

Table of Contents

Editors	v
Contributors	vii
List of Abbreviations	xxv
Foreword by Brando Benifei – AI Act: A European Way for Artificial Intelligence	xxxix
Foreword by Dragoş Tudorache	xli
Preface	xliii
CHAPTER I. GENERAL PROVISIONS	
Article 1	
Subject Matter	1
Patrick Van Eecke & Bartholomäus Regenhardt	
Article 2	
Scope	22
Patrick Van Eecke & Bartholomäus Regenhardt	
Article 3	
Definitions	48
Lukas Feiler & Beat König	
Article 4	
AI Literacy	86
Elora Fernandes, Wayne Holmes & Sopio Zhgenti	
CHAPTER II. PROHIBITED AI PRACTICES	
Article 5	
Prohibited AI Practices	105
Els J. Kindt & Catherine Jasserand	
CHAPTER III. HIGH-RISK AI SYSTEMS	
SECTION 1. CLASSIFICATION OF AI SYSTEMS AS HIGH-RISK	
Article 6	
Classification Rules for High-Risk AI Systems	193
Guillaume Couneson	

Article 7	
Amendments to Annex III	219
Guillaume Couneson	
SECTION 2. REQUIREMENTS FOR HIGH-RISK AI SYSTEMS	
Article 8	
Compliance with the Requirements	224
David M. Schneeberger, Walter Hötendorfer & Christof Tschohl	
Article 9	
Risk Management System	233
David M. Schneeberger, Walter Hötendorfer & Christof Tschohl	
Article 10	
Data and Data Governance	259
Katerina Yordanova	
Article 11	
Technical Documentation	284
Hande Özkayagan Prändl & Katarzyna Barud	
Article 12	
Record-Keeping	312
Thomas Marquenie	
Article 13	
Transparency and Provision of Information to Deployers	333
Ana Maria Corrêa	
Article 14	
Human Oversight	351
Argyri Panezi	
Article 15	
Accuracy, Robustness and Cybersecurity	372
Jorge Constantino	
SECTION 3. OBLIGATIONS OF PROVIDERS AND DEPLOYERS OF HIGH-RISK AI SYSTEMS AND OTHER PARTIES	
Article 16	
Obligations of Providers of High-Risk AI Systems	382
Stavros Tsipras	
Article 17	
Quality Management System	433
Theodoros Karathanasis	
Article 18	
Documentation Keeping	459
Wannes Ooms & Victoria Hendrickx	

Article 19	
Automatically Generated Logs	466
Fabian Schmieder	
Article 20	
Corrective Actions and Duty of Information	474
Daniel Westman & Cecilia Magnusson Sjöberg	
Article 21	
Cooperation with Competent Authorities	479
Klaus M. Steinmaurer	
Article 22	
Authorised Representatives of Providers of High-Risk AI Systems	489
Graziana Kastl-Riemann	
Article 23	
Obligations of Importers	503
Lutz Riede & Oliver Talhoff	
Article 24	
Obligations of Distributors	516
Lutz Riede & Oliver Talhoff	
Article 25	
Responsibilities Along the AI Value Chain	524
Lutz Riede & Oliver Talhoff	
Article 26	
Obligations of Deployers of High-Risk AI Systems	537
Daniel Gallagher	
Article 27	
Fundamental Rights Impact Assessment for High-Risk AI Systems	553
Tünde Fülöp & Philipp Poindl	
SECTION 4. NOTIFYING AUTHORITIES AND NOTIFIED BODIES	
Article 28	
Notifying Authorities	577
Žiga Škorjanc & Kai Korte	
Article 29	
Application of a Conformity Assessment Body for Notification	588
Žiga Škorjanc & Kai Korte	
Article 30	
Notification Procedure	594
Žiga Škorjanc & Kai Korte	
Article 31	
Requirements Relating to Notified Bodies	603
Žiga Škorjanc & Kai Korte	

Article 32	
Presumption of Conformity with Requirements Relating to Notified Bodies	613
Žiga Škorjanc & Kai Korte	
Article 33	
Subsidiaries of and Subcontracting by Notified Bodies	620
Žiga Škorjanc & Kai Korte	
Article 34	
Operational Obligations of Notified Bodies	627
Žiga Škorjanc & Kai Korte	
Article 35	
Identification Numbers and Lists of Notified Bodies	636
Iana Kazeeva	
Article 36	
Changes to Notifications	643
Iana Kazeeva	
Article 37	
Challenge to the Competence of Notified Bodies	651
Iana Kazeeva	
Article 38	
Coordination of Notified Bodies	657
Iana Kazeeva	
Article 39	
Conformity Assessment Bodies of Third Countries	663
Iana Kazeeva	
SECTION 5. STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES, REGISTRATION	
Article 40	
Harmonised Standards and Standardization Deliverables	669
Koen Vranckaert	
Article 41	
Common Specifications	677
Koen Vranckaert	
Article 42	
Presumption of Conformity with Certain Requirements	682
Koen Vranckaert	
Article 43	
Conformity Assessment	686
Hande Özkayagan Prändl & Klaudia Kwiatkowska	

Article 44 Certificates Klaudia Kwiatkowska & Clara Saillant	709
Article 45 Information Obligations of Notified Bodies Victoria Hendrickx & Wannes Ooms	720
Article 46 Derogation from Conformity Assessment Procedure Wannes Ooms & Victoria Hendrickx	731
Article 47 EU Declaration of Conformity Victoria Hendrickx & Wannes Ooms	741
Article 48 CE Marking Victoria Hendrickx & Wannes Ooms	752
Article 49 Registration Adam Harkens	763
 CHAPTER IV. TRANSPARENCY OBLIGATIONS FOR PROVIDERS AND DEPLOYERS OF CERTAIN AI SYSTEMS	
Article 50 Transparency Obligations for Providers and Deployers of Certain AI Systems Thomas Gils	776
 CHAPTER V. GENERAL-PURPOSE AI MODELS	
SECTION 1. CLASSIFICATION RULES	
Article 51 Classification of General-Purpose AI Models as General-Purpose AI Models with Systemic Risk Toby Bond & Shima Abbady	824
Article 52 Procedure Toby Bond & Shima Abbady	836
 SECTION 2. OBLIGATIONS FOR PROVIDERS OF GENERAL-PURPOSE AI MODELS	
Article 53 Obligations for Providers of General-Purpose AI Models Nynke Elske Vellinga & Jeanne Mifsud Bonnici	845

Article 54 Authorised Representative Nynke Elske Vellinga & Jeanne Mifsud Bonnici	858
SECTION 3. OBLIGATIONS OF PROVIDERS OF GENERAL-PURPOSE AI MODELS WITH SYSTEMIC RISK	
Article 55 Obligations of Providers of General-Purpose AI Models with Systemic Risk Nynke Elske Vellinga & Jeanne Mifsud Bonnici	862
SECTION 4. CODES OF PRACTICE	
Article 56 Codes of Practice Nynke Elske Vellinga & Jeanne Mifsud Bonnici	871
CHAPTER VI. MEASURES IN SUPPORT OF INNOVATION	
Article 57 AI Regulatory Sandboxes Norberto de Andrade	878
Article 58 Detailed Arrangements for, and Functioning of, AI Regulatory Sandboxes Norberto de Andrade	895
Article 59 Further Processing of Personal Data for Developing Certain AI Systems in the Public Interest in the AI Regulatory Sandbox Thomas Binder & Iris Eisenberger	900
Article 60 Testing of High-Risk AI Systems in Real-World Conditions Outside AI Regulatory Sandboxes Thomas Binder & Iris Eisenberger	924
Article 61 Informed Consent to Participate in Testing in Real World Conditions Outside AI Regulatory Sandboxes Samson Y. Esayas & Luca Tosoni	942
Article 62 Measures for Providers and Deployers, in Particular SMEs, Including Start-Ups Thomas Binder & Iris Eisenberger	961
Article 63 Derogations for Specific Operators Antonella Zarra	971

CHAPTER VII. GOVERNANCE**SECTION 1. GOVERNANCE AT UNION LEVEL****Article 64**

AI Office 977
Matthias Schmidl & Andreas Rohner

Article 65

Establishment and Structure of the European Artificial Intelligence Board 990
Matthias Schmidl & Andreas Rohner

Article 66

Tasks of the Board 997
Matthias Schmidl & Andreas Rohner

Article 67

Advisory Forum 1002
Matthias Schmidl & Andreas Rohner

Article 68

Scientific Panel of Independent Experts 1008
Matthias Schmidl & Andreas Rohner

Article 69

Access to the Pool of Experts by the Member States 1015
Matthias Schmidl & Andreas Rohner

SECTION 2. NATIONAL COMPETENT AUTHORITIES**Article 70**

Designation of National Competent Authorities and Single Point of Contact 1019
Matthias Schmidl & Andreas Rohner

CHAPTER VIII. EU DATABASE FOR HIGH-RISK AI SYSTEMS**Article 71**

EU Database for High-Risk AI Systems Listed in Annex III 1027
Adam Harkens

**CHAPTER IX. POST-MARKET MONITORING,
INFORMATION SHARING AND MARKET SURVEILLANCE****SECTION 1. POST-MARKET MONITORING****Article 72**

Post-Market Monitoring by Providers and Post-Market Monitoring Plan for High-Risk AI Systems 1039
Ayça Atabey, Lachlan Urquhart & Burkhard Schafer