STATUTORY INSTRUMENTS.

S.I. No. 543 of 2012

EUROPEAN UNION (PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES) REGULATIONS 2012

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S.I. No. 543 of 2012

EUROPEAN UNION (PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES) REGULATIONS 2012

I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), for the purpose of giving effect to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010[1] and for the purpose of giving full effect to Commission Implementing Decision 2012/707/EU of 14 November 2012[2], hereby make the following regulations:

PART 1

PRELIMINARY

Citation

1. These Regulations may be cited as the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012.

Commencement

2. These Regulations come into operation on 1 January 2013.

Interpretation

3. (1) In these Regulations—

"Act" means the Irish Medicines Board Act 1995, as amended by s. 197 of the Finance Act 1999 (No. 2 of 1999), Regulation 3 of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), Regulation 2 of the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. No. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. No. 576 of 2002), the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and the European Communities (Amendment of the Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007);

"activity" means any activity relating to—

(*a*) the use of an animal in a procedure,

(*b*) the breeding, supply, care or accommodation of an animal used, or intended to be used, in a procedure, or

(*c*) the breeding, supply, care or accommodation of an animal specifically so that its organs or tissues may be used for scientific purposes;

[1]OJ No. L 276, 20.10.2010, p. 33.
[2]OJ No. L 320, 17.11.2012, p. 33.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st January*, 2013.

"animal" means—

(*a*) any live non-human vertebrate animal, including—

(i) an independently feeding larval form,

(ii) a foetal form of mammal as from the last third of its normal development,

(*b*) any animal at an earlier stage of development than that referred to in subparagraph (*a*), where the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development; or

(*c*) any live cephalopod;

"animal care and welfare officer" means a person designated by a breeder, supplier or user pursuant to Regulation 45;

"animal welfare body" means a group of persons set up by a breeder, supplier or user pursuant to Regulation 50;

"animal welfare notice" means a notice served by the IMB pursuant to Regulation 76;

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

"breeder authorisation" means an authorisation granted to a breeder under Part 6;

"closure order" means an order served by the IMB pursuant to Regulation 77;

"Commission" means the Commission of the European Union;

"compliance notice" means a notice served by the IMB pursuant to Regulation 74;

"compliance officer" means a person designated by a breeder, supplier or user pursuant to Regulation 44;

"debilitating clinical condition" means a reduction in a person's normal physical or psychological ability to function;

"designated veterinarian or expert" means a person designated by a breeder, supplier or user pursuant to Regulation 48;

"Directive" means Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010[1];

"EEA State" means a member state of the European Economic Area, created by the Agreement on the European Economic Area signed in Oporto on 2 May 1992;

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

"IMB" means the Irish Medicines Board established under section 3 of Irish Medicines Board Act 1995 (No. 29 of 1995);

"killing authorisation" means an authorisation granted to an individual under Part 8 to kill animals used, or intended to be used, in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes;

"Minister" means the Minister for Health;

"premises" means any place (physical or virtual), ship or other vessel, aircraft, railway wagon or other vehicle or other mobile facility, and includes a container used to transport animals or relevant thing;

"procedure" means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues;

"procedures authorisation" means an authorisation granted to an individual under Part 8 to carry out procedures;

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

"project authorisation" means an authorisation granted under Part 5;

"project evaluation" means evaluation carried out by the IMB in accordance with Regulation 31;

"project manager" means a person designated by a user pursuant to Regulation 47;

"project manager authorisation" means an authorisation granted to an individual under Part 8 to carry out the role of project manager;

"revocation order" means an order for the revocation of an authorisation served by the IMB pursuant to Regulation 75;

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

"supplier authorisation" means an authorisation granted to a supplier under Part 6;

"suspension order" means an order for the suspension of an authorisation served by the IMB pursuant to Regulation 75;

"training officer" means a person designated by a breeder, supplier or user pursuant to Regulation 46;

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

"user authorisation" means an authorisation granted to a user under Part 6;

"veterinarian" means a veterinary practitioner registered with the Veterinary Council of Ireland;

"Wildlife Trade Regulation" means Council Regulation (EC) No. 338/97 of 9 December 1996[3], as amended by Commission Regulation (EC) No. 938/97 of 26 May 1997[4], Commission Regulation (EC) No. 2307/97 of 18 November 1997[5], Commission Regulation (EC) No. 2214/98 of 15 October 1998[6], Commission Regulation (EC) No. 1476/1999 of 6 July 1999[7], Commission Regulation (EC) No. 2724/2000 of 30 November 2000[8], Commission Regulation (EC) No. 1579/2001 of 1 August 2001[9], Commission Regulation (EC) No. 2476/2001 of 17 December 2001[10], Commission Regulation (EC) No. 1497/2003 of 18 August 2003[11], Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003[12], Commission Regulation (EC) No. 834/2004 of 28 April 2004[13], Commission Regulation (EC) No. 1332/2005 of 9 August 2005[14], Commission Regulation (EC) No. 318/2008 of 31 March 2008[15], Regulation (EC) No. 398/2009 of the European Parliament and of the Council of 23 April 2009[16], Commission Regulation (EC) No. 407/2009 of 14 May 2009[17], Commission Regulation (EU) No. 709/2010 of 22 July 2010[18] and Commission Regulation (EU) No. 101/2012 of 6 February 2012[19].

[3]OJ No. L 61, 3.3.1997, p. 1.
[4]OJ No. L 140, 30.5.1997, p. 1.
[5]OJ No. L 325, 27.11.1997, p. 1.
[6]OJ No. L 279, 16.10.1998, p. 3.
[7]OJ No. L 171, 7.7.1999, p. 5.
[8]OJ No. L 320, 18.12.2000, p. 1.
[9]OJ No. L 209, 2.8.2001, p. 14.
[10]OJ No. L 334, 18.12.2001, p. 3.
[11]OJ No. L 215, 27.8.2003, p. 3.
[12]OJ No. L 284, 31.10.2003, p. 1.
[13]OJ No. L 127, 29.4.2004, p. 40.
[14]OJ No. L 215, 19.8.2005, p. 1.
[15]OJ No. L 95, 8.4.2008, p. 3.
[16]OJ No. L 126, 21.5.2009, p. 5.
[17]OJ No. L 123, 19.5.2009, p. 3.
[18]OJ No. L 212, 12.8.2010, p. 1.
[19]OJ No. L 39, 11.2.2012, p. 133.

(2) A word or expression which is used in these Regulations and which is also used in the Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive.

(3) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

(4) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(5) A reference in these Regulations to a Schedule is to the Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

Scope

4. (1) These Regulations apply where an animal is used, or intended to be used, in a procedure, or bred specifically so that its organs or tissues may be used for scientific purposes.

(2) These Regulations apply until the animal referred to in paragraph (1) has been killed, rehomed, or returned to a suitable habitat or husbandry system.

(3) The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in a procedure from the scope of these Regulations.

(4) These Regulations shall not apply to:

(*a*) non-experimental agricultural practices;

(*b*) non-experimental clinical veterinary practices;

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

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

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

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

(5) These Regulations shall apply without prejudice to the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004) and—

(*a*) Council Directive 76/768/EEC of 27 July 1976[20], or

(*b*) when applicable, Regulation (EC) No. 1223/2009 of the European Parliament and the Council of 30 November 2009[21].

Responsibility for functions under Directive

5. (1) Subject to paragraph (2), the functions of the State and of the competent authority under the Directive shall be performed by the IMB.

(2) Paragraph (1) shall not apply to those functions of a Member State referred to in Articles 2, 47(2) and (5), 55, 59 and 61 of the Directive.

(3) The IMB may charge fees for its functions under the Directive and these Regulations in accordance with regulations made under s. 13(1) of the Act, read in conjunction with s. 4(1)(v) of the Act.

(4) The IMB may, for the purposes of Regulation 8, 14 or 22, publish guidelines in relation to the qualifications and experience required of a "competent person".

PART 2

GENERAL PROVISIONS

Replacement, reduction and refinement

6. (1) Wherever possible, a person shall use a scientifically satisfactory method or testing strategy not entailing the use of live animals, instead of a procedure.

(2) A user carrying out a project shall use the minimum number of animals possible without compromising the objectives of the project.

(3) Breeders, suppliers and users shall ensure that the breeding, accommodation and care of animals, and the methods used in procedures, are refined to eliminate or reduce to the minimum any possible pain, suffering, distress or lasting harm to animals.

(4) This Regulation shall, in the choice of methods, be implemented in accordance with Regulation 18.

Purposes of procedures

7. A user may carry out procedures for the following purposes only—

(*a*) basic research;

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

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

[20]OJ No. L 262, 27.9.1976, p. 169.
[21]OJ No. L 342, 22.12.2009, p. 59.

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

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

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

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

(*e*) research aimed at preservation of the species;

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

(*g*) forensic inquiries.

Methods of killing

8. (1) Where an animal, used or intended to be used in a procedure, or bred specifically so that their organs or tissues may be used for scientific purposes, is killed the person responsible for the killing shall ensure that—

(*a*) the method of killing with the minimum pain, suffering and distress is used, and

(*b*) subject to paragraphs (2) and (5), the animal is killed by a competent person in the establishment of the breeder, supplier or user, as appropriate.

(2) In the case of a field study, an animal may be killed by a competent person outside of an establishment.

(3) Subject to paragraphs (4) and (5), in the case of the killing of an animal covered by Annex IV to the Directive, the breeder, supplier or user, or other person responsible, shall ensure that the appropriate method of killing as set out in that Annex is used.

(4) The IMB may grant exemptions from the requirement in paragraph (3)—

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

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

(5) Paragraphs (1)(*b*) and (3) shall not apply where an animal has to be killed in emergency circumstances for animal welfare, public health, public security, animal health or environmental reasons.

Setting free of animals and rehoming

9. Breeders, suppliers and users shall not allow an animal used, or intended to be used, in a procedure to be rehomed, or returned to a suitable habitat or husbandry system appropriate to the species concerned, unless—

(*a*) authorised by the IMB to do so in the applicable project authorisation,

(*b*) the state of health of the animal allows it,

(*c*) there is no danger to public health, animal health or the environment,

(*d*) appropriate measures have been taken to safeguard the well-being of the animal,

(*e*) a rehoming scheme is in place that ensures socialisation of the animal, and

(*f*) in the case of a wild animal, where appropriate, a programme of rehabilitation is in place before it is returned to its habitat.

Care and accommodation

10. (1) Subject to paragraph (2), breeders, suppliers and users shall, as far as the care and accommodation of animals is concerned, ensure that—

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

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

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

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

(*e*) animals are transported under appropriate conditions;

(*f*) they apply the standards set out in Section A of Annex III to the Directive; and

(*g*) from the dates provided for therein or, if no date is provided, from 1 January 2013, they apply the standards set out in Section B of Annex III to the Directive.

(2) The IMB may exempt a breeder, supplier or user from the requirements of paragraph (1)(*a*),(f) or (*g*) for scientific, animal welfare or animal health reasons.

Installations and equipment

11. (1) Breeders, suppliers and users shall ensure that their establishments have installations and equipment suited to the species of animals housed and, where procedures are carried out, to the performance of the procedures.

(2) Breeders, suppliers and users shall ensure that the design, construction and method of functioning of the installations and equipment in their establishments—

(*a*) are such as to ensure that procedures are carried out as effectively as possible, and

(*b*) aim at obtaining reliable results using the minimum number of animals and causing the minimum degree of pain, suffering, distress or lasting harm.

(3) For the purposes of implementation of paragraphs (1) and (2), breeders, suppliers and users shall ensure that the relevant requirements as set out in Annex III of the Directive are complied with.

PART 3

RESTRICTIONS IN RELATION TO CERTAIN ANIMALS

Endangered species

12. (1) Subject to paragraph (2), a user shall not use a specimen of an endangered species listed in Annex A to the Wildlife Trade Regulation, which does not fall within the scope of Article 7(1) of that Regulation, in a procedure, unless—

(*a*) the procedure has one of the purposes referred to in Regulation 7(*b*)(i), (*c*) or (*e*); and

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

(2) Paragraph (1) shall not apply to any species of non-human primate.

Non-human primates

13. (1) Subject to paragraph (2) and Regulation 88(1), a user shall not use a specimen of non-human primate in a procedure, unless—

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

(i) Regulation 7(*b*)(i) or (*c*) and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings, or

(ii) Regulation 7(*a*) or (*e*); and

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

(2) In the case of a specimen of non-human primate listed in Annex A to the Wildlife Trade Regulation, which does not fall within the scope of Article 7(1) of that Regulation, a user shall not use such specimen in a procedure, unless—

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

(i) Regulation 7(*b*)(i) or (*c*) and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings, or

(ii) Regulation 7(*e*); and

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

(3) Notwithstanding paragraphs (1) and (2), but subject to Regulation 88(2), a user shall not use a great ape in a procedure.

(4) A breeder shall not breed non-human primates unless he, she or it has in place, maintains and implements, a strategy for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity.

Animals taken from the wild

14. (1) Subject to paragraph (2), a user shall not use an animal taken from the wild in a procedure.

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

(3) A user using an animal taken from the wild in a procedure shall ensure that—

(*a*) the animal is captured by one or more competent persons using methods which do not cause the animal avoidable pain, suffering, distress or lasting harm, and

(*b*) where the animal is found, at or after capture, to be injured or in poor health—

(i) it is examined by a veterinarian or another competent person, and

(ii) subject to paragraph (4), action is taken to minimise the suffering of the animal.

(4) The IMB may grant an exemption from the requirement in paragraph (3)(*b*)(ii) to take action to minimise the suffering of the animal if there is scientific justification.

Animals bred for use in procedures

15. (1) Subject to paragraph (3), a user shall not use an animal belonging to one of the species listed in Annex I to the Directive unless the animal has been bred for use in procedures.

(2) Subject to paragraph (3), from the dates set out in Annex II to the Directive, a user shall not use a non-human primate listed therein in a procedure unless the animal is the offspring of non-human primates which have been bred in captivity or where it is sourced from a self-sustaining colony.

(3) The IMB may grant exemptions from the requirements of paragraphs (1) and (2) on the basis of scientific justification.

(4) In this Regulation, "self-sustaining colony" means a colony in which animals are bred only within the colony or sourced from other colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans.

Stray and feral animals of domestic species

16. (1) Subject to paragraph (2), a user shall not use a stray or feral animal of a domestic species in a procedure.

(2) The IMB may grant an exemption from paragraph (1) where—

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

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

PART 4

PROCEDURES

Restrictions on carrying out of procedures

17. (1) Subject to paragraph (2), a user shall not carry out a procedure otherwise than—

(*a*) in the user's establishment, and

(*b*) within the framework of a project.

(2) The IMB may grant an exemption from the requirement in paragraph (1)(*a*) on the basis of scientific justification.

Choice of methods

18. (1) A user shall not carry out a procedure if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under European Union legislation and not prohibited under national legislation.

(2) A user shall, when choosing between alternative procedures, select the procedure which to the greatest extent meets the following requirements:

(*a*) uses the minimum number of animals;

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

(*c*) causes the least pain, suffering, distress or lasting harm,

and is most likely to provide satisfactory results.

(3) Subject to paragraph (4), a user shall ensure that, as far as possible, the end-point of any procedure carried out by the user is not the death of the animal or animals concerned, but rather an alternative early and humane end-point.

(4) Where the death of the animal or animals concerned is the unavoidable end-point of a procedure carried out by a user, the user shall design the procedure so as to—

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

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

Anaesthesia

19. (1) A user shall—

(*a*) in the case of any procedure involving serious injuries to the animal or animals concerned that may cause severe pain, and

(*b*) unless it is inappropriate, in the case of any other procedure,

carry out the procedure under general or local anaesthesia.

(2) When deciding, under paragraph (1)(*b*), on the appropriateness of using anaesthesia in a procedure coming within that subparagraph, a user shall take into account—

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

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

(3) Subject to paragraph (1), unless it is inappropriate, a user shall use analgesia or another appropriate method in a procedure to ensure that pain, suffering and distress are kept to a minimum.

(4) A user shall not give an animal used in a procedure any drug to stop or restrict the animal from showing pain unless—

(*a*) an adequate level of anaesthesia or analgesia is used,

(*b*) a scientific justification for the use of the drug in such a procedure is established, and

(*c*) a record is kept, and made available to the IMB on request, of the justification referred to in subparagraph (*b*) and the details of the anaesthetic or analgesic regimen.

(5) Where an animal used in a procedure may suffer pain once anaesthesia has worn off, the user carrying out the procedure shall treat the animal with pre-emptive and post-operative analgesics or other appropriate pain-relieving methods, provided that it is compatible with the purpose of the procedure.

(6) As soon as the purpose of a procedure has been achieved, the user carrying out the procedure shall take appropriate action to minimise the suffering of the animal or animals concerned.

Classification of severity of procedures

20. (1) A user shall classify procedures he, she or it carries out as "non-recovery", "mild", "moderate" or "severe", on a case-by-case basis, using the assignment criteria set out in Annex VIII to the Directive.

(2) A user shall keep a record of all classifications made under paragraph (1) and shall make such record available to the IMB on request.

(3) Subject to Regulation 88(4), a user shall not perform a procedure if it involves severe pain, suffering or distress which is likely to be long-lasting and cannot be ameliorated.

Reuse

21. (1) Subject to paragraph (2), a user shall not use an animal already used in a procedure or procedures in a further procedure when a different animal, which has not previously been used in a procedure, could be used, unless—

(*a*) the actual severity of the previous procedure or procedures was classified as "mild" or "moderate" under Regulation 20(1),

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

(*c*) the further procedure is classified as "mild", "moderate" or "non-recovery" under Regulation 20(1), and

(*d*) it is in accordance with veterinary advice, taking into account the life-time experience of the animal.

(2) In exceptional circumstances, after a veterinary examination of the animal concerned, the IMB may grant a derogation from the requirement in paragraph (1)(*a*) allowing the reuse of an animal, provided the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.

End of procedure

22. (1) At the end of a procedure, a user shall—

(*a*) engage a veterinarian or another competent person to decide whether or not to keep the animal or animals used in the procedure alive, and

(*b*) arrange for the killing of any animal used in the procedure which is likely to remain in moderate or severe pain, suffering, distress or lasting harm.

(2) Where an animal is to be kept alive at the end of a procedure, the user shall ensure that the animal receives care and accommodation appropriate to its state of health.

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

Avoidance of duplication of procedures

23. (1) Subject to paragraph (2), a user shall not carry out a procedure if the data sought from the procedure has already been produced through a procedure carried out in an EEA State and recognised by the legislation of the European Union.

(2) Paragraph (1) shall not apply where, in the interests of the protection of public health, safety or the environment, a further procedure needs to be carried out regarding the data produced by the previous procedure.

PART 5

AUTHORISATION OF PROJECTS

Requirement for project authorisation

24. (1) No person may carry out a project without prior authorisation from the IMB in the form of a project authorisation granted under this Part ("a project authorisation"), including any conditions set out in the project authorisation.

(2) The IMB shall maintain registers of projects granted authorisations under this Part.

Application for project authorisation

25. (1) An application for a project authorisation shall be—

(*a*) made in writing to the IMB by the user or the project manager on behalf of the user,

(*b*) signed by or on behalf of the applicant, whether in ink or by means of electronic signature,

(*c*) accompanied by a written undertaking that, in the event of the project authorisation being granted, the applicant shall ensure fulfilment of the obligations arising by virtue of the terms and conditions of the project authorisation, and

(*d*) accompanied by the appropriate fee.

(2) An application for a project authorisation shall include the following information:

(*a*) the project proposal,

(*b*) the name and qualifications of at least one project manager designated under Regulation 47,

(*c*) a non-technical project summary in accordance with Regulation 33,

(*d*) information on the elements set out in Annex VI of the Directive, and

(*e*) such other relevant information as determined by the IMB.

(3) The IMB shall acknowledge the receipt of an application for a project authorisation as quickly as possible and shall indicate to the applicant the period referred to in Regulation 26(2) within which the decision is to be taken.

(4) In the case of an incomplete or incorrect application for a project authorisation, the IMB shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

Project authorisation decision

26. (1) Where an application is made for a project authorisation, the IMB may—

(*a*) refuse to grant the project authorisation,

(*b*) grant the project authorisation, or

(*c*) grant the project authorisation in respect of particular establishments or procedures only,

and in the case of decision pursuant to subparagraph (*b*) or (*c*), the IMB may attach conditions to the authorisation.

(2) Subject to paragraph (4) and Regulation 25(4), the IMB shall make a decision regarding an application for a project authorisation, and communicate same to the applicant, no later than 40 working days after receiving from the applicant a complete and correct application.

(3) The period referred to in paragraph (2) shall include the project evaluation.

(4) The IMB may extend the period referred to in paragraph (2) once, by an additional period not exceeding 15 working days when justified by the complexity or the multi-disciplinary nature of the project concerned.

(5) Where, pursuant to paragraph (4), the IMB extends the period referred to in paragraph (2), it shall notify the applicant of—

(*a*) the decision, and

(*b*) the duration of the extension,

before the expiry of the period referred to in paragraph (2).

Grant of project authorisation

27. (1) The IMB may only grant a project authorisation where the procedures to be carried out as part of the project have been subject to—

(*a*) a favourable project evaluation, and

(*b*) the severity classifications assigned to those procedures.

(2) Where the IMB grants a project authorisation, it shall give notice in writing to the applicant specifying—

(*a*) the user who will undertake the project,

(*b*) the project manager(*s*),

(*c*) the establishment(*s*) in which the project will be undertaken, where applicable,

(*d*) whether, and in what manner, the user is authorised to rehome, or return to a suitable habitat or husbandry system, the animals used, and

(*e*) any specific conditions arising from the project evaluation, including whether and when the project shall be assessed retrospectively and limitations as to the severity of procedures.

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

(4) The IMB may grant a project authorisation in respect of multiple generic projects to be carried out by the same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods.

Refusal to grant project authorisation

28. (1) Where the IMB proposes to refuse to grant a project authorisation, it shall, within 30 working days, serve a notice on the applicant of the proposed refusal, the reasons for same and the extension of the time period for the making of a decision in accordance with Regulation 26(4).

(2) If any representations are made by or on behalf of the applicant in response to a notice under paragraph (1) within 15 working days after the date of such notice, the IMB shall consider such representations.

(3) Where the IMB, having considered representations pursuant to paragraph (2), decides to refuse to grant a project authorisation, it shall notify that person within the extended time period under Regulation 26(4), stating the reasons on which its decision is based.

Removal, variation and addition of conditions to project authorisation

29. (1) Subject to the requirements of paragraph (2), the IMB may at any time remove or vary a condition attaching to a project authorisation or impose an additional condition to a project authorisation.

(2) Where the IMB proposes to remove or vary a condition, or impose an additional condition, in respect of a project authorisation, pursuant to paragraph (1), it shall serve a notice on the user or project manager which shall—

(*a*) give details of the condition which it proposes to remove, or of the variation which it proposes to make to an existing condition, or of the additional condition which it proposes to impose,

(*b*) give the reasons for its decision, and

(*c*) specify the date, which shall be not less than 14 working days from the date on which the notice is served, from which the removal, variation or imposition shall apply.

Amendment or renewal of project authorisation

30. (1) A user or project manager shall not make a substantial change in a project unless granted an amendment or renewal of the relevant project authorisation by the IMB.

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

(3) An application for an amendment or renewal of a project authorisation shall be—

(*a*) made in writing to the IMB by the user or the project manager, on behalf of the user,

(*b*) signed by or on behalf of the applicant, whether in ink or by means of an electronic signature,

(*c*) accompanied by a written undertaking that, in the event of the project authorisation being amended or renewed, the applicant shall ensure fulfilment of the obligations arising by virtue of the terms and conditions of the project authorisation, and

(*d*) accompanied by the appropriate fee.

(4) The IMB shall acknowledge the receipt of an application under paragraph (3) as quickly as possible and shall indicate to the applicant the period within which the decision is to be taken.

(5) In the case of an incomplete or incorrect application under paragraph (3), the IMB shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

(6) For the purpose of this Regulation, "a substantial change in a project" means any change to the project which would result in one or more of the following:

(*a*) a failure to comply with the requirements of these Regulations;

(*b*) a negative impact on animal welfare.

(7) The IMB shall establish and publish conditions for amendment and renewal of project authorisations.

Project evaluation

31. (1) The IMB shall carry out a project evaluation, in accordance with this Regulation, in respect of every application for a project authorisation.

(2) The IMB shall perform the project evaluation with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria:

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

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

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

(3) The project evaluation shall consist in particular of the following:

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

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

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

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

(*e*) an assessment of any justification referred to in Regulations 8, 10, 12 to 17, 19 and 21; and

(*f*) a determination as to whether and when the project should be assessed retrospectively in accordance with Regulation 32.

(4) In carrying out the project evaluation, the IMB shall consider expertise in particular in the following areas:

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

(*b*) experimental design, including statistics where appropriate;

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

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

(5) The project evaluation process shall be transparent.

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

Retrospective assessment

32. (1) When determined in accordance with Regulation 31(3)(*f*), the IMB shall carry out a retrospective assessment which shall, on the basis of the necessary documentation submitted by the user or project manager, evaluate the following:

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

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

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

(2) Where a retrospective assessment is to be carried out by the IMB, the user or project manager concerned shall, on request, provide such documentation to the IMB as the IMB considers necessary for the purposes of the retrospective assessment.

(3) Notwithstanding paragraph (1), all projects using non-human primates and projects involving procedures classified as "severe", including those referred to in Regulation 20(3), shall undergo a retrospective assessment.

Non-technical project summaries

33. (1) Subject to safeguarding intellectual property and confidential information, the non-technical project summary referred to in Regulation 25(2)(*c*) shall provide—

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

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

(2) The non-technical project summary referred to in Regulation 25(2)(*c*) shall be anonymous and shall not contain the names and addresses of the user and his, her or its personnel.

(3) The IMB may require the non-technical project summary to specify whether the project is to undergo a retrospective assessment in accordance with Regulation 32, and by what deadline, and, in such a case, the IMB shall ensure that the non-technical project summary is updated with the results of any retrospective assessment.

(4) The IMB shall publish the non-technical project summaries of authorised projects and any updates thereto.

Documentation

34. (1) Subject to paragraph (2), where a user or project manager applies for a project authorisation, he, she or it shall keep all relevant documentation, including the result of any project evaluation and an end-of-project report, for at least three years from—

(*a*) where the project authorisation is granted, the expiry date of the project authorisation, or

(*b*) where the project authorisation is refused, the expiry of the period referred to in Regulation 26(2),

and shall make such documentation available to the IMB on request.

(2) The user or project manager shall keep the documentation for projects which have to undergo retrospective assessment in accordance with Regulation 32 until the retrospective assessment has been completed.

PART 6

AUTHORISATION OF BREEDERS, SUPPLIERS AND USERS

Requirement for authorisation

35. (1) No person may carry out the activities of a breeder otherwise than in accordance with an appropriate authorisation granted by the IMB under this Part ("a breeder authorisation"), including any conditions to which the breeder authorisation is subject.

(2) No person may carry out the activities of a supplier otherwise than in accordance with an appropriate authorisation granted by the IMB under this Part ("a supplier authorisation"), including any conditions to which the supplier authorisation is subject.

(3) No person may carry out the activities of a user otherwise than in accordance with an appropriate authorisation granted by the IMB under this Part ("a user authorisation"), including any conditions to which the user authorisation is subject.

(4) The IMB shall maintain registers of persons granted authorisations under this Part.

Application for authorisation

36. (1) An application for an authorisation under this Part shall be—

(*a*) made in writing to the IMB by the breeder, supplier or user, as appropriate,

(*b*) signed by or on behalf of the applicant, whether in ink or by means of electronic signature,

(*c*) accompanied by a written undertaking that, in the event of the authorisation being granted, the applicant shall ensure fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation, and

(*d*) accompanied by the appropriate fee.

(2) An application for an authorisation under this Part shall include the following information:

(*a*) the name and contact details of the breeder, supplier or user,

(*b*) the activities for which the breeder, supplier or user seeks authorisation,

(*c*) the establishment(*s*) at which the said activities will be carried out,

(*d*) the name and qualifications of the compliance officer(*s*),

(*e*) the name and qualifications of the animal care and welfare officer(*s*),

(*f*) the name and qualifications of the training officer(*s*),

(*g*) the name and qualifications of the designated veterinarian or expert,

(*h*) a "Site Master File" providing clear information on the breeder, supplier or user's establishment(*s*) including the quality management systems in place in the said establishment(*s*),

(*i*) such other relevant information as determined by the IMB.

(3) The IMB shall acknowledge the receipt of an application for an authorisation under this Part as quickly as possible and shall indicate to the applicant the period within which the decision is to be taken.

(4) In the case of an incomplete or incorrect application for an authorisation under this Part, the IMB shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

Authorisation decision

37. (1) Where an application is made for an authorisation under this Part, the IMB may—

(*a*) refuse to grant the authorisation,

(*b*) grant the authorisation, or

(*c*) grant the authorisation in respect of particular establishment(*s*), activities or species only,

and in the case of decision pursuant to subparagraph (*b*) or (*c*), the IMB may attach conditions to the authorisation.

(2) The IMB shall make a decision regarding an application for an authorisation under this Part, and communicate same to the applicant, within a reasonable time period after receiving from the applicant a complete and correct application.

Restrictions on grant of authorisation

38. (1) The IMB shall not grant an authorisation under this Part unless the breeder, supplier or user and his, her or its establishment(*s*) are in compliance with the requirements of these Regulations.

(2) The IMB shall not grant a breeder authorisation covering the breeding of non-human primates unless the breeder has in place, maintains and implements a strategy for increasing the proportion of animals that are the offspring of non-human primates that have been bred in captivity.

Grant of authorisation

39. (1) Where the IMB grants an authorisation under this Part, it shall give notice in writing to the breeder, supplier or user specifying—

(*a*) the establishment(*s*) to which the authorisation applies,

(*b*) the compliance officer(*s*),

(*c*) the animal care and welfare officer(*s*),

(*d*) the training officer(*s*)

(*e*) the designated veterinarian or expert, and

(*f*) any specific conditions relevant to the authorisation as determined by the IMB.

(2) Authorisations under this Part shall be granted for a period not exceeding 3 years.

Refusal to grant authorisation

40. (1) Where the IMB proposes to refuse to grant an authorisation under this Part, it shall serve a notice on the breeder, supplier or user of the proposed refusal and the reasons for same, and shall, if any representations are made by or on behalf of that person within 21 working days after the date of such notice, consider the representations.

(2) Where the IMB, having considered the representations (if any) made by or on behalf of the breeder, supplier or user in response to a notice under paragraph (1), decides to refuse to grant an authorisation under this Part, it shall notify that person stating the reasons on which its decision is based.

Removal, variation and addition of conditions

41. (1) Subject to the requirements of paragraph (2), the IMB may at any time remove or vary a condition attaching to an authorisation under this Part or impose an additional condition to an authorisation under this Part.

(2) Where the IMB proposes to remove or vary a condition, or impose an additional condition, in respect of an authorisation under this Part, pursuant to paragraph (1), it shall serve a notice on the breeder, supplier or user which shall—

(*a*) give details of the condition which it proposes to remove, or of the variation which it proposes to make to an existing condition, or of the additional condition which it proposes to impose,

(*b*) give the reasons for its decision, and

(*c*) specify the date, which shall be not less than 14 working days from the date on which the notice is served, from which the removal, variation or imposition shall apply.

Amendment or renewal of authorisation

42. (1) A breeder, supplier or user shall notify the IMB without undue delay of any change in the persons designated as compliance officer, animal care and welfare officer, training officer or designated veterinarian or expert in respect of an authorisation granted under this Part.

(2) Where the IMB is notified of a change under paragraph (1), it shall issue an amended authorisation to the breeder, supplier or user, incorporating the said change.

(3) A breeder, supplier or user shall not make any significant change unless granted a renewal of the relevant authorisation by the IMB.

(4) Any application by a breeder, supplier or user for an amendment or renewal of an authorisation under this Part, whether because of the expiry of the authorisation or pursuant to paragraph (3), shall be—

(*a*) made in writing to the IMB by the breeder, supplier or user,

(*b*) signed on behalf of the breeder, supplier or user, whether in ink or by means of an electronic signature, and

(*c*) accompanied by a written undertaking that, in the event of the authorisation being amended or renewed, the applicant shall ensure fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation, and

(*d*) accompanied by the appropriate fee.

(5) The IMB shall acknowledge the receipt of an application under paragraph (4) as quickly as possible and shall indicate to the applicant the period within which the decision is to be taken.

(6) In the case of an incomplete or incorrect application under paragraph (4), the IMB shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

(7) The IMB shall establish and publish conditions for amendment and renewal of authorisations under this Part.

(8) In this Regulation, "significant change" means any significant change to the structure or function of an establishment that could negatively affect animal welfare, including—

(*a*) the addition of a new building, premises, mobile facility or establishment site,

(*b*) the addition of a new species of animal that can be kept at the establishment, or

(*c*) a change in the main type of operations conducted at the establishment.

PART 7

PERSONNEL

Competence of personnel

43. (1) Breeders, suppliers and users shall ensure that they have sufficient staff on site to meet the requirements of these Regulations.

(2) A breeder, supplier or user shall not carry out any of the following functions unless each member of staff involved in that function complies with the education and training requirements published in accordance with paragraph (5):

(*a*) carrying out procedures on animals,

(*b*) designing procedures and projects,

(*c*) taking care of animals, or

(*d*) killing animals.

(3) Without prejudice to paragraph (2), a breeder, supplier or user shall not carry out the designing of procedures and projects unless each member of staff involved in the function has received instruction in a scientific discipline relevant to the work being undertaken and has species-specific knowledge.

(4) A breeder, supplier or user may permit a member of staff who has not yet demonstrated the requisite competence to carry out functions referred to in paragraph (2)(*a*), (*c*) or (*d*), if that member of staff is appropriately supervised in the performance of his or her tasks.

(5) The IMB shall publish, on the basis of the elements set out in Annex V to the Directive, minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions set out in paragraphs (2), (3) and (4).

Compliance officer

44. Breeders, suppliers and users shall designate one or more suitably qualified persons as compliance officer, responsible for ensuring compliance with the provisions of these Regulations.

Animal care and welfare officer

45. Breeders, suppliers and users shall designate one or more persons as animal care and welfare officer, who shall—

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

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

Training officer

46. Breeders, suppliers and users shall designate one or more persons as training officer, who shall be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.

Project manager

47. Users shall, in respect of each project, designate one or more persons as project manager, who shall hold a project manager authorisation pursuant to Part 8, and who shall be responsible for the overall implementation of the project and its compliance with the project authorisation and shall ensure that—

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

(*b*) the project is carried out in accordance with the relevant project authorisation, and

(*c*) in the event of non-compliance, the appropriate measures to rectify it are taken and recorded.

Designated veterinarian or expert

48. (1) Breeders, suppliers and users shall designate a veterinarian with expertise in laboratory animal medicine, or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals.

(2) The designated veterinarian or expert shall assist the animal welfare body in its tasks.

Delegation

49. (1) A person designated under Regulation 44, 45, 46, 47 or 48 may delegate any of his or her respective functions to other persons who shall be qualified by appropriate training and experience to perform them.

(2) Breeders, suppliers and users shall notify the IMB of the name of any persons to whom functions have been delegated under paragraph (1), and the specific functions which have been delegated to such persons.

(3) Where a person delegates functions pursuant to paragraph (1), he or she shall remain accountable for the performance of those functions.

Animal welfare body

50. (1) Subject to paragraph (3), breeders, suppliers and users shall each set up a group, to be known as the animal welfare body, which shall—

(*a*) consist of at least the animal care and welfare officer(*s*) and, in the case of a user, a scientific member, and

(*b*) receive input from the designated veterinarian or expert.

(2) Animal welfare bodies shall, as a minimum, carry out the following tasks:

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

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

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

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

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

(*f*) facilitate, where appropriate, the establishment of programmes for the sharing of organs and tissues of animals killed.

(3) Breeders, suppliers and users shall keep, for at least 3 years, and make available to the IMB upon request, the records of any advice given by the animal welfare body and decisions taken regarding that advice.

PART 8

AUTHORISATION OF INDIVIDUALS

Requirement for authorisation

51. (1) No person may carry out procedures on animals otherwise than in accordance with an appropriate authorisation granted by the IMB under this Part ("a procedures authorisation"), including any conditions to which the procedures authorisation is subject.

(2) No person may carry out the role of project manager otherwise than in accordance with an appropriate authorisation granted by the IMB under this Part ("a project manager authorisation"), including any conditions to which the project manager authorisation is subject.

(3) Subject to paragraph (4) and Regulation 8, no person may kill an animal used, or intended to be used, in a procedure, or where an animal bred specifically so that its organs or tissues may be used for scientific purposes, otherwise than in accordance with an appropriate authorisation granted by the IMB under

this Part ("a killing authorisation"), including any conditions to which the killing authorisation is subject.

(4) Paragraph (3) shall not apply in the case of—

(*a*) killing an animal in emergency circumstances for animal welfare, public health, public security, animal health or environmental reasons,

(*b*) euthanasia by veterinarians of animals under their care, and

(*c*) killing by an authorised officer.

(5) The IMB shall maintain registers of persons granted authorisations under this Part.

Annual maintenance fee

52. The holder of an authorisation granted under this Part shall pay an annual maintenance fee to the IMB in respect of his or her authorisation.

Application for authorisation

53. (1) An application for an authorisation under this Part shall be—

(*a*) made in writing to the IMB,

(*b*) signed by the applicant, whether in ink or by means of electronic signature,

(*c*) accompanied by written confirmation of endorsement by the breeder, supplier or user of the establishment in which the applicant shall perform the activities for which he or she requires authorisation,

(*d*) accompanied by a written undertaking that, in the event of the authorisation being granted, the applicant shall ensure fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation, and

(*e*) accompanied by the appropriate fee.

(2) An application for an authorisation under this Part shall include the following information:

(*a*) the name and contact details of the applicant,

(*b*) details of the activities (including the techniques and species of animals involved) for which the applicant seeks authorisation,

(*c*) details of the establishment(*s*) at which the said activities will be carried out,

(*d*) details of the applicant's education, training and experience relevant to the activities for which the applicant seeks authorisation, and

(*e*) such other relevant information as determined by the IMB.

(3) The IMB shall acknowledge the receipt of an application for an authorisation under this Part as quickly as possible and shall indicate to the applicant the period within which the decision is to be taken.

(4) In the case of an incomplete or incorrect application for an authorisation under this Part, the IMB shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

Authorisation decision

54. (1) Where an application is made for an authorisation under this Part, the IMB may—

(*a*) refuse to grant the authorisation,

(*b*) grant the authorisation, or

(*c*) grant the authorisation in respect of particular establishment(*s*), project(*s*), procedures, species or methods of killing only,

and in the case of decision pursuant to subparagraph (*b*) or (*c*), the IMB may attach conditions to the authorisation.

(2) The IMB shall make a decision regarding an application for an authorisation under this Part, and communicate same to the applicant, within a reasonable time period after receiving from the applicant a complete and correct application.

Grant of authorisation

55. (1) Where the IMB grants an authorisation under this Part, it shall give notice in writing to the applicant specifying—

(*a*) the activities which the individual may carry out under the authorisation in accordance with these Regulations and the Directive,

(*b*) the establishment(*s*) at which such activities may be carried out,

(*c*) any specific conditions relevant to the authorisation as determined by the IMB.

(2) Authorisations under this Part shall be granted for a period not exceeding 5 years.

Refusal to grant authorisation

56. (1) Where the IMB proposes to refuse to grant an authorisation under this Part, it shall serve a notice on the applicant of the proposed refusal and the reasons for same, and shall, if any representations are made by the applicant within 21 working days after the date of such notice, consider the representations.

(2) Where the IMB, having considered the representations (if any) made by the applicant in response to a notice under paragraph (1), decides to refuse to grant an authorisation under this Part, it shall notify the applicant stating the reasons on which its decision is based.

Removal, variation and addition of conditions

57. (1) Subject to the requirements of paragraph (2), the IMB may at any time remove or vary a condition attaching to an authorisation under this Part or impose an additional condition to an authorisation under this Part.

(2) Where the IMB proposes to remove or vary a condition, or impose an additional condition, in respect of an authorisation under this Part, pursuant to paragraph (1), it shall serve a notice on the applicant which shall—

(*a*) give details of the condition which it proposes to remove, or of the variation which it proposes to make to an existing condition, or of the additional condition which it proposes to impose,

(*b*) give the reasons for its decision, and

(*c*) specify the date, which shall be not less than 14 working days from the date on which the notice is served, from which the removal, variation or imposition shall apply.

Amendment of authorisation

58. (1) The holder of an authorisation granted under this Part may apply to the IMB for amendment of his or her authorisation, including the addition of—

(*a*) authorisation to carry out a new type of procedure,

(*b*) authorisation to carry out activities on a new project in the establishment(*s*) at which he or she is authorised to carry out activities, and

(*c*) authorisation to carry out activities in relation to a new species in such establishment(*s*).

(2) An application under paragraph (1) shall—

(*a*) be made in writing to the IMB,

(*b*) be signed by the applicant, whether in ink or by means of electronic signature,

(*c*) be accompanied by written confirmation of endorsement by the breeder, supplier or user of the establishment in which the applicant shall perform the activities for which he or she requires authorisation,

(*d*) accompanied by a written undertaking that, in the event of the authorisation being amended, the applicant shall ensure fulfilment of the

obligations arising by virtue of the terms and conditions of the authorisation and

(*e*) be accompanied by the appropriate fee.

(3) An application under paragraph (1) shall include the following information:

(*a*) the name and contact details of the applicant,

(*b*) details of the amendment sought, and

(*c*) such other relevant information as determined by the IMB.

(4) The IMB shall acknowledge the receipt of an application under paragraph (1) as quickly as possible and shall indicate to the applicant the period within which the decision is to be taken.

(5) In the case of an incomplete or incorrect application under paragraph (1), the IMB shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.

PART 9

NATIONAL COMMITTEE

Establishment of National Committee

59. (1) There shall be a body to be known as the National Committee for the Protection of Animals Used for Scientific Purposes or, in the Irish language, an An Coiste Náisiúnta um Chaomhnú Ainmhithe a úsáidtear ar Mhaithe le hEolaíocht (and in these Regulations referred to as the "National Committee") to perform the functions assigned to it by or under this Part.

(2) The National Committee shall stand established on such day as the Minister by order appoints.

Membership of National Committee

60. (1) The National Committee shall consist of a chairperson and 7 to 9 ordinary members, appointed by the Minister from time to time, based on nomination from the IMB.

(2) The persons appointed to the National Committee shall possess specialist expertise and competence relevant to the functions of the National Committee.

(3) A member of the National Committee shall be appointed for such term (not exceeding five years) as shall be specified by the Minister when appointing him or her and on such terms and conditions as the Minister determines, and a member whose term of office expires by the effluxion of time shall be eligible for reappointment.

(4) A member of the National Committee shall be paid such remuneration, if any, and such allowances for expenses, if any, as the Minister, with the consent of the Minister for Public, Expenditure and Reform, determines.

(5) A member of the National Committee may resign from office by letter addressed to the Minister.

(6) The Minister may at any time remove from office a member of the National Committee if he or she has committed stated misbehaviour or if his or her removal appears necessary for the effective performance by the National Committee of its functions.

(7) Where a member of the National Committee is—

(*a*) nominated as a member of Seanad Éireann,

(*b*) elected as a member of either House of the Oireachtas or of the European Parliament,

(*c*) regarded, pursuant to Part XIII of the Second Schedule to the European Parliament Elections Act 1997, as having been elected to such parliament to fill a vacancy, or

(*d*) elected or co-opted as a member of a local authority

he or she shall thereupon cease to be a member of the Committee.

(8) A person who is for the time being entitled under the Standing Orders of either House of the Oireachtas to sit therein or is a member of the European Parliament or a local authority shall, while he or she is so entitled or is such a member, be disqualified from becoming a member of the National Committee.

Functions of National Committee

61. (1) It shall be the function of the National Committee to advise the IMB and animal welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.

(2) In carrying out its function, the National Committee shall consider the following issues, where appropriate:

(*a*) animal care and welfare, and

(*b*) the principles of replacement, reduction and refinement.

(3) The National Committee shall exchange information on the operation of animal welfare bodies and project evaluation and share best practice with other national committees established pursuant to Article 49 of the Directive.

(4) The National Committee shall be independent in the performance of its functions, and the committee and its members shall not be subject to the direction of any other person in the performance of their duties.

(5) The National Committee shall, subject to these Regulations, regulate its own procedure and business.

(6) The Minister may, from time to time, with the consent of the Minister for Public Expenditure and Reform, advance to the National Committee out of monies provided by the Oireachtas, such sums as the Minister may determine for the purposes of expenditure by the National Committee in the performances of its functions.

Meetings of National Committee

62. (1) The quorum for a meeting of the National Committee shall be 4.

(2) At a meeting of the National Committee—

(*a*) the chairperson of the committee shall, if present, be the chairperson of the meeting, and

(*b*) if and so long as the chairperson of the committee is not present or if the office of chairperson is vacant, the members of the committee who are present shall choose one of their number to be chairperson of the meeting.

(3) The chairperson of the National Committee and each ordinary member of the committee present at a meeting thereof shall have a vote.

(4) In the event of a vote being required on a question arising at a meeting of the National Committee such question shall be determined by a majority of the votes of the members present and voting on the question and, in the case of an equal division of votes, the chairperson of the meeting shall have a second or casting vote.

(5) The National Committee may act notwithstanding one or more than one vacancy among its members, provided there is a quorum.

PART 10

RECORDS AND INFORMATION

Animal records

63. (1) Breeders, suppliers and users shall keep records of at least the following:

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

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

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

(*d*) from whom the animals are acquired;

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

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

(*g*) in the case of users, the projects in which animals are used; and

(*h*) in the case of users, any deviations which negatively impact on animal health or welfare and which vary from the terms and conditions of a project authorisation.

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

(3) The records referred to in paragraph (1) shall be provided to the animal welfare body.

Information on dogs, cats and non-human primates

64. (1) Without prejudice to Regulation 63, breeders, suppliers and users shall keep the following additional information on each dog, cat and non-human primate:

(*a*) identity;

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

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

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

(2) Breeders, suppliers and users shall keep, in respect of each dog, cat and non-human primate, an individual history file, which follows the animal as long as it is kept for the purposes of these Regulations.

(3) Breeders, suppliers and users of dogs, cats and non-human primates shall establish the individual history file referred to in paragraph (2) at birth, or as soon as possible thereafter, and shall cover any relevant reproductive, veterinary and social information on the individual animal and the projects in which it has been used.

(4) The information referred to in this Regulation shall be kept for a minimum of 3 years after the death or rehoming of the animal and shall be made available to the IMB upon request.

(5) In the case of the rehoming of a dog, cat or non-human primate, the breeder, supplier or user shall ensure that relevant veterinary care and social information from the individual history file referred to in paragraph (2) shall accompany the animal.

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

65. (1) Breeders, suppliers and users shall ensure that each dog, cat or non-human primate is provided, at the latest at the time of weaning, with a permanent individual identification mark in the least painful manner possible.

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

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

(4) Breeders, suppliers and users shall provide, at the request of the IMB, the reasons why a dog, cat or non-human primate is not marked in accordance with this Regulation.

Information from breeders, suppliers and users

66. Breeders, suppliers and users, and any other persons involved in activities related to these Regulations, shall, upon request and within a period of 21 working days, or such longer period as may be allowed by the IMB, make available to the IMB any information it requires in order to comply with its obligations under this Part.

Information on implementation

67. The IMB shall by 10 November 2018, and every 5 years thereafter, send information on the implementation of the Directive, and in particular Articles 10(1), 26, 28, 34, 38, 39, 43 and 46, to the Commission using the common reporting format set out in Annex I to Commission Implementing Decision 2012/707/EU of 14 November 2012[2].

Information on use of animals in procedures

68. (1) The IMB shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures and, until 9 May 2013—

(*a*) the number and kinds of animals used in experiments,

(*b*) the number of animals, in selected categories, used in the experiments referred to in Article 3 of Council Directive 86/609/EEC of 24 November 1986[22],

(*c*) the number of animals, in selected categories, used in experiments required by legislation.

(2) The IMB shall submit the statistical information collected pursuant to paragraph (1) to the Commission by 10 November 2015 and every year thereafter using the common reporting format and detailed instructions set out in

[22]OJ No. L 358, 18.12.1986, p. 1.

Annex II to Commission Implementing Decision 2012/707/EU of 14 November 2012[2].

(3) Persons who carried out experiments in 2012 under a licence granted by the Minister for Health under s. 8 of the Cruelty to Animals Act 1876 (39 & 40 Vict., c. 7) shall submit the information referred to in paragraph (1)(*a*), (*b*) and (*c*) in respect of those experiments to the Department of Health on or before 31 March 2013.

Information on exemptions in relation to method of killing

69. The IMB shall submit to the Commission, on an annual basis, detailed information on exemptions granted under Regulation 8(4)(*a*) using the common reporting format set out in Annex III to Commission Implementing Decision 2012/707/EU of 14 November 2012[2].

Commercially sensitive information

70. The IMB shall take all necessary steps to ensure that intellectual property and confidential information, including commercially sensitive information, communicated pursuant to these Regulations is protected.

PART 11

ENFORCEMENT, OFFENCES AND PENALTIES

Interpretation of Part 11

71. In this Part—

"authorised officer" means—

(*a*) a person appointed under Regulation 72(1)(*a*),

(*b*) a person who, immediately before the making of these Regulations, was an authorised officer within the meaning of the Cruelty to Animals Act 1876 (39 & 40 Vict., c.7), until such time as—

(i) he or she ceases to be an employee of the Department of Agriculture, Food and the Marine, or

(ii) the Minister, on the recommendation of the IMB, revokes the said appointment,

whichever is the earlier, or

(*c*) an officer of Customs and Excise;

"inspect" includes search;

"record" includes, in addition to a record in writing—

(*a*) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable, with or without the aid

or some other instrument, of being reproduced in legible or audible form,

(*b*) a film, tape or other device in which visual images are embodied so as to be capable, with or without the aid or some other instrument, of being reproduced in visual form, and

(*c*) a photograph,

and any reference to a copy of a record includes—

(*a*) in the case of a record to which paragraph (*a*) of this definition applies, a transcript of the sounds or signals embodied therein,

(*b*) in the case of a record to which paragraph (*b*) of this definition applies, a still reproduction of the images embodied therein, and

(*c*) in the case of a record to which paragraphs (*a*) and (*b*) of this definition apply, such a transcript together with such a still reproduction;

"relevant thing" means any article, substance, equipment, machinery or plant used in relation to an activity, and any carcass, animal product, animal by-product, or animal residue.

Authorised officers

72. (1) The IMB—

(*a*) may appoint such and so many persons as the IMB thinks fit to be authorised officers for the purposes of these Regulations, and

(*b*) shall furnish each authorised officer appointed by it with a warrant of the authorised officer's appointment.

(2) An authorised officer, other than an authorised officer who is an officer of Customs and Excise, shall, when performing a function imposed under these Regulations on an authorised officer, produce his or her warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of enforcing compliance with these Regulations, including conducting inspections pursuant to Regulation 73, an authorised officer may—

(*a*) subject to paragraph (5), enter, if necessary by the use of reasonable force, at all reasonable times, any establishment which he or she has reasonable grounds to believe that it is necessary to visit, including—

(i) any establishment owned or managed by a breeder, supplier or user, or at which he, she or it carries out an activity, or any premises that is connected to the management, import or export of an animal or relevant thing,

(ii) any establishment of any person who carries out any activity on behalf of, and pursuant to a contractual arrangement, with a breeder, supplier or user,

(iii) where any facilities for an activity are in the establishment of any person or body other than a breeder, supplier or user, those facilities in that person's establishment, and

(iv) any establishment at which books, records or other documents, including financial documents and documents stored in non-legible form, relating to any activity are stored or kept,

(v) any establishment at which activities requiring authorisation under these Regulations are to take place,

(*b*) at such establishments inspect, and take copies of, any books, records, other documents, including documents stored in non-legible form, or extracts therefrom, which he or she finds in the course of his or her inspection,

(*c*) remove any such books, records or other documents from such establishment and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(*d*) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of—

(i) an animal

(ii) the establishment, or

(iii) any relevant thing at the establishment,

as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(*e*) require any person at the establishment or the owner or person in charge of the establishment, and any person employed there, to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as he or she may reasonably require for the purposes of his or her functions under these Regulations, including information as to the ownership, identity and origin of an animal,

(*f*) without payment, take samples of any animal or relevant thing found at the establishment for the purposes of any test, examination or analysis,

(*g*) direct that such animal or relevant thing found at the establishment as he or she, upon reasonable grounds, believes does not comply with the requirements of these Regulations not be sold or distributed or moved from the establishment, without his or her consent,

(*h*) secure for later inspection any establishment or part of any establishment in which an animal or relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under these Regulations,

(*i*) without payment, take possession of and remove from the establishment for any test, examination or analysis any animal or relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations,

(*j*) without payment, take samples of any animal or relevant thing, detained pursuant to subparagraph (i), for the purposes of any test, examination, or analysis,

(*k*) where the taking of samples of any animal or relevant thing pursuant to subparagraph (*f*) or (*j*) is, for whatever reason, not practicable, without payment take the animal or relevant thing concerned for the purposes of any test, examination or analysis,

(*l*) stop any person, vehicle, vessel or container at the establishment,

(*m*) board and search any such vehicle, vessel or container,

(*n*) require the name and address of any person at the establishment, including the person to whom an animal or relevant thing is being delivered or who is causing it to be delivered,

(*o*) make a record whether in writing, by photography or otherwise,

(*p*) inspect and copy or extract information from any data within the meaning of the Data Protection Acts 1988 and 2003,

(*q*) require a person, having authority to do so, to break open any container or package, or to permit him or her to do so, as he or she may reasonably require for the purposes of his or her functions under these Regulations, or

(*r*) require a person, who makes available facilities such as post office boxes, telecommunications, electronic mail addresses, or electronic data storage, or other such like facilities, to give him or her such assistance and information as he or she may reasonably require for the purposes of his or her functions under these Regulations in any case where the officer has reasonable grounds for believing that an animal or any relevant thing is being supplied by mail.

(4) When performing a function under these Regulations, an authorised officer may, subject to any warrant issued under paragraph (6), be accompanied by such number of—

(*a*) other authorised officers,

(*b*) members of the Garda Síochána, or

(*c*) persons with expertise relating to any animal or relevant thing,

as he or she considers appropriate in the circumstances of the case.

(5) An authorised officer shall not enter a dwelling, other than—

(*a*) with the consent of the occupier, or

(*b*) in accordance with a warrant issued under paragraph (6).

(6) Upon the application of an authorised officer, a judge of the District Court, if satisfied that there are reasonable grounds for believing that—

(*a*) an animal is to be found in any dwelling, or is being or has been subjected to any procedures or kept in any dwelling,

(*b*) any relevant thing, books, records or other documents (including documents stored in non-legible form) referred to in paragraph (3)(*a*)(iv) are being stored or kept in any dwelling, any location, physical or virtual, connected to the dwelling or to persons occupying, associated with or using the dwelling, or

(*c*) a dwelling is occupied in whole or in part by an undertaking carrying out an activity,

may issue a warrant authorising a named authorised officer, accompanied by such other authorised officers, members of the Garda Síochána, or persons with expertise relating to any animal or relevant thing as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under paragraph (3)(*b*) to (*r*).

(7) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under these Regulations, he or she may require that person to provide him or her with his or her name, date of birth, and the address at which he or she ordinarily resides, and to produce corroborative evidence of same.

(8) Where an authorised officer has reasonable cause to suspect that-

(*a*) an offence is being or has been committed under these Regulations, or

(*b*) evidence of an offence or contravention may be, is or has been on or in an establishment,

the authorised officer may, in addition to the powers exercisable by him or her under paragraph (3)—

(i) search a person, where the authorised officer considers it necessary,

(ii) seize and detain, an animal, vessel, vehicle, container or relevant thing, or

(iii) dispose of, or require the owner or person in charge of or in possession of an animal, or relevant thing to deal with or dispose of it (or any other thing used in connection with, or that may have been in contact with, the animal, or relevant thing) in a manner that the authorised officer sees fit.

(9) A statement or admission made by a person pursuant to a requirement under paragraph (3)(*e*) shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under Regulation 84(2)(*g*)).

(10) Nothing in this Regulation shall be taken to compel the production by any person of a document which he or she would be exempt from producing in proceedings in a court on the ground of legal professional privilege.

Inspections and requests for information

73. (1) The IMB shall conduct regular inspections of breeders, suppliers and users and their establishments for the purpose of ensuring that—

(*a*) the breeders, suppliers and users comply with the requirements of these Regulations,

(*b*) the establishments comply with the requirements of these Regulations,

(*c*) the projects and procedures carried out at the establishment comply with the requirements of these Regulations,

(*d*) documents or other records relating to the requirements of these Regulations are examined, and

(*e*) problems relating to compliance with the requirements of these Regulations are identified.

(2) The IMB shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of:

(*a*) the number and species of animals housed,

(*b*) the record of the breeder, supplier or user in complying with the requirements of these Regulations,

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

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

(3) The IMB shall carry out inspections on at least one third of the users operating in the State each year in accordance with the risk analysis referred to in paragraph (2).

(4) The IMB shall inspect breeders, suppliers and users of non-human primates and their establishments at least once a year.

(5) The IMB shall carry out an appropriate proportion of the inspections without prior warning.

(6) The IMB shall keep records of all inspections for at least 5 years.

(7) The IMB may conduct such additional inspections, which may be announced or unannounced, of the establishments of breeders, suppliers and users as it considers necessary for the purpose of ensuring compliance with the requirements of these Regulations.

(8) A person shall not obstruct or interfere with the IMB carrying out inspections under this Regulation.

(9) The IMB may serve a notice on a breeder, supplier or user, or any person connected with a breeder, supplier or user, requiring that he, she or it furnish the IMB with such information concerning compliance with these Regulations and within such period as shall be specified in the notice.

(10) Any person who receives a request for information in accordance with paragraph (9) shall provide the information requested within the period specified in the notice.

(11) In the event of actual or suspected non-compliance with these Regulations, the IMB shall take appropriate remedial action or require such action to be taken in accordance with these Regulations, as it shall consider appropriate.

(12) Any reference to an inspection of an establishment which the IMB is required or empowered to conduct by virtue of this Regulation, shall be construed so as to include an inspection of any establishment within the State at which any of the activities are carried out, or suspected of being carried out, by any person on behalf of, and pursuant to a contractual arrangement with a breeder, supplier or user.

(13) For the avoidance of doubt, it is hereby declared that the IMB's functions under this Regulation in relation to an establishment are also applicable in the case of an establishment of a person seeking any authorisation under these Regulations.

(14) The IMB, on receipt of a duly justified request from the competent authority in another EEA State, shall organise such inspection or other control measures as are reasonably required.

(15) The IMB shall cooperate with the officials designated by the Commission to carry out controls under Article 35 of the Directive and shall give all the necessary assistance to enable them to accomplish their tasks.

(16) The IMB shall permit the officials referred to in paragraph (15), and may permit officials from a competent authority in another EEA State, to accompany an authorised officer while carrying out inspections under these Regulations.

(17) The IMB shall take measures to take account of the results of controls undertaken by the Commission under Article 35 of the Directive.

Compliance notice

74. (1) Where—

(*a*) a person has failed, in any material respect, to comply with the requirements of these Regulations, or

(*b*) the information given by a person pursuant to Regulation 25(2), 36(2) or 53(2) was false or incomplete in any material respect,

and the IMB considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the relevant authorisation granted under these Regulations, in the first instance, it may serve a notice on the person concerned in accordance with paragraph (2).

(2) A notice served under this Regulation shall—

(*a*) identify the requirements of these Regulations with which the person has failed to comply, or, in the case of false or incomplete information, the further information which is required,

(*b*) identify the action which the person is required to take, and

(*c*) give the timescale within which the person must take the action identified in subparagraph (*b*).

(3) Where a person fails to comply with the requirements set out in a notice served under this Regulation within the specified timescale, the IMB may, by a further notice served on that person, suspend or revoke the authorisation concerned.

Suspension or revocation of authorisation

75. (1) Subject to paragraph (2), the IMB may, by serving an order ("a suspension order" or "a revocation order") on the holder of the authorisation, suspend or revoke an authorisation granted under these Regulations on one or more of the following grounds:

(*a*) the failure of the holder of the authorisation to comply with the requirements of these Regulations;

(*b*) the failure of the holder of the authorisation to carry out the authorised activities or role in accordance with the authorisation;

(*c*) the information provided pursuant to Regulation 25(2), 36(2) or 53(2) was false or incomplete in any material respect;

(*d*) the holder of the authorisation is not carrying out, or has indicated by a notice in writing that he, she or it no longer intends to carry out, the activities or role to which the authorisation relates;

(*e*) the holder of the authorisation does not have the staff, establishment, equipment or facilities necessary for carrying out properly the activities or role to which the authorisation relates;

(*f*) the failure to comply with a compliance notice.

(2) Where the IMB proposes to suspend or revoke an authorisation under this Regulation, it shall serve a notice on the holder of the authorisation of the proposal and the reasons for same, and shall, if any representations are made by that person within 21 working days after the date of such notice, consider such representations.

(3) Where the IMB, having considered the representations (if any) made in response to a notice under paragraph (2), decides to suspend or revoke an authorisation, it shall notify in writing the holder of the authorisation stating the reasons on which its decision is based.

(4) A suspension of an authorisation under this Regulation shall be for such period as the IMB shall consider necessary having regard to the reasons for the suspension.

(5) A suspension or revocation of an authorisation under this Regulation may be total, or may be limited to a particular activity or to one or more activities carried out at a particular establishment or establishments.

(6) Where, after a suspension has taken effect, the IMB considers that the authorisation should be further suspended or revoked, the IMB shall proceed in accordance with the provisions of this Regulation.

(7) Subject to Regulation 73(11), where an authorisation is suspended or revoked under this Regulation, the holder of the authorisation shall ensure that the welfare of the animals housed in his, her or its establishment is not adversely affected.

Animal welfare notice

76. (1) If an authorised officer is of the opinion that—

(*a*) an animal is being caused unnecessary pain, suffering or injury,

(*b*) an animal is at risk of being caused unnecessary pain, suffering or injury,

(*c*) there is a serious risk to the welfare of an animal, or

(*d*) the conditions under which an animal is being bred or kept contravene these Regulations,

he or she may serve or cause to be served on the breeder, supplier or user, or other person responsible for the animal, a notice ("an animal welfare notice") stating that opinion and directing that—

(i) an ill or injured animal be cared for in an appropriate manner,

(ii) veterinary or other specialist advice be obtained in respect of an ill or injured animal,

(iii) an animal be supplied with feed appropriate to its age and species and in such quantity as will maintain it in good health,

(iv) an animal be given access to such a supply of suitable liquid as will enable it to fulfil its fluid intake needs,

(v) one or more animals be moved to and kept in such place as the officer specifies in the notice,

(vi) one or more animals be re-homed, set free, killed or otherwise disposed of in such manner and at such place (if any) as the officer may specify in the notice,

(vii) such alterations or additions be made to the establishment at which the animal is kept, or to any relevant thing or facilities found there, as the officer may specify in the notice,

(viii) such alterations be made to the manner in which the animal is kept as the authorised officer may specify in the notice, or

(ix) such other measures be taken as are necessary to ensure that the animal is kept in a manner that complies with these Regulations.

(2) An animal welfare notice may specify one or more requirements or refer to one or more animals or species of animal.

(3) A requirement contained in an animal welfare notice may specify a time limit within which it is to be complied with.

(4) An animal welfare notice may require the person served with the notice to choose between two or more of the requirements specified in the notice.

(5) A requirement specified in an animal welfare notice (in this Regulation referred to as "the earlier animal welfare notice") may be modified or withdrawn in a further animal welfare notice and in that event the earlier animal welfare notice shall have effect subject to such modification or withdrawal.

(6) A person, including a person served with an animal welfare notice, shall not deal with an animal to which the notice relates other than in accordance with the terms of the notice.

(7) In the event of an appeal made pursuant to Regulation 78, a person, including the person appealing, shall not deal with an animal to which an animal welfare notice relates pending the determination of the appeal other than in accordance with such directions as shall be given in writing to the appellant by an authorised officer.

(8) If the terms of an animal welfare notice are confirmed with or without modification on appeal under Regulation 78, a person including the person who made the appeal shall not deal with an animal to which the notice relates other than in accordance with the notice as confirmed.

(9) Any costs pertaining to action required to comply with an animal welfare notice shall be borne by the person served with the notice.

Closure order

77. (1) Where an authorised officer is of the opinion that there is or is likely to be a grave and immediate danger to animal welfare at, in or on any establishment of a breeder, supplier or user, or part thereof, or where the authorised officer is unable to establish to his or her satisfaction, due to any obstruction, the level of or the extent to which such a danger, if any, exists, the authorised officer may, following consultations with the chief executive of the IMB, serve, or arrange to have served, on the breeder, supplier or user a notice ("a closure order") signed by the officer or the chief executive of the IMB, stating that he or she is of that opinion, and the closure order shall, as appropriate—

(*a*) state that the authorised officer is of the opinion that the establishment or part thereof to which the order relates should be closed,

(*b*) specify the matters which in his or her opinion give or, as the case may be, are likely to give rise to the said risk,

(*c*) where in his or her opinion any of those matters involves or, as the case may be, will involve a contravention of these Regulations, state that he or she is of that opinion, specify the provision or provisions as to which he or she is of that opinion, and give particulars of the reasons why he or she is of that opinion, and

(*d*) direct that the establishment be closed unless and until the matters specified in the order in pursuance of subparagraph (*b*) and any associated contravention of provisions so specified in pursuance of subparagraph (*c*) have been remedied.

(2) A closure order shall take effect—

(*a*) where the order so declares, immediately the closure order is received by the person served with the closure order, or

(*b*) in any other case—

(i) where no appeal is taken against the closure order, on the expiration of the period during which such an appeal may be taken or the day specified in the closure order as the day on which it is to come into effect, whichever is the later, or

(ii) in case such an appeal is taken, on the day next following the day on which the closure order is confirmed on appeal or the appeal is withdrawn or the day specified in the closure order as that on which it is to come into effect, whichever is the later.

(3) The chief executive of the IMB may, for stated reasons, revoke or vary a closure order made in accordance with this Regulation.

(4) Where a closure order has been served and activities are carried on in contravention of the order, the High Court may, on the application of an authorised officer, by order prohibit the continuance of the activities and order the closure of the premises.

(5) An application to the High Court for an order under this subsection shall be by motion and the court, when considering the matter, may make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under this paragraph is determined may contain such terms and conditions (if any) as to the payment of costs as the court considers appropriate.

(6) Any costs pertaining to action required to comply with a closure order shall be borne by the person served with the notice.

Appeals

78. (1) A person who is aggrieved by—

(*a*) a compliance notice,

(*b*) a suspension order,

(*c*) a revocation order,

(*d*) an animal welfare notice,

(*e*) a closure order, or

(*f*) a refusal to grant an authorisation under these Regulations,

may appeal the decision of the IMB to grant the notice or order, or refuse to grant the authorisation.

(2) The IMB shall publish guidelines in relation to the procedure for appeals under paragraph (1) and shall inform any person who is the subject of a decision in relation to a matter referred to in paragraph (1) of his or her right to appeal.

Power to seize and dispose of an animal

79. (1) Without prejudice to Regulations 72, 74, 75 and 76, if—

(*a*) a person fails to comply with the terms of a notice or order under these Regulations within the time limit specified therein,

(*b*) an authorised officer has reasonable grounds for believing that the terms of a notice or order under these Regulations will not be complied with,

(*c*) a notice or order under these Regulations has been confirmed with or without modification under Regulation 78 and the notice or order has not been complied with,

(*d*) an authorised officer has reasonable grounds for believing that the terms of a notice or order under these Regulations which has been confirmed with or without modification under Regulation 78 will not be complied with, or

(*e*) pending the determination of an appeal made under Regulation 78, an authorised officer has reasonable grounds for believing that—

(i) a notice or order under these Regulations, or

(ii) a direction given pursuant to Regulation 72,

has not been or will not be complied with, an authorised officer may at any time seize the animal at such establishment as he or she thinks fit.

(2) An authorised officer may dispose of or kill a seized animal, or cause it to be disposed of or killed, in such manner and at such place as the authorised officer considers appropriate in the circumstances of the case.

(3) Any profits arising out of the disposal of an animal under this Regulation shall be paid to the owner of the animal less any expenses incurred in connection with seizure, maintenance, disposal or destruction of the animal.

(4) The costs (including ancillary costs) of seizure, maintenance, disposal or destruction of an animal under Regulation 72, this Regulation or Regulation 80 are, subject to paragraph (3), recoverable-

(*a*) by deducting the costs from any sum that is or becomes payable by the IMB to the owner of the animal, or

(*b*) as a simple contract debt in any court of competent jurisdiction from the person who was the owner of the animal at the time of seizure, disposal or destruction took place.

Emergency measures

80. (1) Notwithstanding Regulation 76(1), if an authorised officer is of the opinion that an animal—

(*a*) is suffering a degree of pain, suffering or injury in breach of the relevant project authorisation, or

(*b*) is seriously at risk of being subject to a degree of pain, suffering or injury in breach of the relevant project authorisation,

and that emergency measures should be taken immediately to relieve its pain or suffering or risk of pain or suffering or injury, he or she may seize, dispose of or destroy, or may arrange for the disposal or destruction of, the animal.

(2) Notwithstanding Regulation 76(1), if an authorised officer is of the opinion that an animal has been abandoned by a breeder, supplier or user and that emergency measures should be taken immediately, he or she may seize, dispose of or destroy, or may arrange for the disposal or destruction of, the animal.

Fixed penalty notice

81. (1) If an authorised officer has reasonable grounds for suspecting that a person is committing or has committed an offence under these Regulations, he or she may serve a notice in writing on that person stating—

(*a*) that the person is alleged to have committed the offence,

(*b*) when and where the offence is alleged to have been committed,

(*c*) that the person may during the period of 28 days from the date of the notice make to the IMB a payment of €250 accompanied by the notice, and

(*d*) that a prosecution in respect of the alleged offence will not be instituted during the period specified in the notice and, if the payment specified in the notice is made during that period, no prosecution in respect of the alleged offence will be instituted.

(2) If notice is given under paragraph (1)—

(*a*) a person to whom the notice applies may, during the period specified in the notice, make to the IMB, at the address specified in the notice, the payment specified in the notice,

(*b*) the IMB may receive the payment, issue a receipt for it and retain the money so paid, and any payment so received shall not be recoverable in any circumstances by the person who made it, and

(*c*) a prosecution in respect of the alleged offence shall not be instituted in the period specified in the notice, and if the payment so specified is made during that period, no prosecution in respect of the alleged offence shall be instituted.

(3) In a prosecution for an offence under these Regulations, the onus of proving that a payment pursuant to a notice under this Regulation has been made lies on the accused.

Taking of samples by authorised officers

82. (1) Subject to paragraph (3), where an authorised officer takes a sample of an animal or relevant thing, he or she shall—

(*a*) divide the sample into 3 approximately equal parts,

(*b*) place each part into separate containers, and

(*c*) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by that authorised officer.

(2) Where an authorised officer has complied with paragraph (1), he or she shall—

(*a*) offer one of the sealed containers to the owner or person for the time being in charge or possession of the animal or relevant thing from which the sample concerned was taken,

(*b*) retain one of the sealed containers, and

(c) forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by a person mentioned in Regulation 83.

(3) Where an animal or relevant thing is contained in a container and its division into parts pursuant to paragraph (1) is, for whatever reason, not practicable, an authorised officer, who wishes to take samples of the animal or relevant thing for the purposes of any test, examination or analysis, shall take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of paragraph (1), and the provisions of paragraphs (1) and (2) shall apply thereto accordingly.

(4) Where an authorised officer takes an animal or relevant thing pursuant to Regulation 72(3)(i), he or she shall—

(*a*) place the animal or relevant thing in a container,

(*b*) forthwith seal and mark the container in such a manner as to identify it as an animal or relevant thing taken pursuant to that section, and

(c) forward, or cause to be forwarded, the sealed container for test, examination or analysis of the animal or relevant thing by a person mentioned in Regulation 83.

Certificate of result of test, examination or analysis of sample, etc

83. In any proceedings for an offence under these Regulations, a certificate in the form specified in the Schedule to these Regulations signed by—

(*a*) the State Chemist,

(*b*) another chemist employed or engaged at the State Laboratory and authorised by the State Chemist to sign the certificate,

(*c*) a chemist or analyst appointed by the IMB,

stating the result of any test, examination or analysis of a sample of any animal or relevant thing, as the case may be, forwarded under Regulation 82 shall, with regard to that sample of the animal or relevant thing, as the case may be, be evidence of the matters stated in the certificate unless the contrary is proved.

Offences

84. (1) A person who contravenes Regulation 6, 7, 8(1) or (3), 9, 10(1), 11, 12(1), 13, 14(1) or (3), 15(1) or (2), 16(1), 17(1), 18, 19, 20, 21(1), 22(1) or (2), 23(1), 24(1), 30(1), 32(2), 34, 35(1), (2) or (3), 42(1) or (3), 43(1), (2), (3) or (4), 44, 45, 46, 47, 48, 49, 50(1), (2) or (3), 51, 63, 64, 65, 66, 68(3), 73(10), 75(7), 76(6), (7), (8) or (9) or 77(6) is guilty of an offence.

(2) A person who—

(*a*) in purported compliance with a request or requirement under these Regulations gives information to the IMB that he or she knows to be false or misleading in any material respect,

(*b*) fails to comply with a notice or order under these Regulations, except where the operation of that notice or order has been suspended or has been withdrawn or revoked by the IMB,

(*c*) knowingly supplies an animal which is not marked and identified in accordance with the requirements of Regulation 65,

(*d*) discloses any confidential information to which he or she has access by virtue of these Regulations, otherwise than in accordance with these Regulations,

(*e*) obstructs or interferes with the IMB, an authorised officer, a member of the Garda Síochána or a person with expertise relating to any animal or relevant thing, in the course of performing a function conferred on him or her by these Regulations or a warrant under Regulation 72(6),

(*f*) impedes the performance by the officer, member of the Garda Síochána, or person with expertise, as the case may be, referred to in subparagraph (*d*), of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the officer, member, or person with expertise, as the case may be, pursuant to Regulation 72,

(*g*) in purported compliance with a request or requirement referred to in subparagraph (*e*), or in answer to a question referred to in subparagraph (*e*), gives information to the officer, member, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect,

(*h*) falsely represents himself or herself to be an authorised officer,

(*i*) forges, or utters knowing it to be forged, a certificate of analysis or other document purporting to be issued, granted or given under these Regulations or required for the purposes of these Regulations (in this Regulation referred to as "a forged document"),

(*j*) alters with intent to defraud or deceive, or utters knowing it to be so altered, a certificate of analysis or other document issued, granted or given under these Regulations, or required for the purposes of these Regulations (in this Regulation referred to as "an altered document"),

(*k*) without lawful authority, has in his or her possession a forged document or an altered document, knowing it to be a forged or altered document as the case may be,

(*l*) with the intent to defraud or deceive, tampers with any substance or thing with the result that a sample taken pursuant to these Regulations does not correctly represent the substance sampled, or

(*m*) with the intent to defraud or deceive, tampers or interferes with any sample taken under these Regulations.

is guilty of an offence.

(3) For the purposes of these Regulations, every contravention of a provision of these Regulations shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph of such provision shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any such provision.

(4) Where a body corporate, or a person acting on behalf of a body corporate, commits an offence under these Regulations and the offence is committed with the consent, connivance or approval of, or is attributable to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(5) Where the affairs of a body corporate are managed by its members, paragraph (4) applies as if the reference to a director in that subsection were a reference to a member of the body corporate.

(6) In proceedings for an offence under these Regulations, it is a defence for a person charged with the offence to prove both of the following—

(*a*) commission of the offence was due to a reasonable mistake or the reliance on information supplied to him or her, or to the act or default of another person, an accident or some other cause beyond his or her control, and

(*b*) he or she exercised due diligence and took all reasonable precautions to avoid commission of the offence.

(7) If reliance on the defence provided by paragraph (6) involves the allegation that the commission of the offence was due to reliance on information supplied by another person or to the act or default of another person, the person charged with the offence shall not, without leave of the court, be entitled to rely on that defence unless, not less than 7 working days before the hearing, he or she has served on the prosecutor written notice providing information identifying, or assisting in the identification of, that other person.

Penalties

85. (1) A person guilty of an offence under these Regulations is liable—

(*a*) on summary conviction to a class A fine or at the discretion of the Court to imprisonment for a term not exceeding one year or both, or

(*b*) on conviction on indictment—

(i) in the case of a first offence, to a fine not exceeding €120,000 or imprisonment for a term not exceeding 3 years or both, and

(ii) in the case of any subsequent offence, to a fine not exceeding €300,000 or imprisonment for a term not exceeding 3 years or both.

(2) Where a person is convicted of an offence under these Regulations, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the IMB, as the case may be, the costs and expenses, measured by the court, incurred by the IMB in relation to the investigation, detection and prosecution of the offence, including costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisors engaged by the IMB.

(3) On conviction for an offence under these Regulations, the court may, in addition to any other penalty or costs—

(*a*) order any animal or relevant thing or any vehicle, vessel or container to which the offence relates to be forfeited to the IMB for sale, destruction or disposal as the IMB thinks fit, and

(*b*) upon application made to it by or on behalf of the IMB, order the person convicted of the offence to pay to the IMB all or part of the costs of the destruction or disposal of such animal or relevant thing

or any vehicle, vessel or container, subject to such conditions, if any, as are specified in the order.

(4) An order for costs and expenses under paragraph (2) or (3) is in addition to, and not instead of, any fine or penalty the court may impose under paragraph (1).

(5) In any proceedings for an offence under these Regulations, where no conviction is recorded, the court may, upon application made to it by or on behalf of the IMB, order any animal or relevant thing to which the offence relates to be forfeited to the IMB for sale, destruction or disposal.

Summary proceedings may be brought by IMB

86. Summary proceedings for an offence under these Regulations may be brought and prosecuted by the IMB.

PART 12

TRANSITIONAL PROVISIONS AND PROVISIONAL SAFEGUARD MEASURES

Transitional provisions

87. (1) Notwithstanding Part 5, the following transitional provisions shall apply to a person granted a licence before 1 January 2013 by the Minister for Health under s. 8 of the Cruelty to Animals Act 1876 (39 & 40 Vict., c. 7), as amended by the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (S.I. No. 566 of 2002):

(*a*) where the licence expires on or before 1 January 2018, the person may carry out the licensed experiments without a project authorisation until such licence expires;

(*b*) where the licence expires after 1 January 2018, the person may only continue carrying out the licensed experiments in accordance with that licence until 1 January 2018 and thereafter may only carry out the relevant activities under a project authorisation;

(*c*) where the person wishes to make a change in the licensed experiments, he or she shall apply for a project authorisation under Part 5.

(2) Notwithstanding Part 6, a person carrying out the activities of a breeder, supplier or user in an establishment granted a registration before 1 January 2013 by the Minister for Health under s. 7 of the Cruelty to Animals Act 1876 (39 & 40 Vict., c. 7), as amended by the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (S.I. No. 566 of 2002), may continue to carry out such activities under the said registration until the earlier of—

(*a*) 31 December 2014, or

(*b*) the date on which the IMB makes a decision in relation to an application for an authorisation under Part 6 in respect of the said establishment.

(3) Notwithstanding Part 8—

(*a*) a person listed in a licence granted before 1 January 2013 by the Minister for Health under s. 8 of the Cruelty to Animals Act 1876 (39 & 40 Vict., c. 7), as amended by the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (S.I. No. 566 of 2002), may continue to perform the duties or activities for which he or she is listed in the said licence, in respect of the licensed experiments, until the expiry of the said licence, or 1 January 2018, whichever is the earlier, and

(*b*) a person listed in an establishment registration granted before 1 January 2013 by the Minister for Health under s. 7 of the Cruelty to Animals Act 1876 (39 & 40 Vict., c. 7), as amended by the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (S.I. No. 566 of 2002), may continue to perform the duties or activities for which he or she is listed in the said registration until the earlier of the dates referred to in paragraph (2).

(4) A licence or registration remaining in effect under this Regulation, and any person carrying out an activity or role under such licence or registration, shall be subject to the enforcement, offences and penalties provisions in Part 11, as if the licence or registration was an authorisation granted under these Regulations.

Provisional safeguard measures

88. (1) The Minister, after consultation with the IMB, and in accordance with Article 55(1) of the Directive, may by order adopt a provisional measure providing for an exemption from the requirement in Regulation 13(1)(*a*)(i) that a procedure coming within that clause must be undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings.

(2) Subject to paragraph (3), the Minister, after consultation with the IMB, and in accordance with Article 55(2) of the Directive, may by order adopt a provisional measure allowing the use of great apes in procedures having one of the purposes referred to in Regulation 7(*b*)(i), (*c*) or (*e*), provided that the purpose of the procedure cannot be achieved by the use of species other than great apes or by the use of alternative methods.

(3) The reference in paragraph (2) to Regulation 7(*b*)(i) shall not be taken to include the reference to animals and plants.

(4) The Minister, after consultation with the IMB, and in accordance with Article 55(3) of the Directive, may by order adopt a provisional measure providing an exemption from Regulation 20(3), in the case of species other than non-human primates.

(5) Where the Minister adopts a provisional measure in accordance with paragraph (1), (2) or (4), he or she shall immediately inform the Commission and the other EEA States thereof, giving reasons for his or her decision and submitting evidence of the situation on which the provisional measure is based.

(6) The Minister shall by order revoke any order made under this Regulation where—

(*a*) the time period defined by the Commission in accordance with Article 55(4)(*a*) of the Directive has expired, or

(*b*) the Commission requires its revocation in accordance with Article 55(4)(*b*) of the Directive.

PART 13

REPEALS AND REVOCATIONS

Repeal of Cruelty to Animals Act 1876

89. The Cruelty to Animals Act 1876 (39 & 40 Vict., c.7) is repealed.

Revocations

90. The following are revoked:

(*a*) the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (S.I. No. 566 of 2002), and

(*b*) the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2005 (S.I. No. 613 of 2005).

SCHEDULE *Regulation 83*

Form of official certificate of result of test, examination or analysis of sample, etc

European Union (Protection of Animals Used for Scientific Purposes) Regulations 2012

CERTIFICATE STATING RESULTS OF TEST, EXAMINATION OR ANALYSIS

This certificate is issued by me, the undersigned, for the purpose of Regulation 83 of the European Union (Protection of Animals Used for Scientific Purposes) Regulations 2012 being—

1. .....

I hereby certify that I received on the ..... day of .....,

from 2. .....

of ..... a sample of the relevant thing/the relevant thing*,

being 3. .....

for test, examination or analysis; which was undamaged, duly sealed and marked

4. ..... .

I further certify that the said sample/relevant thing* has been tested, examined or analysed by me or under my direction and that the results are as follows—

5.

Signature .....

Date .....

Address .....

.....

.....

1. Here insert official title of person signing the certificate.
2. Here insert the name of the authorised officer who submitted the sample of the relevant thing, or the relevant thing, as the case may be.
3. Here insert the name or description of the relevant thing.
4. Here insert distinguishing mark on the sample of the relevant thing, or the relevant thing, as the case may be, and the date shown on its container as the date of sampling, or the date on which the relevant thing was taken into possession, as the case may be.
5. Here insert the relevant results as appropriate.

*Delete whichever is inapplicable.

L.S.

GIVEN under my Official Seal,
20 December 2012.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations give effect to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes and give full effect to Commission Implementing Decision 2012/707/EU of 14 November 2012.

These Regulations repeal the Cruelty to Animals Act 1876 and revoke the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2002 (S.I. No. 566 of 2002), and the European Communities (Amendment of Cruelty to Animals Act 1876) Regulations 2005 (S.I. No. 613 of 2005).

These Regulations may be cited as the European Union (Protection of Animals Used for Scientific Purposes) Regulations 2012.

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nó trí aon díoltóir leabhar.

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(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)
or through any bookseller.

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ISBN 978-1-4468-1060-6

€12.95

9 781446 810606

Wt. (B29624). 285. 1/13. Clondalkin. Gr 30-15.