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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 23 November 2017

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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Subject: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT  
AND THE COUNCIL on the exercise of the power to adopt delegated acts  
conferred on the Commission pursuant 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

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Delegations will find attached document COM(2017) 680 final.

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Brussels, 23.11.2017  
COM(2017) 680 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND  
THE COUNCIL**

**on the exercise of the power to adopt delegated acts conferred on the Commission  
pursuant 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**

# **REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL**

## **on the exercise of the power to adopt delegated acts conferred on the Commission pursuant 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**

### 1. INTRODUCTION

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<sup>1</sup> regulates the care and use of animals for scientific purposes. It lays down rules on the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures; the origin, breeding, marking, care and accommodation, and killing of animals; the operations and authorisation of breeders, suppliers and users; and the evaluation and authorisation of projects involving the use of live animals in procedures.

This Directive empowers the Commission to adopt delegated acts to adapt the Annexes I and III to VIII (with the exception of provisions of Sections I and II of Annex VIII) to scientific and technical progress:

- ANNEX I: List of animals referred to in Article 10 [requiring these specifically bred for use in procedures]
- ANNEX III: Requirements for establishments and for the care and accommodation of animals
- ANNEX IV: Methods of killing animals
- ANNEX V: List of elements referred to in Article 23(3) [as the basis for Member States to establish minimum requirements for education and training of staff ]
- ANNEX VI: List of elements referred to in Article 37(1)(c) [on obligatory information to be included in a project application]
- ANNEX VII: Duties and tasks of the Union Reference Laboratory [established for the co-ordination of validation of alternative methods at Union level]
- ANNEX VIII: Severity classification of procedures [examples of different types of procedures assigned to each of the severity categories ]

### 2. LEGAL BASIS

This report is required under Article 51(1) of Directive 2010/63/EU. Pursuant to this provision, the power to adopt delegated acts was conferred on the Commission for a period of 8 years beginning on 9 November 2010 and the Commission is required to prepare a report in respect of the delegation of power, at the latest 12 months before the end of the eight-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.

### 3. EXERCISE OF THE DELEGATION

The exercise of the empowerment was deemed necessary for adapting several provisions foreseen by the Directive to scientific and technical progress. Until today, however, no sufficient scientific information has become available to warrant such an update of the relevant Annexes.

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<sup>1</sup> OJ L276, 20.10.2010, p.33-79

In addition, the Directive took longer than was foreseen until its transposition in all Member State legislation was completed (the last of which was completed only in 2015) Therefore, there is at present only limited experience on the provisions contained in the Annexes of the Directive.

However, as more experience is gained with the application of the Directive in practice, including Member State reports on exemptions granted to elements in some of the Annexes on the basis of new scientific evidence, as research continues to deliver new knowledge on the welfare needs of the species used, and as new investigation techniques and tools become available, the Commission will be required to use its delegated powers to ensure the Directive is adapted to scientific and technical progress.

#### 4. CONCLUSION

The Commission has, over the past seven years, not exercised the delegated powers conferred to it under Directive 2010/63/EU. It invites the European Parliament and the Council to take note of this report.