition, Regulation (EU) No 576/2013 provides that the Commission is to adopt two lists of territories or third countries from which dogs, cats or ferrets moved for non-commercial purposes into a Member State are not required to undergo a rabies antibody titration test. One of those lists should include those territories or third countries that have demonstrated that they apply rules the content and effect of which are the same as those applied by Member States and the other list should include those territories or third countries that have demonstrated that they meet at least the criteria laid down in Article 13(2) of Regulation (EU) No 576/2013. It is therefore appropriate to set out those lists in an Annex to this Regulation.

(5) In addition, those lists should take account of the provisions of Treaty of Accession of Croatia, according to which Croatia is to become a member of the European Union on 1 July 2013 and European Council Decision 2012/419/EU of 11 July 2012 amending the status of Mayotte with regard to the European Union [3] which provides that from 1 January 2014 Mayotte is to

[1] See page 1 of this Official Journal.
[2] OJ L 146, 13.6.2003, p. 1.
[3] OJ L 204, 31.7.2012, p. 131.

cease to be an overseas country or territory to which the provisions of Part Four of the Treaty on the Functioning of the European Union apply and is to become an outermost region of the Union within the meaning of Article 349 of that Treaty.

(6) Regulation (EU) No 576/2013 also provides that dogs, cats and ferrets are not to be moved into a Member State from a territory or a third country other than those listed in an Annex to this Regulation unless they have undergone a rabies antibody titration test that complies with the validity requirements set out in Annex IV to Regulation (EU) No 576/2013. The transit through one of those territories or third countries is however not subject to that test where the owner or the authorised person provides a signed declaration that the animals have had no contact with animals of species susceptible to rabies and remain secured within a means of transport or within the perimeter of an international airport. It is therefore appropriate to set out the format, layout and language requirements for that declaration in this Regulation.

(7) The validity requirements set out in Annex IV to Regulation (EU) No 576/2013 include the obligation to perform that test in a laboratory approved in accordance with Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines ([1]), which provides that the Agence française de sécurité sanitaire des aliments (AFSSA) in Nancy, France (integrated since 1 July 2010 into the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, ANSES) is to appraise the laboratories in Member States and third countries for the purposes of their authorisation to carry out serological tests to monitor the effectiveness of rabies vaccines in dogs, cats and ferrets.

(8) Regulation (EU) No 576/2013 also provides that dogs, cats and ferrets moved into a Member State from another Member State for non-commercial purposes are to be accompanied by an identification document in the format of a passport in accordance with a model to be adopted by the Commission. That model is to contain the entries for the insertion of the information laid down in Regulation (EU) No 576/2013. The model and additional requirements for the passport should be set out in an Annex to this Regulation and, for the sake of clarity and simplification of Union legislation, Commission Decision 2003/803/EC of 26 November 2003 establishing a model passport for the intra-Community movements of dogs, cats and ferrets ([2]) should be repealed.

(9) Regulation (EU) No 576/2013 also provides that dogs, cats and ferrets moved into a Member State from a territory or a third country for non-commercial purposes are to be accompanied by an identification document in the format of an animal health certificate in accordance with a model to be adopted by the Commission. That model is to contain the entries for the insertion of the information laid down in Regulation (EU) No 576/2013. It is therefore appropriate to set out that model in an Annex to this Regulation.

(10) By way of derogation from the format of the animal health certificate provided for in the case of a movement into a Member State from a territory or a third country, Regulation (EU) No 576/2013 provides that Member States are to authorise the non-commercial movement of dogs, cats and ferrets from a territory or a third country that has demonstrated that it applies rules the content and effect of which are the same as those applied by Member States, where the identification document accompanying them has been issued in accordance with the procedure provided for in the case of a movement into a Member State from another Member State. However, a number of technical adaptations are necessary to the model passport to be used in such cases, with regard in particular to features on the cover page that cannot fully comply with the requirements applicable to passports issued by a Member State. For reasons of clarity, it is therefore appropriate to set out a model for such passports in this Regulation.

(11) Regulation (EU) No 576/2013 provides that where the number of dogs, cats or ferrets moved for non-commercial purposes during a single movement exceeds five, the relevant animal health requirements laid down in Council Directive 92/65/EEC ([3]) of 13 July 1992 laying down the animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC are to apply to those animals, except under specific conditions and for certain categories of animals.

(12) In addition Commission Decision 2004/839/EC of 3 December 2004 establishing conditions for non-commercial movements of young dogs and cats from third countries into the Community ([4]) and Commission Decision 2005/91/EC of 2 February 2005 establishing the period after which the anti-rabies vaccination is considered as valid ([5]) were adopted in order to provide for uniform rules for the implementation of Regulation (EC) No 998/2003. The rules provided for in those acts have been reviewed and are now incorporated in the provisions of Regulation (EU) No 576/2013. For the sake of clarity and simplification of Union legislation, Decisions 2004/839/EC and 2005/91/EC should therefore be repealed.

([1]) OJ L 79, 30.3.2000, p. 40.
([2]) OJ L 312, 27.11.2003, p. 1.
([3]) OJ L 268, 14.9.1992, p. 54.
([4]) OJ L 361, 8.12.2004, p. 40.
([5]) OJ L 31, 4.2.2005, p. 61.

(13) Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products [1] lays down the rules to be observed in issuing the certificates required by veterinary legislation to prevent misleading or fraudulent certification. It is appropriate to ensure that rules and principles at least equivalent to those laid down in that Directive are applied by official veterinarians of third countries.

(14) Commission Delegated Regulation (EU) No 1152/2011 of 14 July 2011 supplementing Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards preventive health measures for the control of *Echinococcus multilocularis* infection in dogs [2] provides that from 1 January 2012, dogs entering Member States or parts thereof listed in Annex I thereto are to be treated against the parasite *Echinococcus multilocularis* in accordance with the requirements set out in that Regulation.

(15) This Regulation should apply without prejudice to Commission Decision 2006/146/EC of 21 February 2006 on certain protection measures with regard to certain fruit bats, dogs and cats coming from Malaysia (Peninsula) and Australia [3] which prohibits imports of dogs and cats from Malaysia (Peninsula) and cats from Australia unless certain conditions are met regarding respectively Nipah disease and Hendra disease.

(16) This Regulation should apply from the date of application of Regulation (EU) No 576/2013.

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

HAS ADOPTED THIS REGULATION:

Article 1

Format, layout and language requirements of the declarations referred to in Articles 7, 11 and 12 of Regulation (EU) No 576/2013

1. The declarations referred to in point (a) of Article 7(2) and of Article 11(2) of Regulation (EU) No 576/2013 shall be drawn up in accordance with the format and layout set out in Part 1 of Annex I to this Regulation and shall comply with the language requirements set out in Part 3 of that Annex.

2. The declaration referred to in point (c) of Article 12(1) of Regulation (EU) No 576/2013 shall be drawn up in accordance with the format and layout set out in Part 2 of Annex I to this Regulation and shall comply with the language requirements set out in Part 3 of that Annex.

Article 2

Lists of territories and third countries referred to in Article 13 of Regulation (EU) No 576/2013

1. The list of territories and third countries referred to in Article 13(1) of Regulation (EU) No 576/2013 is set out in Part 1 of Annex II to this Regulation.

2. The list of territories and third countries referred to in Article 13(2) of Regulation (EU) No 576/2013 is set out in Part 2 of Annex II to this Regulation.

Article 3

Model of passports for the non-commercial movement of dogs, cats or ferrets

1. The passport referred to in Article 21(1) of Regulation (EU) No 576/2013 shall be drawn up in accordance with the model set out in Part 1 of Annex III to this Regulation and shall comply with the additional requirements set out in Part 2 of that Annex.

2. By way of derogation from paragraph 1, passports issued, pursuant to point (a) of Article 27 of Regulation (EU) No 576/2013, in one of the territories or third countries listed in Part 1 of Annex II to this Regulation shall be drawn up in accordance with the model set out in Part 3 of Annex III to this Regulation and shall comply with the additional requirements set out in Part 4 of that Annex.

Article 4

Animal health certificate for the non-commercial movement into the Union of dogs, cats or ferrets

The animal health certificate referred to in Article 25(1) of Regulation (EU) No 576/2013 shall be:

(a) drawn up in accordance with the model set out in Part 1 of Annex IV to this Regulation;

(b) duly completed and issued in accordance with the explanatory notes set out in Part 2 of that Annex;

(c) supplemented by the written declaration referred to in Article 25(3) of Regulation (EU) No 576/2013 which is drawn up in accordance with the model set out in Section A of Part 3 of that Annex and which complies with the additional requirements set out in Section B of Part 3 of that Annex.

[1] OJ L 13, 16.1.1997, p. 28.
[2] OJ L 296, 15.11.2011, p. 6.
[3] OJ L 55, 25.2.2006, p. 44.

Article 5

Repeals

Decisions 2003/803/EC, 2004/839/EC and 2005/91/EC are repealed.

Article 6

Entry into force and applicability

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

It shall apply from 29 December 2014.

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

Done at Brussels, 28 June 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Format, layout and language requirements of the declarations

referred to in point (a) of Article 7(2) and of Article 11(2) and in point (c) of Article 12(1) of Regulation (EU) No 576/2013

PART 1

Format and layout of the declaration referred to in point (a) of Article 7(2) and of Article 11(2) of Regulation (EU) No 576/2013

DECLARATION

I, the undersigned

..... (1)

[owner or natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the pet animals on behalf of the owner (2)]

declare that from birth until the time of the non-commercial movement the following pet animals have had no contact with wild animals of species susceptible to rabies:

Transponder/tattoo (2) alphanumeric code	Passport/Animal health certificate (2) number

Place and date: Signature:

(1) To be completed in block letters.

(2) Delete as appropriate.

PART 2

Format and layout of the declaration referred to in point (c) of Article 12(1) of Regulation (EU) No 576/2013

DECLARATION

I, the undersigned

..... (1)

[owner or natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the pet animals on behalf of the owner (2)]

declare that, during the transit through one of the territories or third countries other than those listed in Annex II to Commission Implementing Regulation (EU) No 577/2013, the following pet animals have had no contact with animals of species susceptible to rabies and remain secure within a means of transport or within the perimeter of an international airport (2):

Transponder/tattoo (2) alphanumeric code	Animal health certificate number

Place and date: Signature:

(1) To be completed in block letters.
(2) Delete as appropriate.

PART 3

Language requirements for the declarations referred to in point (a) of Article 7(2) and of Article 11(2) and in point (c) of Article 12(1) of Regulation (EU) No 576/2013

The declarations shall be drawn up in at least one of the official language(s) of the Member State of destination/entry and in English.

ANNEX II

List of territories and third countries referred to in Article 13 of Regulation (EU) No 576/2013

PART 1

List of territories and third countries referred to in Article 13(1) of Regulation (EU) No 576/2013

ISO code	Territory or third country
AD	Andorra
CH	Switzerland
FO	Faeroe Islands
GI	Gibraltar
GL	Greenland
HR (*)	Croatia
IS	Iceland
LI	Liechtenstein
MC	Monaco
NO	Norway
SM	San Marino
VA	Vatican City State

(*) Only applicable until this Acceding State becomes a Member State of the Union.

PART 2

List of territories and third countries referred to in Article 13(2) of Regulation (EU) No 576/2013

ISO code	Territory or third country	Included territories
AC	Ascension Island	
AE	United Arab Emirates	
AG	Antigua and Barbuda	
AR	Argentina	
AU	Australia	
AW	Aruba	
BA	Bosnia and Herzegovina	
BB	Barbados	
BH	Bahrain	
BM	Bermuda	
BQ	Bonaire, Sint Eustatius and Saba (the BES Islands)	
BY	Belarus	
CA	Canada	
CL	Chile	

ISO code	Territory or third country	Included territories
CW	Curaçao	
FJ	Fiji	
FK	Falkland Islands	
HK	Hong Kong	
JM	Jamaica	
JP	Japan	
KN	Saint Kitts and Nevis	
KY	Cayman Islands	
LC	Saint Lucia	
MS	Montserrat	
MU	Mauritius	
MX	Mexico	
MY	Malaysia	
NC	New Caledonia	
NZ	New Zealand	
PF	French Polynesia	
PM	Saint Pierre and Miquelon	
RU	Russia	
SG	Singapore	
SH	Saint Helena	
SX	Sint Maarten	
TT	Trinidad and Tobago	
TW	Taiwan	
US	United States of America	AS – American Samoa GU – Guam MP – Northern Mariana Islands PR – Puerto Rico VI – US Virgin Islands
VC	Saint Vincent and the Grenadines	
VG	British Virgin Islands	
VU	Vanuatu	
WF	Wallis and Futuna	
YT (*)	Mayotte	

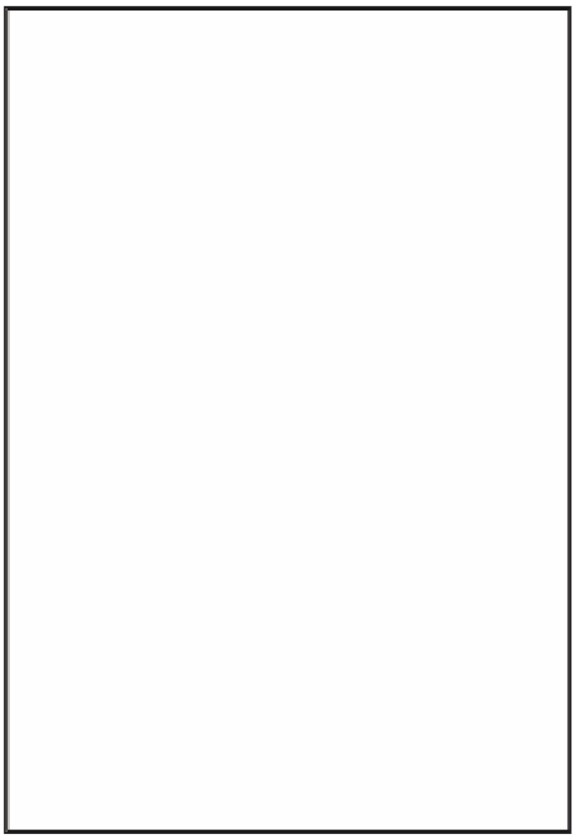
(*) Only applicable until this territory becomes an outermost region of the Union within the meaning of Article 349 TFEU.

ANNEX III

Models of passports for the non-commercial movement of dogs, cats or ferrets

PART 1

Model of passport issued in a Member State



Explanatory notes for completing the passport

- In each Section of the passport the following format shall be used to indicate
  - — a date: dd/mm/yyyy
  - — a time: 00:00
- Section III, point 5: information required where the animal has a clearly readable tattoo applied before 3 July 2011 and is not marked by the implantation of a transponder.
- Section V: only required
  - — before movement into another Member State in accordance with EU animal health legislation; or
  - — where the animal re-enters the Union after a movement to territories or third countries in accordance with EU animal health legislation (to be completed before the animal leaves the Union); or
  - — in accordance with national legislation.
- Section V, "VALID FROM[2]": information not required for booster vaccinations.

ISO Country Code + Number

Explanatory notes for completing the passport

- Section VI: only required where the animal re-enters the Union after a movement to certain territories or a third countries in accordance with EU animal health legislation (to be completed before the animal leaves the Union).
- Section VII: only required before movement into certain Member States in accordance with EU animal health legislation.
- Section VIII to XI: may be required by territories or third countries of destination which accept the passport.
- Section X: only required where the animal is accompanied by a health certificate in accordance with EU animal health legislation.
- Section XII: additional information required under national legislation.

ISO Country Code + Number

I. DETAILS OF OWNERSHIP

1. Name: _____
   Surrname: _____
   Addres: _____
   _____
   Post-Code: _____
   City: _____
   Country _____
   Telephone number*: _____
   Signature:

2. Name: _____
   Surrname: _____
   Addres: _____
   _____
   Post-Code: _____
   City: _____
   Country _____
   Telephone number*: _____
   Signature:

* optional

ISO Country Code + Number

II. DESCRIPTION OF ANIMAL

PICTURE OF THE ANIMAL
(optional)

1. Name*: _____
2. Species: _____
3. Breed*: _____
4. Sex _____
5. Date of Birth*: _____
6. Colour: _____
7. Any notable or discernable features or characteristics: _____

_____

* as stated by owner

ISO Country Code + Number

III. MARKING OF ANIMAL

1. Transponder alphanumeric code

_____

2. Date of application or reading* of the transponder

_____

3. Location of the transponder

_____

4. Tattoo alphanumeric code

_____

5. Date of application/date of reading of the tattoo

_____/_____

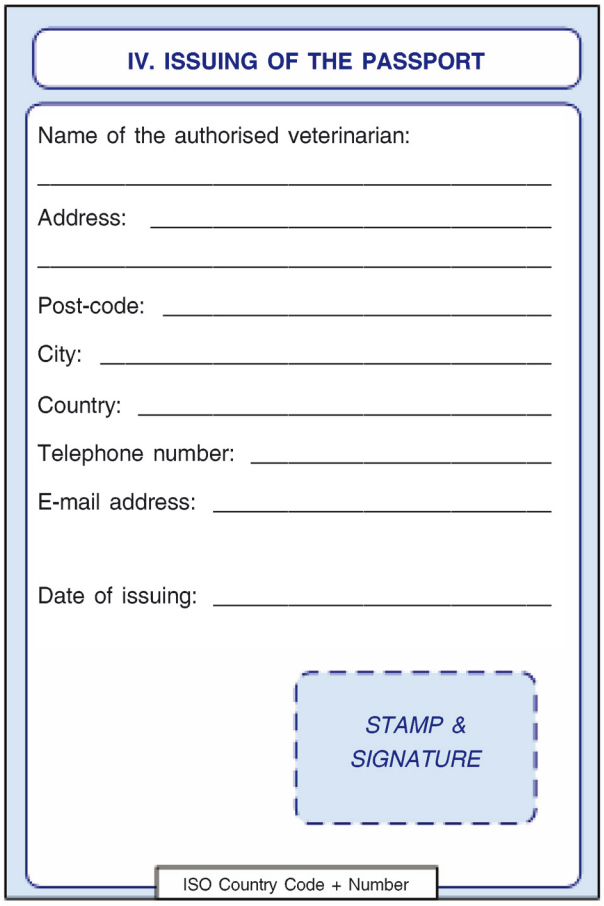
6. Location of the tattoo

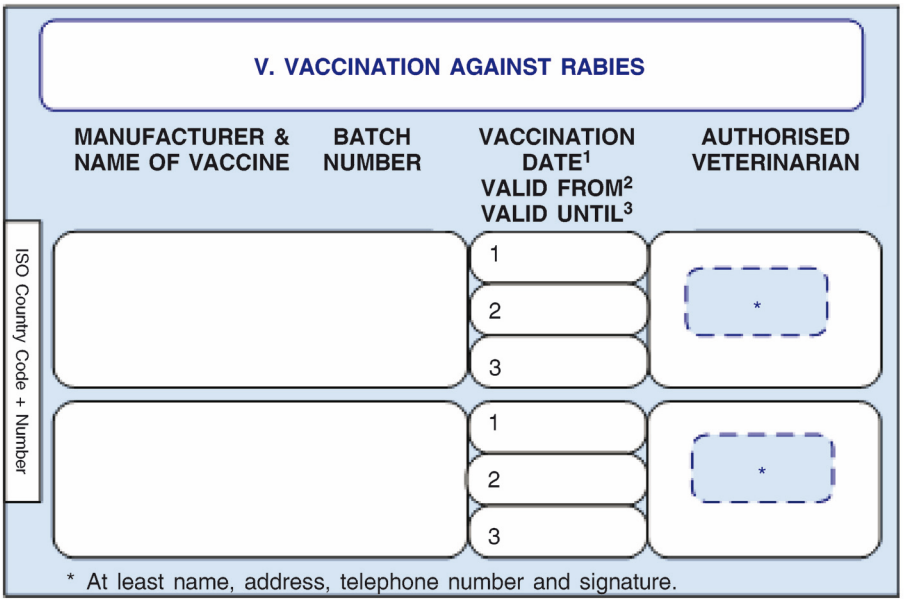
_____

The marking must be verified before any new entry is made on this passport

* delete as necessary

ISO Country Code + Number


IV. ISSUING OF THE PASSPORT
Name of the authorised veterinarian:
Address:
Post-code:
City:
Country:
Telephone number:
E-mail address:
Date of issuing:
STAMP & SIGNATURE
ISO Country Code + Number


V. VACCINATION AGAINST RABIES
MANUFACTURER & NAME OF VACCINE
BATCH NUMBER
VACCINATION DATE[1] VALID FROM[2] VALID UNTIL[3]
AUTHORISED VETERINARIAN
ISO Country Code + Number
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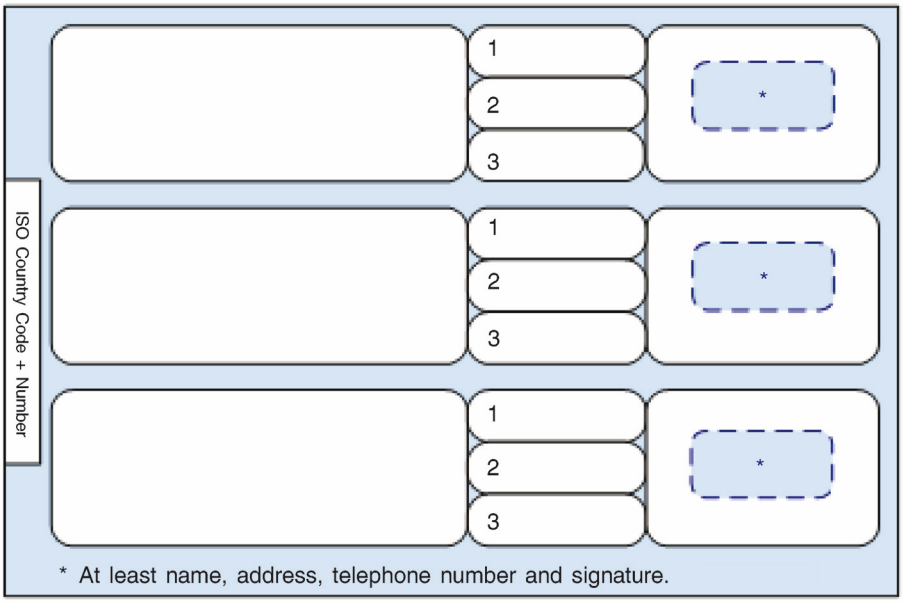
* At least name, address, telephone number and signature.


ISO Country Code + Number
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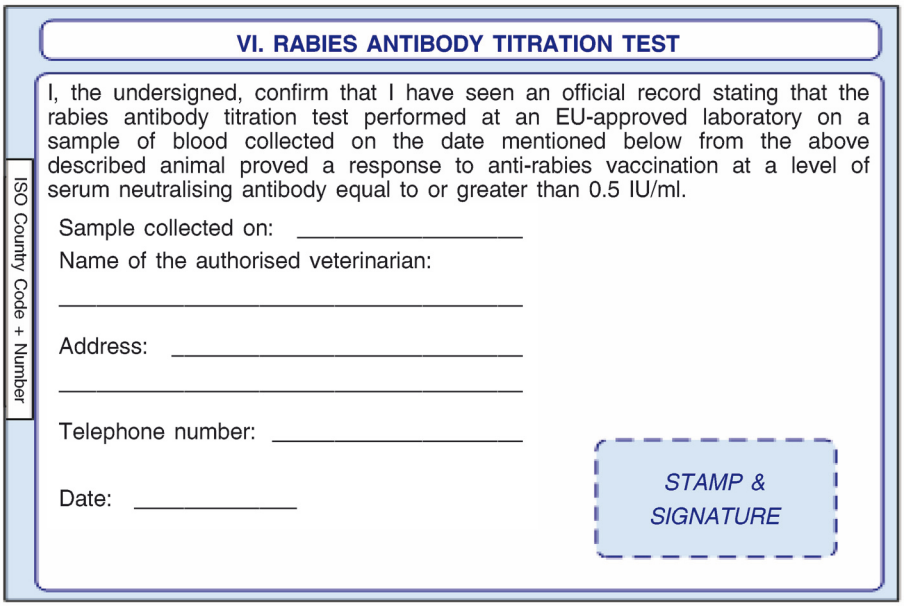
* At least name, address, telephone number and signature.


VI. RABIES ANTIBODY TITRATION TEST
ISO Country Code + Number
I, the undersigned, confirm that I have seen an official record stating that the rabies antibody titration test performed at an EU-approved laboratory on a sample of blood collected on the date mentioned below from the above described animal proved a response to anti-rabies vaccination at a level of serum neutralising antibody equal to or greater than 0.5 IU/ml.
Sample collected on: _____
Name of the authorised veterinarian:
_____
Address: _____
_____
Telephone number: _____
Date: _____
STAMP & SIGNATURE

IN CASE OF A FURTHER TEST

ISO Country Code + Number

I, the undersigned, confirm that I have seen an official record stating that the rabies antibody titration test performed at an EU-approved laboratory on a sample of blood collected on the date mentioned below from the above described animal proved a response to anti-rabies vaccination at a level of serum neutralising antibody equal to or greater than 0.5 IU/ml.

Sample collected on: _____

Name of the authorised veterinarian:

_____

Address: _____

_____

Telephone number: _____

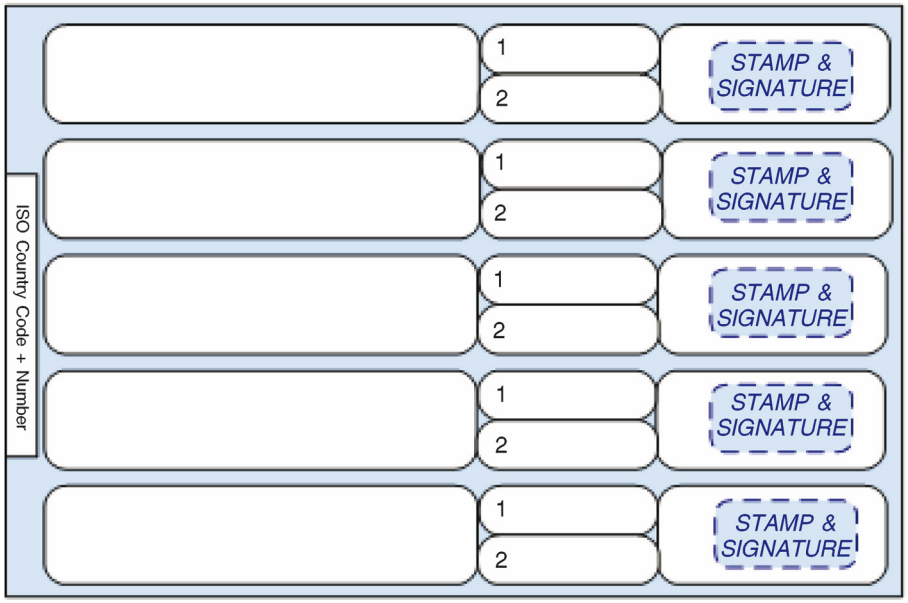
Date: _____

STAMP & SIGNATURE

VII. ANTI-ECHINOCOCCUS TREATMENT

MANUFACTURER & NAME OF PRODUCT	DATE[1] TIME[2]	VETERINARIAN
	1 2	*STAMP & SIGNATURE*
	1 2	*STAMP & SIGNATURE*
	1 2	*STAMP & SIGNATURE*

ISO Country Code + Number


ISO Country Code + Number
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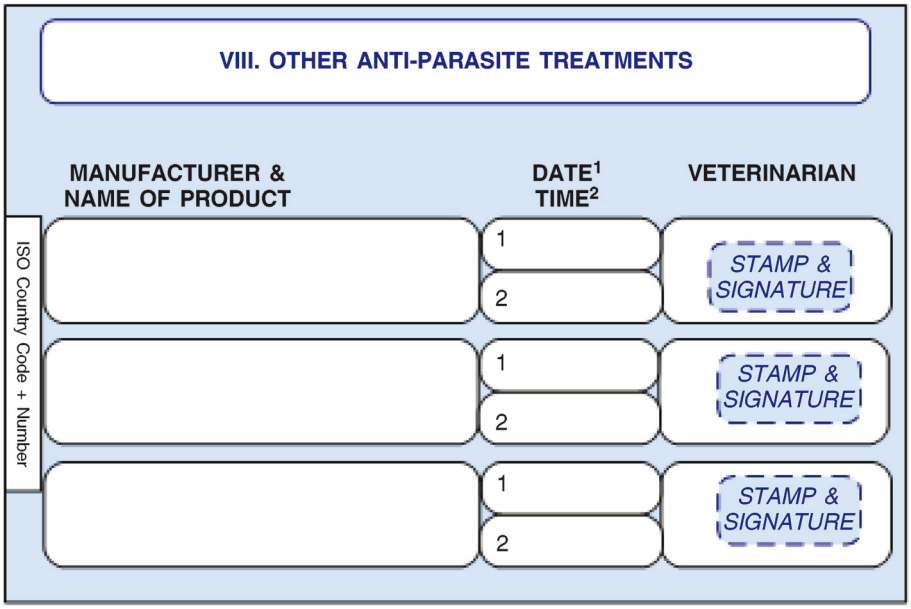
VIII. OTHER ANTI-PARASITE TREATMENTS
MANUFACTURER & NAME OF PRODUCT
DATE[1] TIME[2]
VETERINARIAN
ISO Country Code + Number
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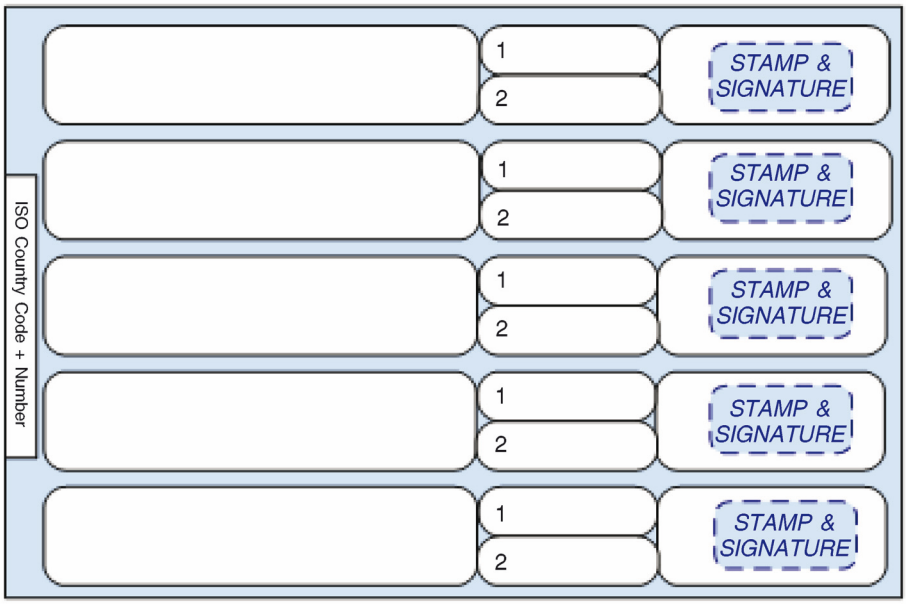
ISO Country Code + Number
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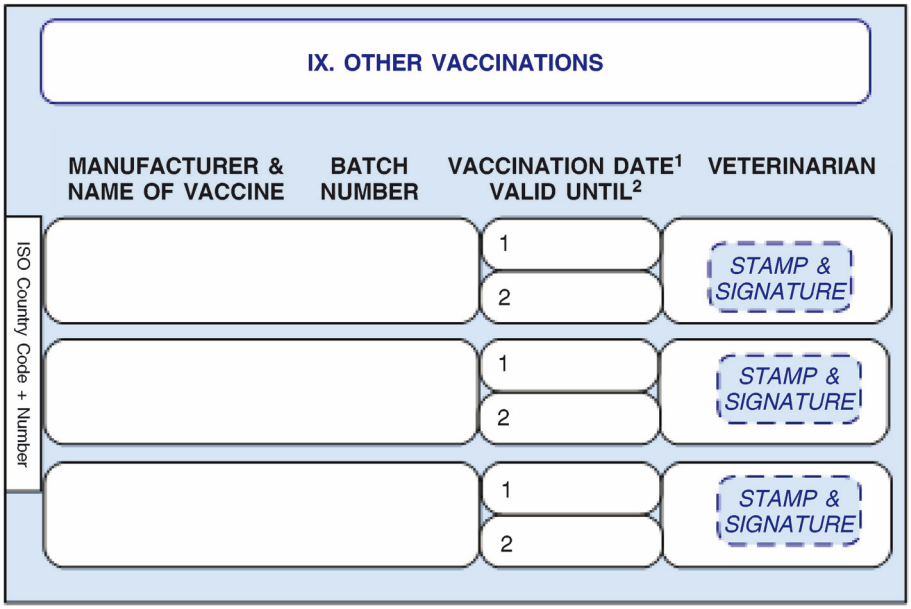
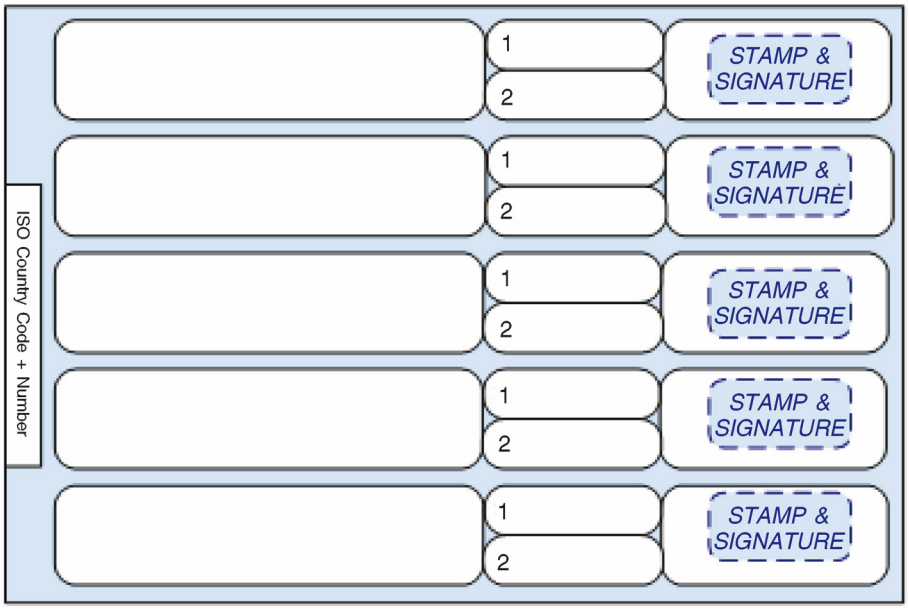

IX. OTHER VACCINATIONS
MANUFACTURER & NAME OF VACCINE
BATCH NUMBER
VACCINATION DATE[1] VALID UNTIL[2]
VETERINARIAN
ISO Country Code + Number
1
2
STAMP & SIGNATURE
1
2
STAMP & SIGNATURE
1
2
STAMP & SIGNATURE


ISO Country Code + Number
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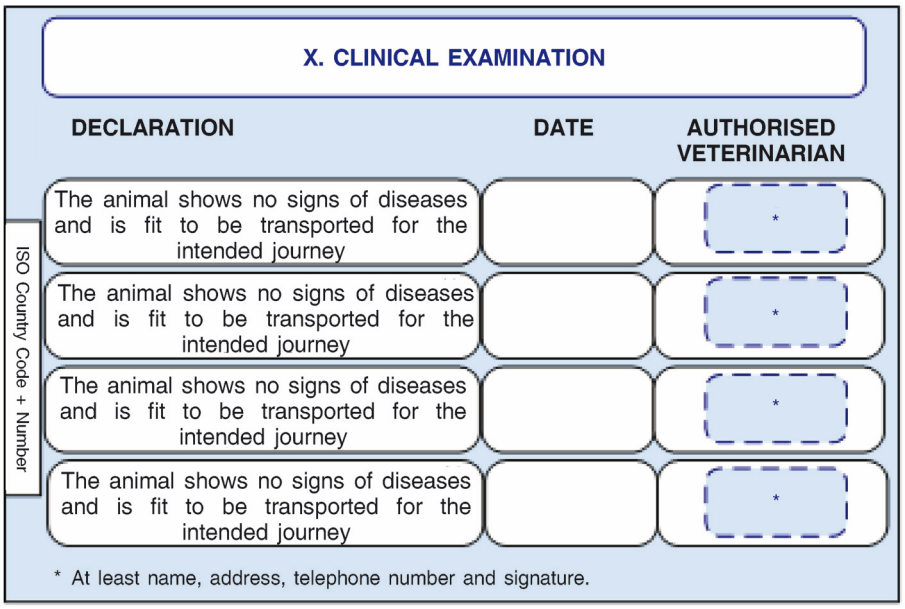
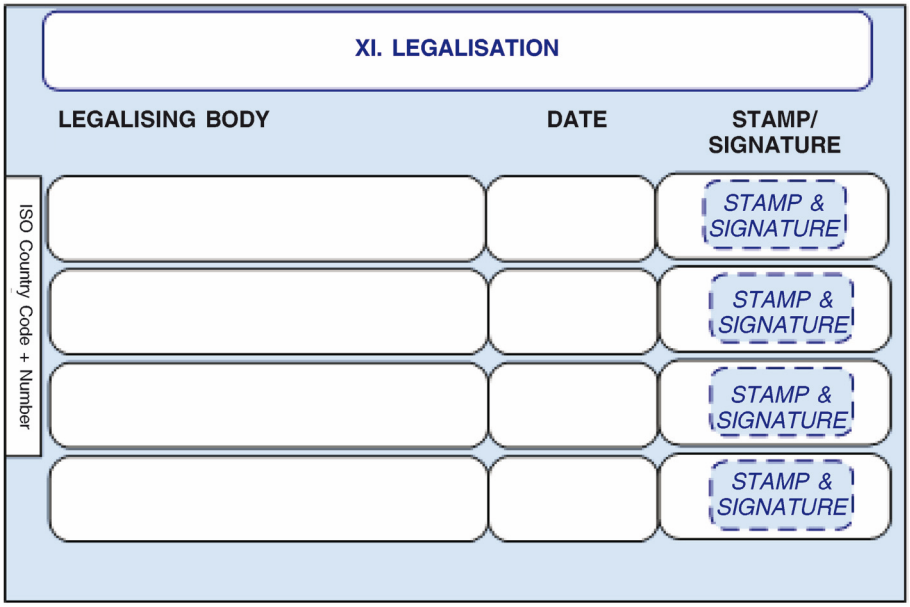

X. CLINICAL EXAMINATION
DECLARATION
DATE
AUTHORISED VETERINARIAN
ISO Country Code + Number
The animal shows no signs of diseases and is fit to be transported for the intended journey
The animal shows no signs of diseases and is fit to be transported for the intended journey
The animal shows no signs of diseases and is fit to be transported for the intended journey
The animal shows no signs of diseases and is fit to be transported for the intended journey
*
*
*
*
* At least name, address, telephone number and signature.


XI. LEGALISATION
LEGALISING BODY
DATE
STAMP/ SIGNATURE
ISO Country Code + Number
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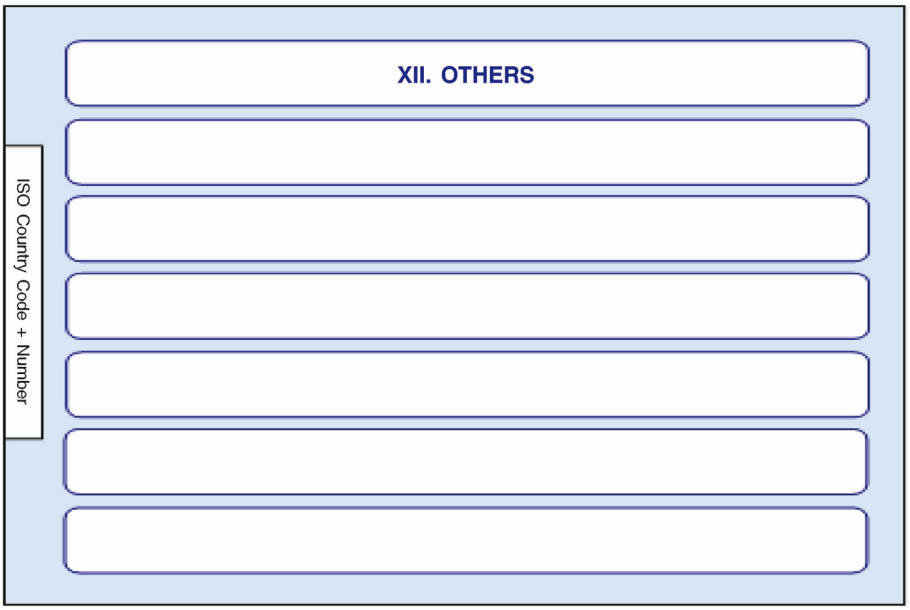
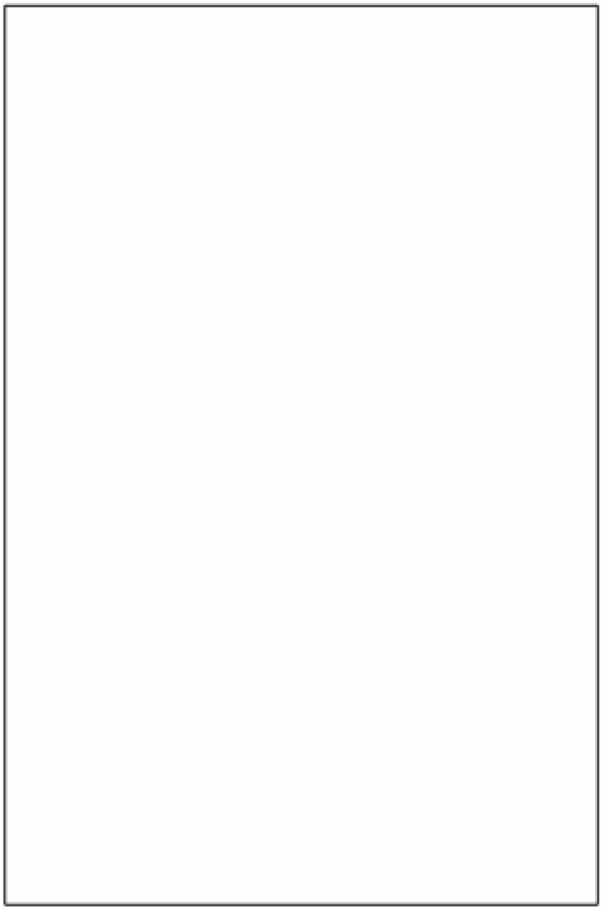
STAMP & SIGNATURE


XII. OTHERS
ISO Country Code + Number



PART 2

Additional requirements concerning the passport issued in a Member State

1. Format of the passport:

The dimension of the passport shall be 100 × 152 mm.

2. Cover of the passport:

(a) front cover:

(i) colour: blue (PANTONE® Reflex Blue) and yellow stars (PANTONE® Yellow) in the upper quarter complying with the specification of the European emblem ([1]);

(ii) the words 'European Union' and the name of the Member State of issue shall be printed in the same typeface;

(iii) the ISO country code of the Member State of issue followed by a unique alphanumeric code (indicated as 'number' in the model of passport set out in Part 1) shall be printed on the bottom;

(b) inside front cover and inside back cover: colour white;

(c) back cover: colour blue (PANTONE® Reflex Blue).

3. Sequences of the headings and numbering of pages of the passport:

(a) the sequence of the headings (with the roman numbers) must be strictly respected;

(b) the pages of the passport shall be numbered at the bottom of each page in the following format: 'x out of n', where x is the current page and n is the total number of pages of the passport;

(c) the ISO country code of the Member State of issue followed by a unique alphanumeric code shall be printed on each page of the passport;

(d) the number of pages and the size and shape of the boxes in the model of passport set out in Part 1 are indicative.

4. Languages:

All printed text shall be in the official language(s) of the Member State of issue and in English.

5. Security features:

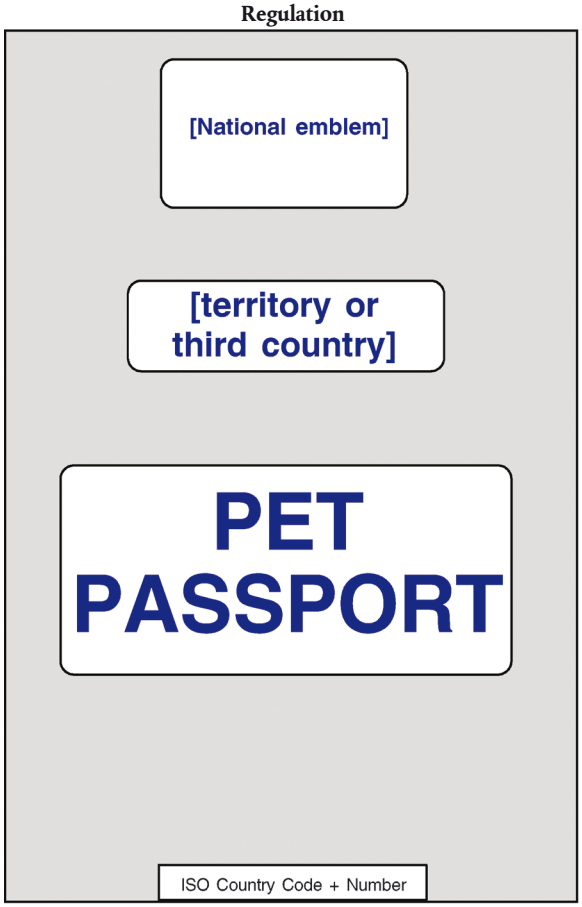
(a) after the required information has been entered in Section III of the passport, a transparent adhesive laminate shall seal the page;

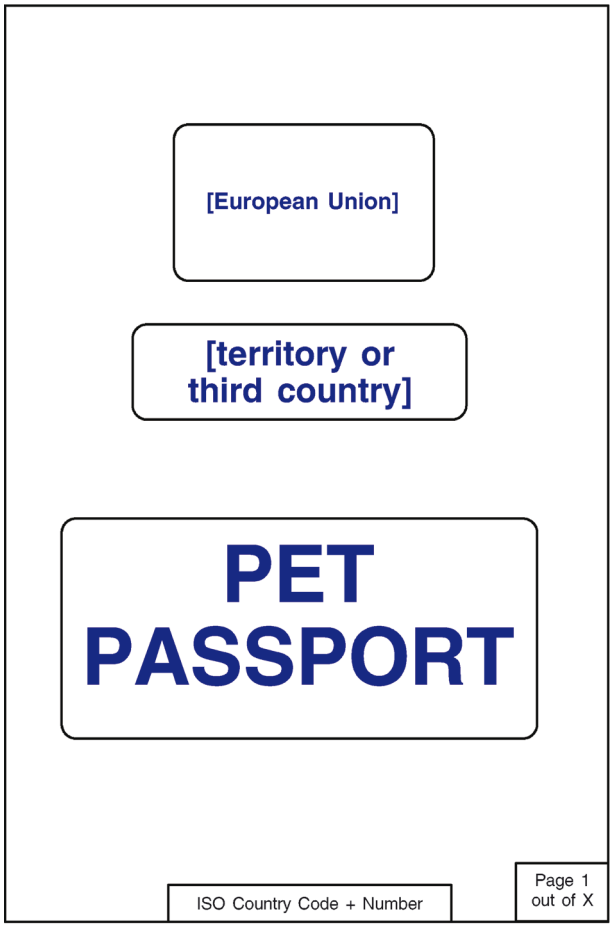
(b) where the information on one of the pages of the passport takes the form of a sticker, a transparent adhesive laminate shall seal that sticker in the case where the latter is not self-destructed when it is removed.

([1]) Graphics guide to the European Emblem: http://publications.europa.eu/code/en/en-5000100.htm

PART 3

Model of passport issued in one of the territories or third countries listed in Part 1 of Annex II to this Regulation





Explanatory notes for completing the passport

- In each Section of the passport the following format shall be used to indicate
  - — a date: dd/mm/yyyy
  - — a time: 00:00
- Section III, point 5: information required where the animal has a clearly readable tattoo applied before 3 july 2011 and is not marked by the implantation of a transponder.
- Section V: only required
  - — before movement into another Member State/… in accordance with EU animal health legislation; or
  - — where the animal re-enters the Union/… after a movement to territories or third countries in accordance with EU animal health legislation (to be completed before the animal leaves the Union/…); or
  - — in accordance with national legislation.
- Section V, "VALID FROM[2]": information not required for booster vaccinations.

ISO Country Code + Number

Explanatory notes for completing the passport

- Section VI: only required where the animal re-enters the Union/… after a movement to certain territories or third countries in accordance with EU animal health legislation (to be completed before the animal leaves the Union/…).
- Section VII: only required before movement into certain Member States/… in accordance with EU animal health legislation.
- Section VIII to XI: may be required by territories or third countries of destination which accept the passport.
- Section X: only required where the animal is accompanied by a health certificate in accordance with EU animal health legislation.
- Section XII: additional information required under national legislation.

ISO Country Code + Number

I. DETAILS OF OWNERSHIP

1. Name: _____
   Surrname: _____
   Addres: _____
   _____
   Post-Code: _____
   City: _____
   Country _____
   Telephone number*: _____
   Signature:

2. Name: _____
   Surrname: _____
   Addres: _____
   _____
   Post-Code: _____
   City: _____
   Country _____
   Telephone number*: _____
   Signature:

* optional

ISO Country Code + Number

II. DESCRIPTION OF ANIMAL

PICTURE OF THE ANIMAL
(optional)

1. Name*: _____
2. Species: _____
3. Breed*: _____
4. Sex: _____
5. Date of Birth*: _____
6. Colour: _____
7. Any notable or discernable features or characteristics: _____
_____

* as stated by owner

ISO Country Code + Number

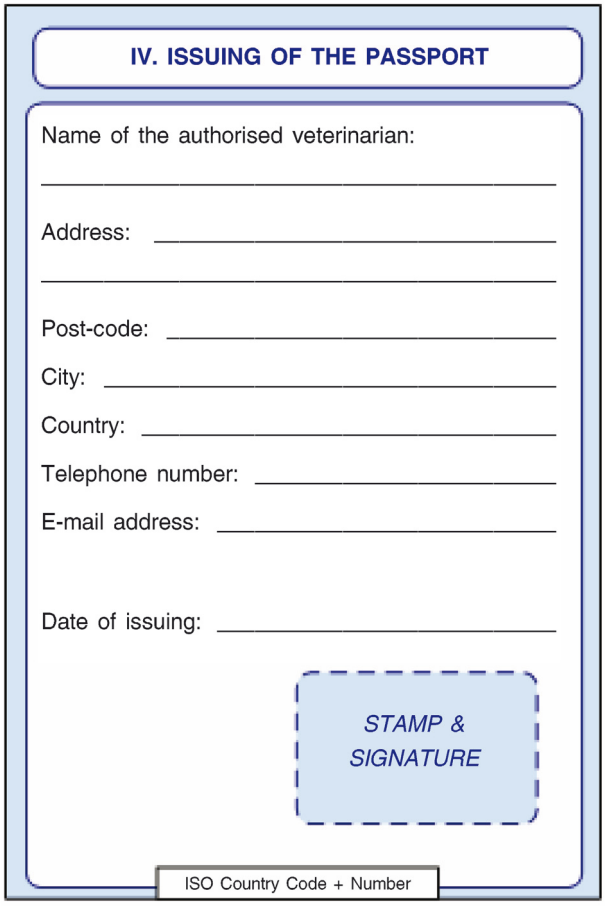
III. MARKING OF ANIMAL

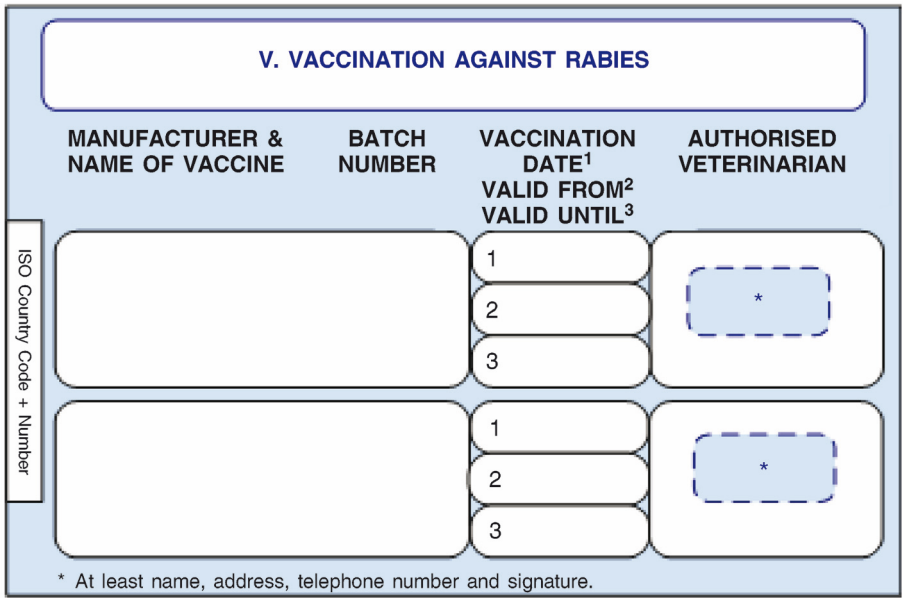
1. Transponder alphanumeric code
_____
2. Date of application or reading* of the transponder
_____
3. Location of the transponder
_____
4. Tattoo alphanumeric code
_____
5. Date of application/date of reading of the tattoo
_____ / _____
6. Location of the tattoo
_____

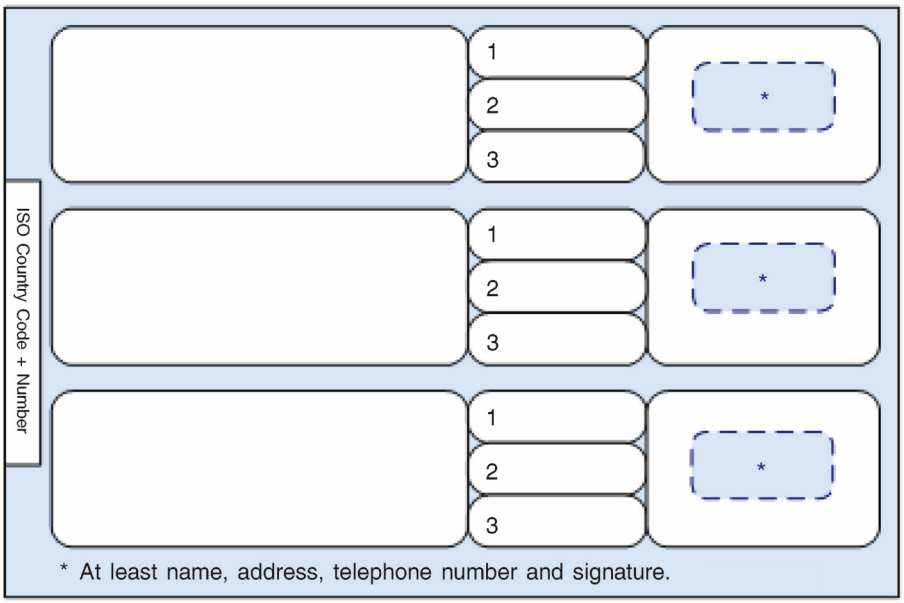
The marking must be verified before any new entry is made on this passport

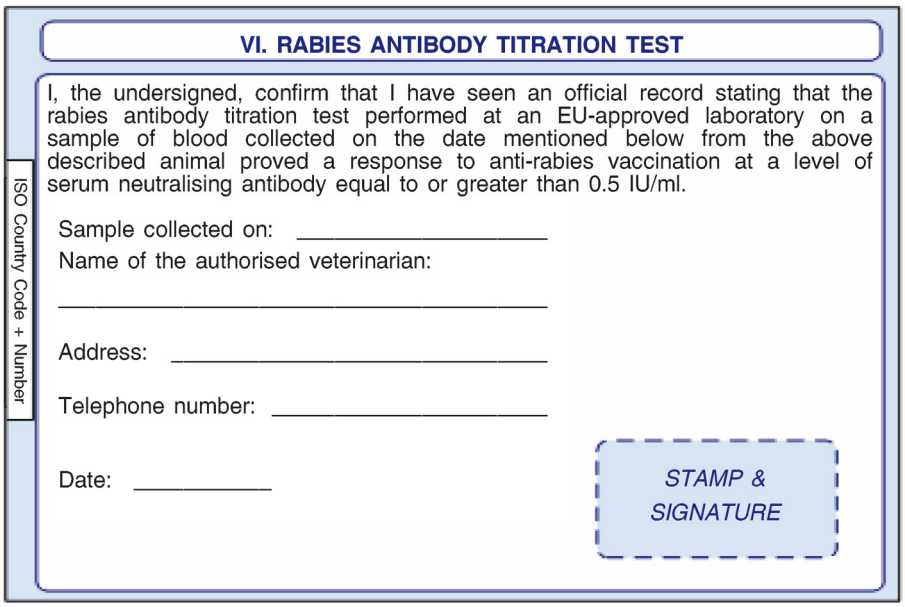
* delete as necessary

ISO Country Code + Number


IV. ISSUING OF THE PASSPORT
Name of the authorised veterinarian:
Address:
Post-code:
City:
Country:
Telephone number:
E-mail address:
Date of issuing:
STAMP & SIGNATURE
ISO Country Code + Number


V. VACCINATION AGAINST RABIES
MANUFACTURER & NAME OF VACCINE
BATCH NUMBER
VACCINATION DATE[1] VALID FROM[2] VALID UNTIL[3]
AUTHORISED VETERINARIAN
ISO Country Code + Number
1
2
3
*
1
2
3
*
* At least name, address, telephone number and signature.


ISO Country Code + Number
1
2
3
*
1
2
3
*
1
2
3
*
* At least name, address, telephone number and signature.


VI. RABIES ANTIBODY TITRATION TEST
ISO Country Code + Number
I, the undersigned, confirm that I have seen an official record stating that the rabies antibody titration test performed at an EU-approved laboratory on a sample of blood collected on the date mentioned below from the above described animal proved a response to anti-rabies vaccination at a level of serum neutralising antibody equal to or greater than 0.5 IU/ml.
Sample collected on: _____
Name of the authorised veterinarian:
_____
Address: _____
Telephone number: _____
Date: _____
STAMP & SIGNATURE

IN CASE OF A FURTHER TEST

I, the undersigned, confirm that I have seen an official record stating that the rabies antibody titration test performed at an EU-approved laboratory on a sample of blood collected on the date mentioned below from the above described animal proved a response to anti-rabies vaccination at a level of serum neutralising antibody equal to or greater than 0.5 IU/ml.

ISO Country Code + Number

Sample collected on: _____

Name of the authorised veterinarian:

_____

Address: _____

Telephone number: _____

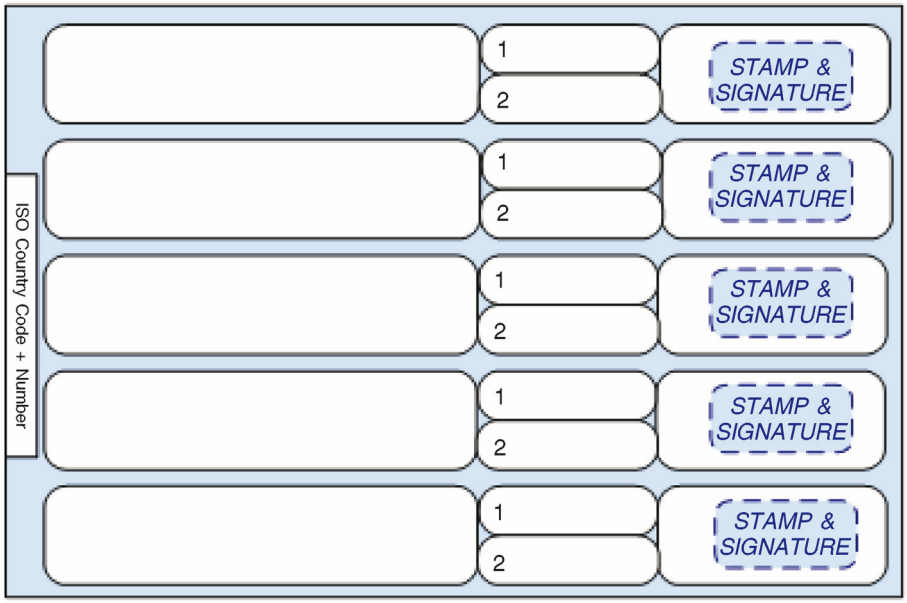
Date: _____

STAMP & SIGNATURE

VII. ANTI-ECHINOCOCCUS TREATMENT

MANUFACTURER & NAME OF PRODUCT	DATE[1] TIME[2]	VETERINARIAN
	1 2	*STAMP & SIGNATURE*
	1 2	*STAMP & SIGNATURE*
	1 2	*STAMP & SIGNATURE*

ISO Country Code + Number


ISO Country Code + Number
1
2
STAMP & SIGNATURE
1
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STAMP & SIGNATURE
1
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STAMP & SIGNATURE
1
2
STAMP & SIGNATURE
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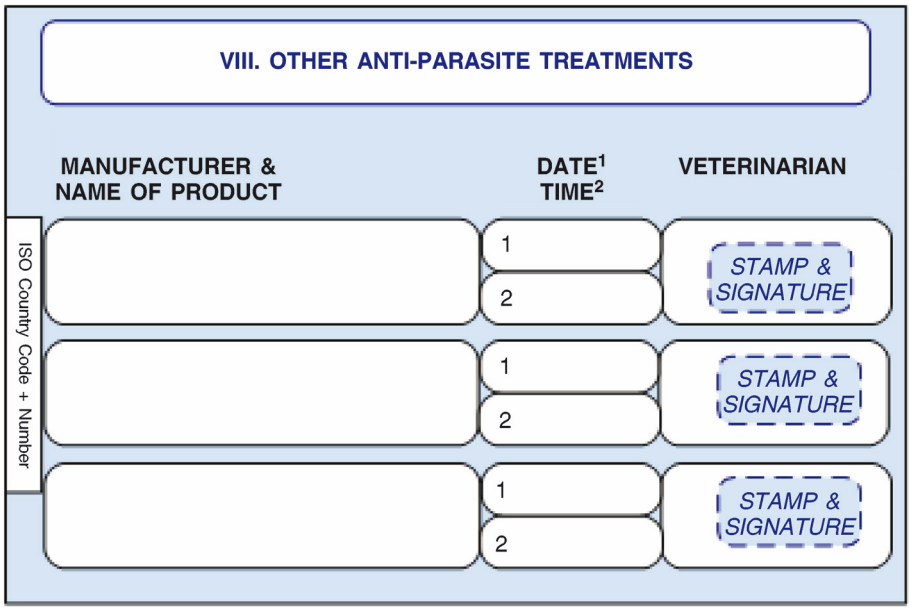
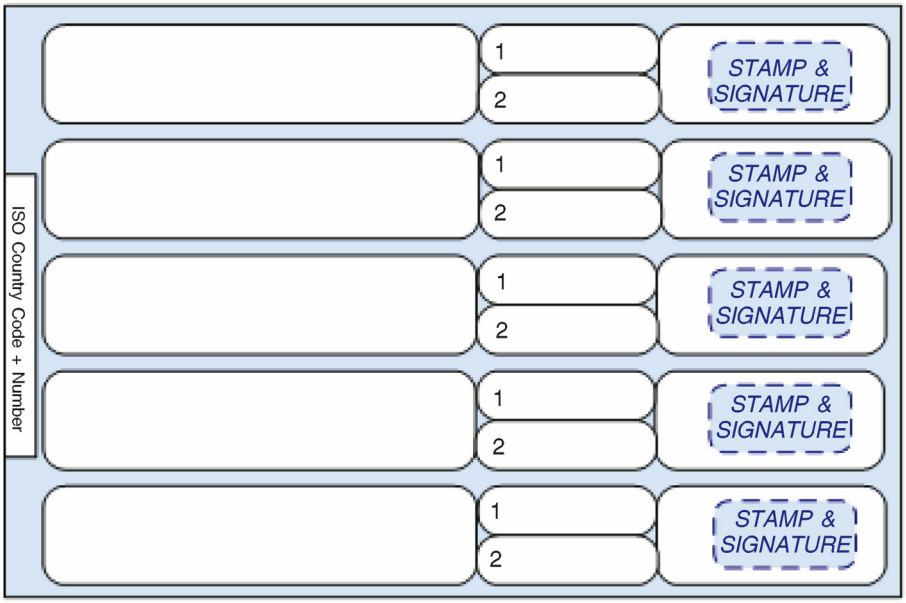
2
STAMP & SIGNATURE


VIII. OTHER ANTI-PARASITE TREATMENTS
MANUFACTURER & NAME OF PRODUCT
DATE[1] TIME[2]
VETERINARIAN
ISO Country Code + Number
1
2
STAMP & SIGNATURE
1
2
STAMP & SIGNATURE
1
2
STAMP & SIGNATURE


ISO Country Code + Number
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STAMP & SIGNATURE
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STAMP & SIGNATURE
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STAMP & SIGNATURE
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STAMP & SIGNATURE
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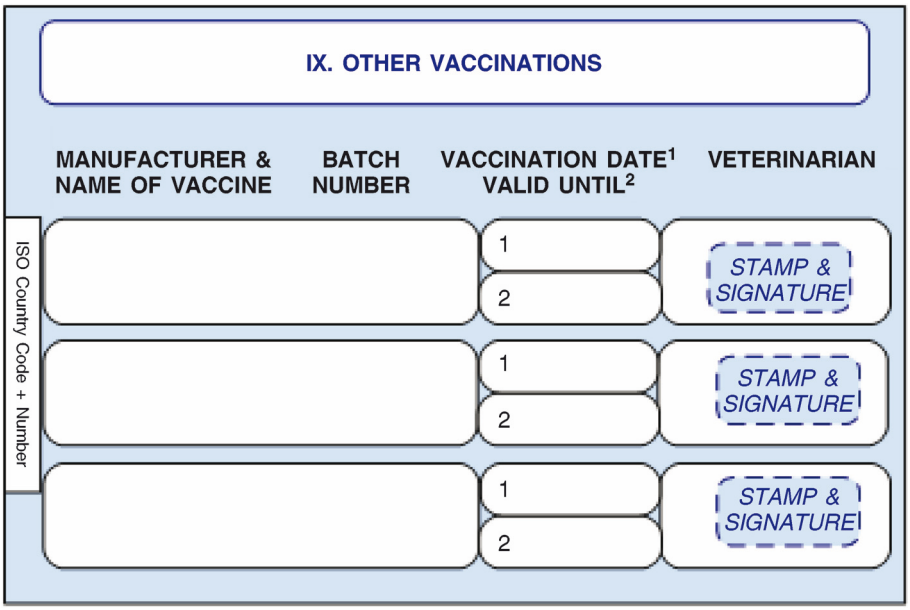
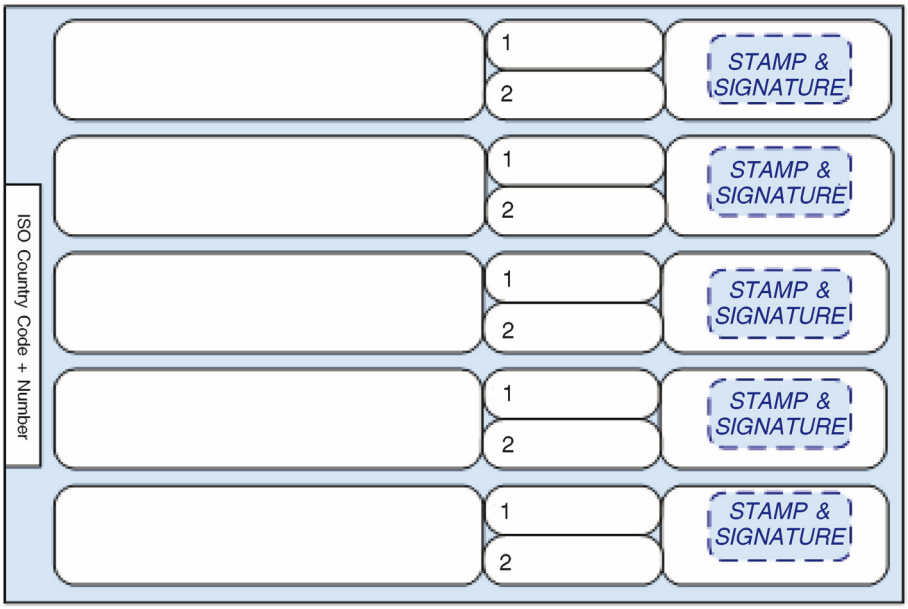
STAMP & SIGNATURE


IX. OTHER VACCINATIONS
MANUFACTURER & NAME OF VACCINE
BATCH NUMBER
VACCINATION DATE[1] VALID UNTIL[2]
VETERINARIAN
ISO Country Code + Number
1
2
STAMP & SIGNATURE
1
2
STAMP & SIGNATURE
1
2
STAMP & SIGNATURE


ISO Country Code + Number
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STAMP & SIGNATURE
1
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STAMP & SIGNATURE
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STAMP & SIGNATURE
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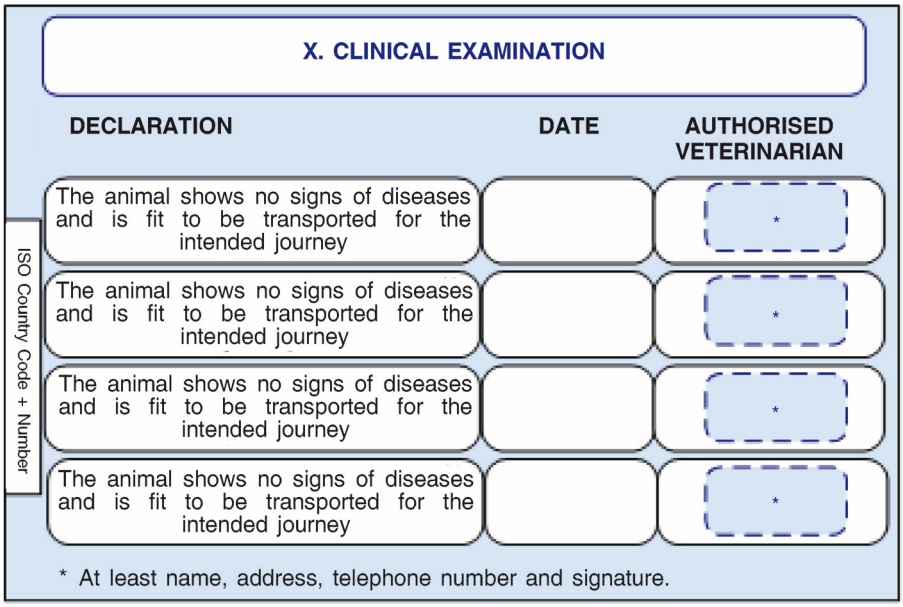
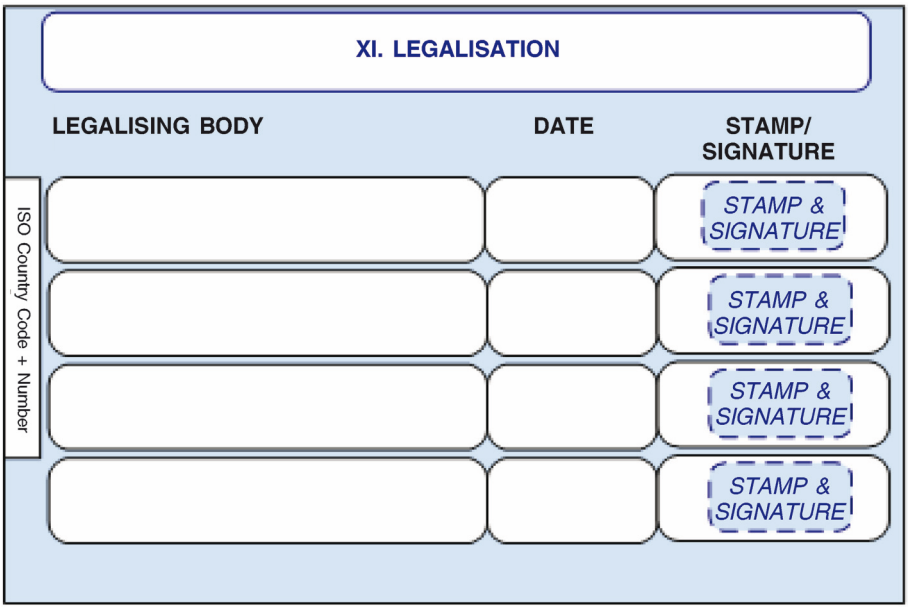
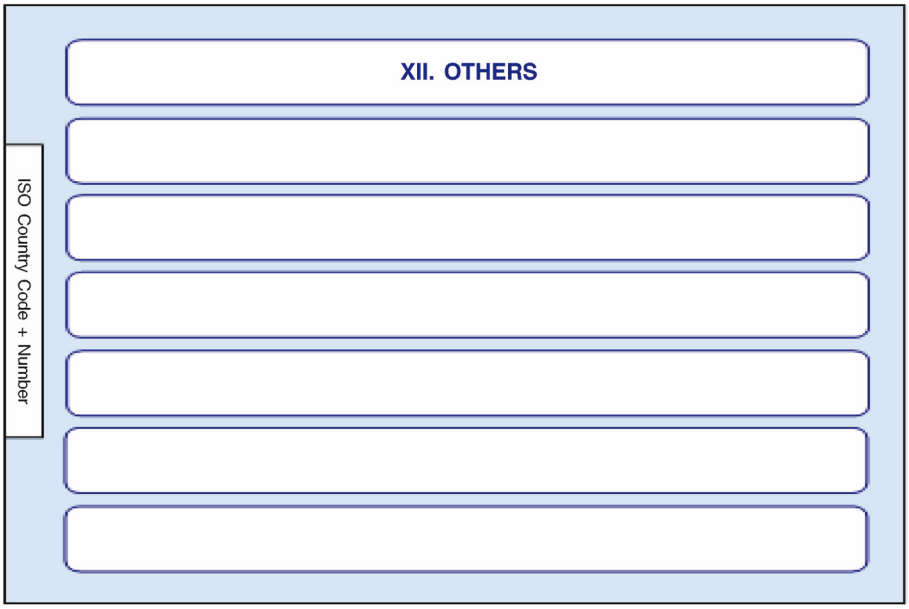
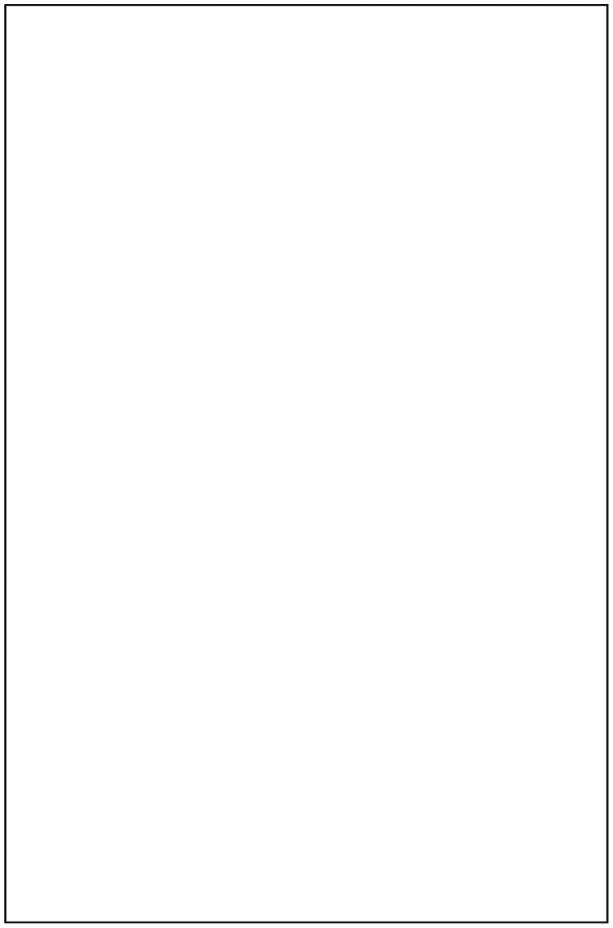
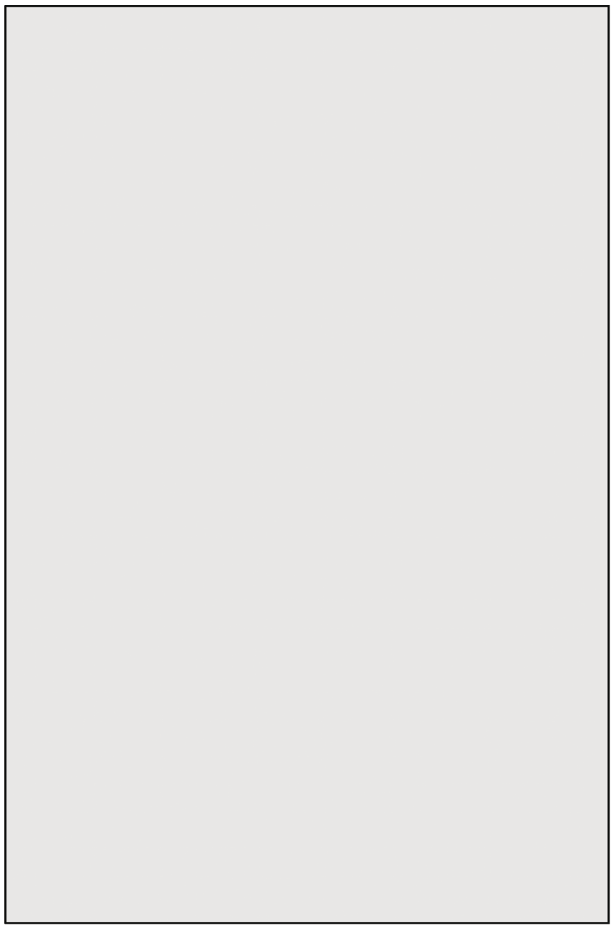
STAMP & SIGNATURE
1
2
STAMP & SIGNATURE


X. CLINICAL EXAMINATION
DECLARATION
DATE
AUTHORISED VETERINARIAN
ISO Country Code + Number
The animal shows no signs of diseases and is fit to be transported for the intended journey
*
The animal shows no signs of diseases and is fit to be transported for the intended journey
*
The animal shows no signs of diseases and is fit to be transported for the intended journey
*
The animal shows no signs of diseases and is fit to be transported for the intended journey
*
* At least name, address, telephone number and signature.


XI. LEGALISATION
LEGALISING BODY
DATE
STAMP/ SIGNATURE
ISO Country Code + Number
STAMP & SIGNATURE
STAMP & SIGNATURE
STAMP & SIGNATURE
STAMP & SIGNATURE


XII. OTHERS
ISO Country Code + Number





PART 4

Additional requirements concerning the passport issued in one of the territories or third countries listed in Part 1 of Annex II to this Regulation

1. Format of the passport:

   The dimension of the passport shall be 100 × 152 mm.

2. Cover of the passport:

   (a) front cover:

      (i) colour: PANTONE® monochrome and national emblem in the upper quarter;

      (ii) the ISO country code of the territory or third country of issue followed by a unique alphanumeric code (indicated as 'number' in the model of passport set out in Part 3), shall be printed on the bottom;

   (b) inside front cover and inside back cover: colour white;

   (c) back cover: colour PANTONE® monochrome.

3. Sequences of the headings and numbering of pages of the passport:

   (a) the sequence of the headings (with the roman numbers) must be strictly respected;

   (b) the pages of the passport shall be numbered at the bottom of each page in the following format: 'x out of n', where x is the current page and n is the total number of pages of the passport;

   (c) the ISO country code of the territory or third country of issue followed by a unique alphanumeric code shall be printed on each page of the passport;

   (d) the number of pages and the size and shape of the boxes in the model of passport set out in Part 3 are indicative.

4. Languages:

   All printed text shall be in the official language(s) of the territory or third country of issue and in English.

5. Security features:

   (a) after the required information has been entered in Section III of the passport, a transparent adhesive laminate shall seal the page;

   (b) where the information on one of the pages of the passport takes the form of a sticker, a transparent adhesive laminate shall seal that sticker in the case where the latter is not self-destructed when it is removed.

ANNEX IV

PART 1

Model animal health certificate for the non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

COUNTRY: **Veterinary certificate to EU**

Part I : Details of dispatched consignment

I.1. Consignor Name Address Tel.	I.2. Certificate reference No	I.2.a.
	I.3. Central competent authority	
	I.4. Local competent authority	
I.5. Consignee Name Address Postal code Tel.	I.6.	
I.7. Country of origin ISO code I.8.	I.9.	I.10.
I.11.	I.12.	
I.13.	I.14.	
I.15.	I.16.	
	I.17.	
I.18. Description of commodity	I.19. Commodity code (HS code) **010619**	
	I.20. Quantity	
I.21.	I.22.	
I.23.	I.24.	
I.25. Commodities certified for: Pets ☐		
I.26.	I.27.	

I.28. Identification of the commodities

Species (Scientific name)	Sex	Identification system	Colour	Breed	Date of application and/or reading of the transponder or tattoo [dd/mm/yyyy]	Identification number	Date of birth [dd/mm/yyyy]

COUNTRY

Non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

Part II: Certification

II.	Health information	II.a. Certificate reference No	II.b.

I, the undersigned official veterinarian (1)/veterinarian authorised by the competent authority (1) of ..... (*insert name of territory or third country*) certify that:

Purpose/nature of journey attested by the owner:

II.1. the attached declaration (2) by the owner or the natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the animals on behalf of the owner, supported by evidence (3), states that the animals described in Box I.28 will accompany the owner or the natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the animals on behalf of the owner within not more than five days of his movement and are not subject to a movement that aims at their sale or a transfer of ownership, and during the non-commercial movement will remain under the responsibility of

(1) *either* [the owner;]

(1) *or* [the natural person who has authorisation in writing from the owner to carry out the non-commercial movement of the animals on behalf of the owner;]

(1) *or* [the natural person designated by a carrier contracted by the owner to carry out the non-commercial movement of the animals on behalf of the owner;]

(1) *either* [II.2. the animals described in Box I.28 are moved in a number of five or less;]

(1) *or* [II.2. the animals described in Box I.28 are moved in a number of more than five, are more than six months old and are going to participate in competitions, exhibitions or sporting events or in training for those events, and the owner or the natural person referred to in point II.1 has provided evidence (3) that the animals are registered

(1) *either* [to attend such event;]

(1) *or* [with an association organising such events;]

Attestation of rabies vaccination and rabies antibody titration test:

(1) *either* [II.3. the animals described in Box I.28 are less than 12 weeks old and have not received an anti-rabies vaccination, or are between 12 and 16 weeks old and have received an anti-rabies vaccination, but 21 days at least have not elapsed since the completion of the primary vaccination against rabies carried out in accordance with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 (4), and

II.3.1 the territory or third country of provenance of the animals indicated in Box I.1 is listed in Annex II to Commission Implementing Regulation (EU) No 577/2013 and the Member State of destination indicated in Box I.5 has informed the public that it authorises the movement of such animals into its territory, and they are accompanied by

(1) *either* [II.3.2 the attached declaration (5) of the owner or the natural person referred to in point II.1 stating that from birth until the time of the non-commercial movement the animals have had no contact with wild animals of species susceptible to rabies;].

(1) *or* [II.3.2 their mother, on whom they still depend, and it can be established that the mother received before their birth an anti-rabies vaccination which complied with the validity requirements set out in Annex III to Regulation (EU) No 576/2013;].

(1) *or/and* [II.3. the animals described in Box I.28 were at least 12 weeks old at the time of vaccination against rabies and at least 21 days have elapsed since the completion of the primary anti-rabies vaccination (4) carried out in accordance with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 and any subsequent revaccination was carried out within the period of validity of the preceding vaccination (6); and

(1) *either* [II.3.1 the animals described in Box I.28 come from a territory or a third country listed in Annex II to Implementing Regulation (EU) No 577/2013, either directly, through a territory or a third country listed in Annex II to Implementing Regulation (EU) No 577/2013 or through a territory or a third country other than those listed in Annex II to Implementing Regulation (EU) No 577/2013 in accordance with point (c) of Article 12(1) of Regulation (EU) No 576/2013 (7), and the details of the current anti-rabies vaccination are provided in the table below;]

(1) *or* [II.3.1 the animals described in Box I.28 come from, or are scheduled to transit through, a territory or third country other than those listed in Annex II to Commission Implementing Regulation (EU) No 577/2013 and a rabies antibody titration test (8), carried out on a blood sample taken by the veterinarian authorised by the competent authority on the date indicated in the table below not less than 30 days after the preceding vaccination and at least three months prior to the date of issue of this certificate, proved an antibody titre equal to or greater than 0,5 IU/ml and any subsequent revaccination was carried out within the period of validity of the preceding vaccination (6), and the details of the current anti-rabies vaccination and the date of sampling for testing the immune response are provided in the table below:

COUNTRY

Non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

II. Health information	II.a. Certificate reference No	II.b.

Transponder or tattoo alphanumeric code of the animal	Date of vaccination [dd/mm/yyyy]	Name and manufacturer of vaccine	Batch number	Validity of vaccination		Date of the blood sampling [dd/mm/yyyy]
				From [dd/mm/yyyy]	to [dd/mm/yyyy]	

Attestation of anti-parasite treatment:

(1) *either* [II.4. the dogs described in Box I.28 are destined for a Member State listed in Annex I to Commission Delegated Regulation (EU) No 1152/2011 and have been treated against *Echinococcus multilocularis*, and the details of the treatment carried out by the administering veterinarian in accordance with Article 7 of Commission Delegated Regulation (EU) No 1152/2011 ([9])([10])([11]) are provided in the table below.]

(1) *or* [II.4. the dogs described in Box I.28 have not been treated against *Echinococcus multilocularis* ([11]).]

Transponder or tattoo number of the dog	Anti-echinococcus treatment		Administering veterinarian
	Name and manufacturer of the product	Date [dd/mm/yyyy] and time of treatment [00:00]	Name in capitals, stamp and signature
			]]

Notes

(a) This certificate is meant for dogs (*Canis lupus familiaris*), cats (*Felis silvestris catus*) and ferrets (*Mustela putorius furo*).

(b) This certificate is valid for 10 days from the date of issue by the official veterinarian until the date of the documentary and identity checks at the designated Union travellers' point of entry (available at http://ec.europa.eu/food/animal/liveanimals/pets/pointsentry_en.htm).

In the case of transport by sea, that period of 10 days is extended by an additional period corresponding to the duration of the journey by sea.

For the purpose of further movement into other Member States, this certificate is valid from the date of the documentary and identity checks for a total of four months or until the date of expiry of the validity of the anti-rabies vaccination or until the conditions relating to animals less than 16 weeks old referred to in point II.3 cease to apply, whichever date is earlier. Please note that certain Member States have informed that the movement into their territory of animals less than 16 weeks old referred to in point II.3 is not authorised. You may wish to inquire at http://ec.europa.eu/food/animal/liveanimals/pets/index_en.htm

Part I:

Box I.5: *Consignee:* indicate Member State of first destination.

Box I.28: *Identification system:* select of the following: transponder or tattoo.

In the case of a *transponder*: select date of application or reading.

In the case of a *tattoo:* select date of application and reading. The tattoo must be clearly readable and applied before 3 July 2011.

Identification number: indicate the transponder or tattoo alphanumeric code.

Date of birth/breed: as stated by the owner.

COUNTRY

Non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

II. Health information	II.a. Certificate reference No	II.b.

Part II:

(1) Keep as appropriate.

(2) The declaration referred to in point II.1 shall be attached to the certificate and comply with the model and additional requirements set out in Part 3 of Annex IV to Implementing Regulation (EU) No 577/2013.

(3) The evidence referred to in point II.1 (e.g. boarding pass, flight ticket) and in point II. 2 (e.g. receipt of entry to the event, proof of membership) shall be surrendered on request by the competent authorities responsible for the checks referred to in point (b) of the Notes.

(4) Any revaccination must be considered a primary vaccination if it was not carried out within the period of validity of a previous vaccination.

(5) The declaration referred to in point II.3.2 to be attached to the certificate complies with the format, layout and language requirements laid down in Parts 1 and 3 of Annex I to Implementing Regulation (EU) No 577/2013.

(6) A certified copy of the identification and vaccination details of the animals concerned shall be attached to the certificate.

(7) The third option is subject to the condition that the owner or the natural person referred to in point II.1 provides, on request by the competent authorities responsible for the checks referred to in point (b), a declaration stating that the animals have had no contact with animals of species susceptible of rabies and remain secure within the means of transport or the perimeter of an international airport during the transit through a territory or a third country other than those listed in Annex II to Implementing Regulation (EU) No 577/2013. This declaration shall comply with the format, layout and language requirements set out in Parts 2 and 3 of Annex I to Implementing Regulation (EU) No 577/2013.

(8) The rabies antibody titration test referred to in point II.3.1:

— must be carried out on a sample collected by a veterinarian authorised by the competent authority, at least 30 days after the date of vaccination and three months before the date of import;

— must measure a level of neutralising antibody to rabies virus in serum equal to or greater than 0,5 IU/ml;

— must be performed by a laboratory approved in accordance with Article 3 of Council Decision 2000/258/EC (list of approved laboratories available at http://ec.europa.eu/food/animal/liveanimals/pets/approval_en.htm);

— does not have to be renewed on an animal, which following that test with satisfactory results, has been revaccinated against rabies within the period of validity of a previous vaccination.

A certified copy of the official report from the approved laboratory on the results of the rabies antibody test referred to in point II.3.1 shall be attached to the certificate.

(9) The treatment against *Echinococcus multilocularis* referred to in point II.4 must:

— be administered by a veterinarian within a period of not more than 120 hours and not less than 24 hours before the time of the scheduled entry of the dogs into one of the Member States or parts thereof listed in Annex I to Delegated Regulation (EU) No 1152/2011;

— consist of an approved medicinal product which contains the appropriate dose of praziquantel or pharmacologically active substances, which alone or in combination, have been proven to reduce the burden of mature and immature intestinal forms of *Echinococcus multilocularis* in the host species concerned.

(10) The table referred to in point II.4 must be used to document the details of a further treatment if administered after the date the certificate was signed and prior to the scheduled entry into one of the Member States or parts thereof listed in Annex I to Delegated Regulation (EU) No 1152/2011.

(11) The table referred to in point II.4 must be used to document the details of treatments if administered after the date the certificate was signed for the purpose of further movement into other Member States described in point (b) of the Notes and in conjunction with footnote (9).

COUNTRY

Non-commercial movement into a Member State from a territory or third country of dogs, cats or ferrets in accordance with Article 5(1) and (2) of Regulation (EU) No 576/2013

II. Health information	II.a. Certificate reference No	II.b.

Official veterinarian/Authorised veterinarian

Name (in capital letters): Qualification and title:

Address

Telephone:

Date: Signature:

Stamp:

Endorsement by the competent authority (not necessary when the certificate is signed by an official veterinarian)

Name (in capital letters): Qualification and title:

Address

Telephone:

Date: Signature:

Stamp:

Official at the travellers' point of entry (for the purpose of further movement into other Member States)

Name (in capital letters): Title:

Address

Telephone:

E-mail address:

Date of completion of the documentary and identity checks: Signature: Stamp:

PART 2

Explanatory notes for completing the animal health certificates

(a) Where the certificate states that certain statements shall be kept as appropriate, statements which are not relevant may be crossed out and initialled and stamped by the official veterinarian, or completely deleted from the certificate.

(b) The original of each certificate shall consist of a single sheet of paper, or, where more text is required it must be in such a form that all sheets of paper required are part of an integrated whole and indivisible.

(c) The certificate shall be drawn up in at least one of the official languages of the Member State of entry and in English. It shall be completed in block letters in at least one of the official languages of the Member State of entry or in English.

(d) If additional sheets of paper or supporting documents are attached to the certificate, those sheets of paper or document shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the official veterinarian, on each of the pages.

(e) When the certificate, including additional sheets referred to in point (d), comprises more than one page, each page shall be numbered (page number of total number of pages) at the end of the page and shall bear at the top of each page the certificate reference number that has been designated by the competent authority.

(f) The original of the certificate shall be issued by an official veterinarian of the territory or third country of dispatch or by an authorised veterinarian and subsequently endorsed by the competent authority of the territory or third country of dispatch. The competent authority of the territory or third country of dispatch shall ensure that rules and principles of certification equivalent to those laid down in Directive 96/93/EC are followed.

The colour of the signature shall be different from that of the printing. This requirement also applies to stamps other than those embossed or watermarked.

(g) The certificate reference number referred to in Boxes I.2 and II.a shall be issued by the competent authority of the territory or third country of dispatch.

PART 3

Written declaration referred to in Article 25(3) of of Regulation (EU) No 576/2013

Section A

Model of declaration

I, the undersigned

.....

[owner or the natural person who has authorisation in writing from the owner to carry out the non-commercial movement on behalf of the owner (1)]

declare that the following pet animals are not subject to a movement that aims at their sale or a transfer of ownership and will accompany the owner or the natural person who has authorisation in writing from the owner to carry out the non-commercial movement on behalf of the owner (1) within not more than five days of his movement.

Transponder/tattoo (1) alphanumeric code	Animal health certificate number

During the non-commercial movement, the above animals will remain under the responsibility of

(1) *either* [the owner];

(1) *or* [the natural person who has authorisation in writing from the owner to carry out the non-commercial movement on behalf of the owner]

(1) *or* [the natural person designated by the carrier contracted to carry out the non-commercial movement on behalf of the owner: ..... (*insert name of the carrier*)]

Place and date:

Signature of the owner or natural person who has authorisation in writing from the owner to carry out the non-commercial movement on behalf of the owner (1):

(1) Delete as appropriate.

Section B

Additional requirements for the declaration

The declaration shall be drawn up in at least one of the official language(s) of the Member State of entry and in English and shall be completed in block letters.

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