Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance)

CHAPTER VI

FINAL PROVISIONS

Article 50

Adaptation of Annexes to technical progress

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

Article 51

Exercise of the delegation

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

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

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

Article 52

Revocation of the delegation

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

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

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

Article 53

Objections to delegated acts

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

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

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

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

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

Article 54

Reporting

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

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

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

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

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

Article 55

Safeguard clauses

1 Where a Member State has scientifically justifiable grounds for believing it is essential to use non-human primates for the purposes referred to in Article 8(1)(a)(i) with regard to human

beings, but where the use is not undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, it may adopt a provisional measure allowing such use, provided the purpose cannot be achieved by the use of species other than non-human primates.

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

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

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

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

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

b require the Member State to revoke the provisional measure.

Article 56

Committee

1 The Commission shall be assisted by a Committee.

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

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

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

Article 57

Commission report

1 By 10 November 2019 and every 5 years thereafter, the Commission shall, based on the information received from the Member States under Article 54(1), submit to the European Parliament and the Council a report on the implementation of this Directive.

2 By 10 November 2019 and every 3 years thereafter, the Commission shall, based on the statistical information submitted by Member States under Article 54(2), submit to the European Parliament and the Council a summary report on that information.

Article 58

Review

The Commission shall review this Directive by 10 November 2017, taking into account advancements in the development of alternative methods not entailing the use of animals, in particular of non-human primates, and shall propose amendments, where appropriate.

The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge.

Article 59

Competent authorities

1 Each Member State shall designate one or more competent authorities responsible for the implementation of this Directive.

Member States may designate bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof that the body:

a has the expertise and infrastructure required to carry out the tasks; and

b is free of any conflict of interests as regards the performance of the tasks.

Bodies thus designated shall be considered competent authorities for the purposes of this Directive.

2 Each Member State shall communicate details of a national authority serving as contact point for the purposes of this Directive to the Commission by 10 February 2011, as well as any update to such data.

The Commission shall make publicly available the list of those contact points.

Article 60

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 10 February 2013, and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 61

Transposition

1 Member States shall adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 January 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The method of making such reference shall be laid down by Member States.

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

Article 62

Repeal

1 Directive 86/609/EEC is repealed with effect from 1 January 2013 with the exception of Article 13, which shall be repealed with effect from 10 May 2013.

2 References to the repealed Directive shall be construed as references to this Directive.

Article 63

Amendment of Regulation (EC) No 1069/2009

Point (a)(iv) of Article 8 of Regulation (EC) No 1069/2009 is replaced by the following:

(iv) animals used in a procedure or procedures defined in Article 3 of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[(1)], in cases where the competent authority decides that such animals or any of their body parts have the potential to pose serious health risks to humans or to other animals, as a result of that procedure or those procedures without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;.

Article 64

Transitional provisions

1 Member States shall not apply laws, regulations and administrative provisions adopted in accordance with Articles 36 to 45 to projects which have been approved before 1 January 2013 and the duration of which does not extend beyond 1 January 2018.

2 Projects which have been approved before 1 January 2013 and the duration of which extends beyond 1 January 2018 shall obtain project authorisation by 1 January 2018.

Article 65

Entry into force

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

Article 66

Addressees

This Directive is addressed to the Member States.

(**1**) OJ L 276, 20.10.2010, p. 33’.