

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance)

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1	Subject matter
Article 2	Scope
Article 3	Conflict of laws
Article 4	Definitions

CHAPTER II

MARKETING AUTHORISATIONS – GENERAL PROVISIONS AND RULES ON APPLICATIONS

Section 1

General provisions

Article 5	Marketing authorisations
Article 6	Submission of applications for marketing authorisations
Article 7	Languages

Section 2

Dossier requirements

Article 8	Data to be submitted with the application
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Section 3

Clinical trials

Article 9	Clinical trials
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Section 4

Labelling and package leaflet

Article 10	Labelling of the immediate packaging of veterinary medicinal products
Article 11	Labelling of the outer packaging of veterinary medicinal products
Article 12	Labelling of small immediate packaging units of veterinary medicinal products
Article 13	Additional information on the immediate packaging or outer packaging of veterinary medicinal products

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- Article 14 Package leaflet of veterinary medicinal products
- Article 15 General requirement regarding product information
- Article 16 Package leaflet of registered homeopathic veterinary medicinal products
- Article 17 Implementing powers with respect to this Section

Section 5

Specific requirements for generic, hybrid and combination veterinary medicinal products and for applications based on informed consent and bibliographic data

- Article 18 Generic veterinary medicinal products
- Article 19 Hybrid veterinary medicinal products
- Article 20 Combination veterinary medicinal products
- Article 21 Application based on informed consent
- Article 22 Application based on bibliographic data

Section 6

Marketing authorisations for limited market and in exceptional circumstances

- Article 23 Applications for limited markets
- Article 24 Validity of a marketing authorisation for a limited market and procedure for its re-examination
- Article 25 Applications in exceptional circumstances
- Article 26 Terms of the marketing authorisation in exceptional circumstances
- Article 27 Validity of a marketing authorisation in exceptional circumstances and procedure for its re-examination

Section 7

Examination of applications and basis for granting marketing authorisations

- Article 28 Examination of applications
- Article 29 Requests to laboratories in the course of the examination of applications
- Article 30 Information on manufacturers in third countries
- Article 31 Additional information from the applicant
- Article 32 Withdrawal of applications
- Article 33 Outcome of the assessment
- Article 34 Classification of veterinary medicinal products
- Article 35 Summary of the product characteristics
- Article 36 Decisions granting marketing authorisations
- Article 37 Decisions refusing marketing authorisations

Section 8

Protection of technical documentation

- Article 38 Protection of technical documentation
- Article 39 Periods of the protection of technical documentation

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- Article 40 Prolongation and additional periods of the protection of technical documentation
- Article 41 Patent-related rights

CHAPTER III

PROCEDURES FOR MARKETING AUTHORISATIONS

Section 1

Marketing authorisations valid throughout the Union ('centralised marketing authorisations')

- Article 42 Scope of the centralised marketing authorisation procedure
- Article 43 Application for centralised marketing authorisation
- Article 44 Procedure for centralised marketing authorisation
- Article 45 Re-examination of the opinion of the Agency

Section 2

Marketing authorisations valid in a single Member State ('national marketing authorisations')

- Article 46 Scope of national marketing authorisation
- Article 47 Procedure for national marketing authorisation

Section 3

Marketing authorisations valid in several Member States ('decentralised marketing authorisations')

- Article 48 Scope of decentralised marketing authorisation
- Article 49 Procedure for decentralised marketing authorisation
- Article 50 Request by the applicant for re-examination of the assessment report

Section 4

Mutual recognition of national marketing authorisations

- Article 51 Scope of mutual recognition of national marketing authorisations
- Article 52 Procedure for mutual recognition of national marketing authorisations

Section 5

Subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures

- Article 53 Subsequent recognition of marketing authorisations by additional Member States concerned

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Section 6

Review procedure

Article 54 Review procedure

CHAPTER IV

POST-MARKETING AUTHORISATION MEASURES

Section 1

Union product database

Article 55 Union database on veterinary medicinal products

Article 56 Access to the product database

Section 2

Collection of data by Member States and responsibilities of marketing authorisation holders

Article 57 Collection of data on antimicrobial medicinal products used in animals

Article 58 Responsibilities of the marketing authorisation holders

Article 59 Small and medium-sized enterprises

Section 3

Changes to the terms of the marketing authorisations

Article 60 Variations

Article 61 Variations that do not require assessment

Article 62 Application for variations requiring assessment

Article 63 Consequential changes to product information

Article 64 Groups of variations

Article 65 Work-sharing procedure

Article 66 Procedure for variations requiring assessment

Article 67 Measures to close the procedure for variations requiring assessment

Article 68 Implementation of variations requiring assessment

Section 4

Harmonisation of the summaries of product characteristics for nationally authorised products

Article 69 Scope of the harmonisation of summaries of product characteristics of a veterinary medicinal product

Article 70 Procedure for harmonisation of summaries of product characteristics for the reference veterinary medicinal products

Article 71 Procedure for harmonisation of summaries of product characteristics for generic and hybrid veterinary medicinal products

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Article 72 Environmental safety documentation and environmental risk assessment of certain veterinary medicinal products

Section 5

Pharmacovigilance

Article 73 Union pharmacovigilance system
Article 74 Union pharmacovigilance database
Article 75 Access to the pharmacovigilance database
Article 76 Reporting and recording of suspected adverse events
Article 77 Pharmacovigilance responsibilities of the marketing authorisation holder
Article 78 Qualified person responsible for pharmacovigilance
Article 79 Pharmacovigilance responsibilities of the competent authorities and the Agency
Article 80 Delegation of tasks by competent authority
Article 81 Signal management process

Section 6

Union interest referral

Article 82 Scope of the Union interest referral
Article 83 Union interest referral procedure
Article 84 Decision following the Union interest referral

CHAPTER V

HOMEOPATHIC VETERINARY MEDICINAL PRODUCTS

Article 85 Homeopathic veterinary medicinal products
Article 86 Registration of homeopathic veterinary medicinal products
Article 87 Application and procedure for registration of homeopathic veterinary medicinal products

CHAPTER VI

MANUFACTURING, IMPORT AND EXPORT

Article 88 Manufacturing authorisations
Article 89 Application for manufacturing authorisation
Article 90 Procedure for granting of manufacturing authorisations
Article 91 Database on manufacturing and wholesale distribution
Article 92 Changes to manufacturing authorisations on request
Article 93 Obligations of the holder of a manufacturing authorisation
Article 94 Certificates of good manufacturing practice
Article 95 Importers, manufacturers and distributors of active substances established in the Union
Article 96 Record keeping
Article 97 Qualified person responsible for manufacturing and batch release
Article 98 Certificates of veterinary medicinal products

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CHAPTER VII

SUPPLY AND USE

Section 1

Wholesale distribution

- Article 99 Wholesale distribution authorisations
- Article 100 Application and procedures for wholesale distribution authorisations
- Article 101 Obligations of wholesale distributors
- Article 102 Parallel trade in veterinary medicinal products

Section 2

Retail

- Article 103 Retail of veterinary medicinal products and record keeping
- Article 104 Retail of veterinary medicinal products at a distance
- Article 105 Veterinary prescriptions

Section 3

Use

- Article 106 Use of medicinal products
- Article 107 Use of antimicrobial medicinal products
- Article 108 Record-keeping by owners and keepers of food-producing animals
- Article 109 Record-keeping obligations for equine animals
- Article 110 Use of immunological veterinary medicinal products
- Article 111 Use of veterinary medicinal products by veterinarians providing services in other Member States
- Article 112 Use of medicinal products outside the terms of the marketing authorisation in non-food-producing animal species
- Article 113 Use of medicinal products outside the terms of the marketing authorisation in food-producing terrestrial animal species
- Article 114 Use of medicinal products for food-producing aquatic species
- Article 115 Withdrawal period for medicinal products used outside the terms of the marketing authorisation in food-producing animal species
- Article 116 Health situation
- Article 117 Collection and disposal of waste of veterinary medicinal products
- Article 118 Animals or products of animal origin imported into the Union

Section 4

Advertising

- Article 119 Advertising of veterinary medicinal products
- Article 120 Advertising of veterinary medicinal products subject to veterinary prescription
- Article 121 Promotion of medicinal products used in animals

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Article 122 Implementation of advertising provisions

CHAPTER VIII

INSPECTIONS AND CONTROLS

Article 123 Controls
Article 124 Audits by the Commission
Article 125 Certificate of suitability
Article 126 Specific rules on pharmacovigilance inspections
Article 127 Proof of the product quality for veterinary medicinal products
Article 128 Proof of the product quality specific for immunological veterinary medicinal products

CHAPTER IX

RESTRICTIONS AND PENALTIES

Article 129 Temporary safety restrictions
Article 130 Suspending, revoking, or varying the terms, of marketing authorisations
Article 131 Suspending or revoking a wholesale distribution authorisation
Article 132 Removal of importers, manufacturers and distributors of active substance from the manufacturing and wholesale distribution database
Article 133 Suspending or revoking manufacturing authorisations
Article 134 Prohibiting the supply of veterinary medicinal products
Article 135 Penalties imposed by Member States
Article 136 Financial penalties imposed by the Commission on holders of marketing authorisation for centrally authorised veterinary medicinal products

CHAPTER X

REGULATORY NETWORK

Article 137 Competent authorities
Article 138 Scientific opinion for international organisations for animal health
Article 139 Committee for Veterinary Medicinal Products
Article 140 Members of the Committee
Article 141 Tasks of the Committee
Article 142 Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products
Article 143 Members of the coordination group
Article 144 Tasks of the coordination group

CHAPTER XI

COMMON AND PROCEDURAL PROVISIONS

Article 145 Standing Committee on Veterinary Medicinal Products
Article 146 Amendments to Annex II

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Article 147	Exercise of the delegation
Article 148	Data protection

CHAPTER XII

TRANSITIONAL AND FINAL PROVISIONS

Article 149	Repeal
Article 150	Relation with other Union acts
Article 151	Prior applications
Article 152	Existing veterinary medicinal products, marketing authorisations and registrations
Article 153	Transitional provisions regarding delegated and implementing acts
Article 154	Establishment of the pharmacovigilance database and of the manufacturing and wholesale distribution database
Article 155	Initial input to the product database by competent authorities
Article 156	Review of rules for environmental risk assessment
Article 157	Commission report on traditional herbal products used to treat animals
Article 158	Review of measures regarding animals of the equine species
Article 159	Transitional provisions regarding certain certificates of good manufacturing practice
Article 160	Entry into force and application Signature

ANNEX I

INFORMATION REFERRED TO IN POINT (A) OF ARTICLE 8(1)

1. Legal basis for the application for the marketing authorisation
2. Applicant
 - 2.1. Name or company name and permanent address or registered place...
 - 2.2. Name or company name and permanent address or registered place...
 - 2.3. Name and address of the sites involved in the different...
3. Identification of the veterinary medicinal product
 - 3.1. Name of the veterinary medicinal product and Anatomical Therapeutic Chemical...
 - 3.2. Active substance(s) and, if applicable, diluent(s)
 - 3.3. Strength or, in case of immunological veterinary medicinal product, biological...
 - 3.4. Pharmaceutical form

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- 3.5. Route of administration
- 3.6. Target species
- 4. Manufacturing and pharmacovigilance information
 - 4.1. Proof of a manufacturing authorisation or certificate of good manufacturing...
 - 4.2. Reference number of pharmacovigilance system master file
- 5. Veterinary medicinal product information
 - 5.1. Proposed summary of the product characteristics drawn up in accordance...
 - 5.2. Description of the final presentation of the veterinary medicinal product,...
 - 5.3. Proposed text of the information to be provided on the...
- 6. Other information
 - 6.1. List of countries in which a marketing authorisation has been...
 - 6.2. Copies of all the summaries of product characteristics as included...
 - 6.3. List of countries in which an application has been submitted...
 - 6.4. List of Member States in which the veterinary medicinal product...
 - 6.5. Critical expert reports on quality, safety and efficacy of the...

ANNEX II

REQUIREMENTS REFERRED TO IN POINT (B) OF ARTICLE 8(1)

INTRODUCTION AND GENERAL PRINCIPLES

1. The particulars and documents accompanying an application for marketing authorisation...
2. In assembling the dossier for application for marketing authorisation, applicants...
3. For veterinary medicinal products other than immunological veterinary medicinal products,...
4. The manufacturing process shall comply with the requirements of Commission...
5. All information which is relevant to the evaluation of the...
6. Pharmacological, toxicological, residue and safety tests shall be carried out...
7. Member States shall ensure that all experiments on animals are...
8. In order to monitor the risk/benefit assessment, any new information...
9. The environmental risk assessment connected with the release of veterinary...
10. In cases of applications for marketing authorisations for veterinary medicinal...

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TITLE I

Requirements for veterinary medicinal products other than immunological veterinary medicinal products

PART 1

summary of the dossier

- A. ADMINISTRATIVE INFORMATION
- B. SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET
- C. DETAILED AND CRITICAL SUMMARIES

PART 2

Pharmaceutical (physico-chemical, biological or microbiological information (quality))

Basic principles and requirements

- A. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS
 - 1. Qualitative particulars
 - 2. Usual terminology
 - 3. Quantitative particulars
 - 3.1. In order to give ‘quantitative particulars’ of all the active...
 - 3.2. Active substances present in the form of compounds or derivatives...
 - 3.3. For veterinary medicinal products containing an active substance which is...
 - 4. Development pharmaceuticals
- B. DESCRIPTION OF THE MANUFACTURING METHOD
- C. CONTROL OF STARTING MATERIALS
 - 1. General requirements
 - 1.1. Active substances
 - 1.1.1. Active substances listed in pharmacopoeias
 - 1.1.2. Active substances not in a pharmacopoeia
 - 1.1.3. Physico-chemical characteristics liable to affect bioavailability
 - 1.2. Excipients
 - 1.3. Container-closure systems
 - 1.3.1. Active substance
 - 1.3.2. Finished product
 - 1.4. Substances of biological origin
- D. CONTROL TESTS CARRIED OUT AT INTERMEDIATE STAGES OF THE MANUFACTURING...
- E. TESTS ON THE FINISHED PRODUCT
 - 1. General characteristics of the finished product
 - 2. Identification and assay of active substance(s)
 - 3. Identification and assay of excipient components
 - 4. Safety tests

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- F. STABILITY TEST
 - 1. Active substances(s)
 - 2. Finished product

- G. OTHER INFORMATION

PART 3

Safety and residues tests

- A. SAFETY TESTS

Chapter I

Performance of tests

- 1. Precise identification of the product and of its active substance(s)...
- 2. Pharmacology
 - 2.1. Pharmacodynamics
 - 2.2. Pharmacokinetics
- 3. Toxicology
 - 3.1. Single-dose toxicity
 - 3.2. Repeat-dose toxicity
 - 3.3. Tolerance in the target species
 - 3.4. Reproductive toxicity including developmental toxicity
 - 3.4.1. Study of the effects on reproduction
 - 3.4.2. Study of developmental toxicity
 - 3.5. Genotoxicity
 - 3.6. Carcinogenicity
 - 3.7. Exceptions
- 4. Other requirements
 - 4.1. Special studies
 - 4.2. Microbiological properties of residues
 - 4.2.1. Potential effects on the human gut flora
 - 4.2.2. Potential effects on the microorganisms used for industrial food processing...
 - 4.3. Observations in humans
 - 4.4. Development of resistance
- 5. User safety
- 6. Environmental risk assessment
 - 6.1. Environmental risk assessment of veterinary medicinal products not containing or...
 - 6.2. Environmental risk assessment for veterinary medicinal products containing or consisting...

Chapter II

Presentation of particulars and documents

- B. RESIDUE TESTS

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Chapter I

Performance of tests

1. Introduction
2. Metabolism and residue kinetics
 - 2.1. Pharmacokinetics (absorption, distribution, metabolism, excretion)
 - 2.2. Depletion of residues
3. Residue analytical method

Chapter II

Presentation of particulars and documents

1. Identification of the product

PART 4

Pre-clinical and clinical trial

Chapter I

Pre-clinical requirements

- A. PHARMACOLOGY
 - A.1. Pharmacodynamics
 - A.2. Development of resistance
 - A.3. Pharmacokinetics
- B. TOLERANCE IN THE TARGET ANIMAL SPECIES

Chapter II

Clinical requirements

1. General principles
2. Conduct of clinical trials

Chapter III

Particulars and documents

1. Results of pre-clinical trials
2. Results of clinical trials

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TITLE II

Requirements for immunological veterinary medicinal products

PART 1

Summary of the dossier

- A. ADMINISTRATIVE INFORMATION
- B. SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET
- C. DETAILED AND CRITICAL SUMMARIES

PART 2

Chemical, pharmaceutical and biological/microbiological information (quality)

- A. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS
 - 1. Qualitative particulars
 - 2. 'Usual terminology'
 - 3. Quantitative particulars
 - 4. Product development
- B. DESCRIPTION OF MANUFACTURING METHOD
- C. PRODUCTION AND CONTROL OF STARTING MATERIALS
 - 1. Starting materials listed in pharmacopoeias
 - 2. Starting materials not listed in a pharmacopoeia
 - 2.1. Starting materials of biological origin
 - 2.2. Starting materials of non-biological origin
- D. CONTROL TESTS DURING THE MANUFACTURING PROCESS
 - (1) The dossier shall include particulars relating to the control tests,...
 - (2) For inactivated or detoxified vaccines, inactivation or detoxification shall be...
- E. CONTROL TESTS ON THE FINISHED PRODUCT
 - 1. General characteristics of the finished product
 - 2. Identification of active substance(s)
 - 3. Batch titre or potency
 - 4. Identification and assay of adjuvants
 - 5. Identification and assay of excipient components
 - 6. Safety tests
 - 7. Sterility and purity test
 - 8. Residual humidity
 - 9. Inactivation
- F. BATCH-TO-BATCH CONSISTENCY
- G. STABILITY TESTS
- H. OTHER INFORMATION

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PART 3

Safety tests

- A. INTRODUCTION AND GENERAL REQUIREMENTS
- B. LABORATORY TESTS
 - 1. Safety of the administration of one dose
 - 2. Safety of one administration of an overdose
 - 3. Safety of the repeated administration of one dose
 - 4. Examination of reproductive performance
 - 5. Examination of immunological functions
 - 6. Special requirements for live vaccines
 - 6.1. Spread of the vaccine strain
 - 6.2. Dissemination in the vaccinated animal
 - 6.3. Reversion to virulence of attenuated vaccines
 - 6.4. Biological properties of the vaccine strain
 - 6.5. Recombination or genomic reassortment of strains
 - 7. User safety
 - 8. Study of residues
 - 9. Interactions
- C. FIELD STUDIES
- D. ENVIRONMENTAL RISK ASSESSMENT
- E. ASSESSMENT REQUIRED FOR VETERINARY MEDICINAL PRODUCTS CONTAINING OR CONSISTING OF...

PART 4

Efficacy tests

Chapter I

- 1. General principles
- 2. Performance of trials

Chapter II

- A. GENERAL REQUIREMENTS
 - 1. The choice of antigens or vaccine strains shall be justified...
 - 2. Efficacy trials carried out in the laboratory shall be controlled...
 - 3. The efficacy of an immunological veterinary medicinal product shall be...
 - 4. The efficacy of each of the components of multivalent and...
 - 5. Whenever a product forms part of a vaccination scheme recommended...
 - 6. The dose to be used shall be the quantity of...
 - 7. If there is a compatibility statement with other immunological products...
 - 8. For diagnostic immunological veterinary medicinal products administered to animals, the...
 - 9. For vaccines intended to allow a distinction between vaccinated and...

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- B. LABORATORY TRIALS
 - 1. In principle, demonstration of efficacy shall be undertaken under well-controlled...
 - 2. If possible, the immune mechanism (cell-mediated/humoral, local/general classes of immunoglobulin)...

- C. FIELD TRIALS
 - 1. Unless justified, results from laboratory trials shall be supplemented with...
 - 2. Where laboratory trials cannot be supportive of efficacy, the performance...

PART 5

Particulars and documents

- A. INTRODUCTION
- B. LABORATORY STUDIES
- C. FIELD STUDIES

PART 6

Bibliographical references

TITLE III

Requirements for specific marketing authorisation applications

- 1. Generic veterinary medicinal products
- 2. Similar biological veterinary medicinal products
- 3. Well-established veterinary use
- 4. Combination veterinary medicinal products
- 5. Informed consent applications
- 6. Documentation for applications in exceptional circumstances
- 7. Mixed marketing authorisation applications

TITLE IV

Requirements for marketing authorisation applications for particular veterinary medicinal products

- 1. Immunological veterinary medicinal products
 - A. VACCINE ANTIGEN MASTER FILE
 - B. MULTI-STRAIN DOSSIER
- 2. Homeopathic veterinary medicinal products

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PART 2

The provisions of Part 2 shall apply to the documents...

- (a) Terminology
- (b) Control of starting materials
- (c) Control tests on the finished medicinal product
- (d) Stability tests

PART 3

The provisions of Part 3 shall apply to the simplified...

ANNEX III

LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 136(1)

the obligation, as an applicant, to provide accurate information and...

ANNEX IV

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- (1) [OJ C 242, 23.7.2015, p. 54.](#)
- (2) Position of the European Parliament of 25 October 2018 (not yet published in the Official Journal) and Decision of the Council of 26 November 2018.
- (3) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ([OJ L 311, 28.11.2001, p. 1.](#))
- (4) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([OJ L 136, 30.4.2004, p. 1.](#))
- (5) Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (see page 1 of this Official Journal).
- (6) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([OJ L 152, 16.6.2009, p. 11.](#))
- (7) 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 ([OJ L 276, 20.10.2010, p. 33.](#))
- (8) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ([OJ L 145, 31.5.2001, p. 43.](#))
- (9) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ([OJ L 327, 22.12.2000, p. 1.](#))
- (10) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) ([OJ L 334, 17.12.2010, p. 17.](#))
- (11) Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising ([OJ L 376, 27.12.2006, p. 21.](#))
- (12) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([OJ L 95, 7.4.2017, p. 1.](#))
- (13) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([OJ L 311, 28.11.2001, p. 67.](#))
- (14) Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use ([OJ L 44, 14.2.2009, p. 10.](#))
- (15) [OJ L 123, 12.5.2016, p. 1.](#)
- (16) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13.](#))
- (17) Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications ([OJ L 255, 30.9.2005, p. 22.](#))

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- (18) Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market ([OJ L 376, 27.12.2006, p. 36](#)).

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