Table of contents

Preface 11		3.	Risk-based regulation of AI systems	
			and AI models	31
List of abbreviations 13			3.1 Prohibited AI systems	31
			3.2 High-risk AI systems	32
Li	st of recitals of the AI Act 21		3.3 GenAI and certain biometric	
			AI systems that are subject to	
Aı	n introduction to the AI Act 23		special transparency regulations.	34
			3.4 Other AI systems	35
1.	The scope of application of		3.5 General-purpose AI models	35
	the AI Act23			
	1.1 The material scope of	4.	An overview of the obligations	
	application: What types of		of the AI Act	36
	AI are covered?		4.1 Obligations of the providers	36
	1.2 The personal scope of		4.1.1 Obligations regarding	
	application: To whom does		high-risk AI systems	36
	the AI Act apply?24		4.1.2 Obligations regarding	
	1.3 The territorial scope of		GenAI systems pursuant to	
	application: Where does the		Article 50	40
	AI Act apply?26		4.1.3 Obligations regarding	
	1.4 The temporal scope of		other AI systems	40
	application: When does the		4.1.4 Obligations regarding	
	AI Act apply?26		general-purpose AI models	41
			4.1.5 Obligations regarding	
2.	The AI Act as an instrument of		general-purpose AI systems	42
	product regulation28		4.2 Obligations of importers	42
	2.1 An overview of European		4.2.1 Obligations regarding	
	Union product regulation28		high-risk AI systems	42
	2.2 The role of harmonised		4.2.2 Obligations regarding	
	standards and common		other AI systems	
	specifications30		4.3 Obligations of distributors	43
	2.3 External conformity assessment		4.3.1 Obligations regarding	
	bodies and their accreditation		high-risk AI systems	43
	and notification30		4.3.2 Obligations regarding	
	2.4 The relationship with other		other AI systems	44
	harmonisation legislation30			

	4.4 Obligations of the deployers44	Article 3 Definitions85	5
	4.4.1 Obligations regarding	Article 4 AI literacy 12:	5
	high-risk AI systems44		
	4.4.2 Obligations regarding	Chapter II – Prohibited	
	GenAI and certain biometric AI	AI practices 127	7
	systems pursuant to Article 5046	Article 5 Prohibited AI practices12	7
	4.4.3 Obligations regarding		
	other AI systems47	Chapter III – High-risk	
	4.5 Obligations for authorised	AI systems149	9
	representatives47	•	
	4.5.1 Obligations regarding	Section 1 – Classification of	
	high-risk AI systems47	AI systems as high-risk	9
	4.5.2 Obligations regarding	Article 6 Classification rules for	
	general-purpose AI models48	high-risk AI systems14	9
		Article 7 Amendments to	
5.	Measures to promote	Annex III158	3
	innovation48		
	5.1 AI regulatory sandboxes48	Section 2 – Requirements for	
	5.2 Testing in real-world	high-risk AI systems160)
	conditions49	Article 8 Compliance with the	
		requirements160)
6.	Enforcement by the	Article 9 Risk management	
	authorities51	system 162	2
	6.1 Market surveillance of	Article 10 Data and data	
	AI systems51	governance16	7
	6.1.1 Regulatory responsibility	Article 11 Technical	
	for market surveillance51	documentation	3
	6.1.2 Powers of the market	Article 12 Record-keeping17	5
	surveillance authorities54	Article 13 Transparency and provision	
	6.1.3 The market surveillance	of information to deployers17	7
	procedure55	Article 14 Human oversight	1
	6.2 The AI Office as a supervisory	Article 15 Accuracy, robustness	
	authority for providers of general-	and cybersecurity 18	5
	purpose AI models56		
	6.3 Fines	Section 3 – Obligations of providers	
		and deployers of high-risk AI systems	
7.	Liability law and enforcement	and other parties	1
	by private individuals58	Article 16 Obligations of providers	
		of high-risk AI systems	1
Te	ext of the EU AI Act and	Article 17 Quality management	
co	mmentary 61	system 194	4
		Article 18 Documentation	
Ch	apter I – General provisions <u> </u> 63	keeping198	3
	Article 1 Subject matter63	Article 19 Automatically	
	Article 2 Scope70	generated logs200)

Article 20 Corrective actions and	Section 5 – Standards,
duty of information201	conformity assessment, certificates,
Article 21 Cooperation with	registration
competent authorities	Article 40 Harmonised standards
Article 22 Authorised representatives	and standardisation deliverables250
of providers of high-risk	Article 41 Common
AI systems204	specifications253
Article 23 Obligations of	Article 42 Presumption of conformity
importers208	with certain requirements256
Article 24 Obligations of	Article 43 Conformity
distributors 212	assessment257
Article 25 Responsibilities along	Article 44 Certificates262
the AI value chain215	Article 45 Information obligations
Article 26 Obligations of deployers	of notified bodies263
of high-risk AI systems221	Article 46 Derogation from
Article 27 Fundamental rights	conformity assessment procedure 264
impact assessment for	Article 47 EU declaration of
high-risk AI systems228	conformity266
	Article 48 CE marking267
Section 4 – Notifying authorities	Article 49 Registration269
and notified bodies 233	
Article 28 Notifying authorities 233	Chapter IV – Transparency
Article 29 Application of a	obligations for providers
conformity assessment body for	and deployers of certain
notification 235	AI systems 273
Article 30 Notification procedure236	Article 50 Transparency obligations
Article 31 Requirements relating	for providers and deployers of
to notified bodies238	certain AI systems273
Article 32 Presumption of	
conformity with requirements	Chapter V – General-purpose
relating to notified bodies240	AI models281
Article 33 Subsidiaries of notified	
bodies and subcontracting241	Section 1 – Classification rules281
Article 34 Operational obligations	Article 51 Classification of general-
of notified bodies242	purpose AI models as general-purpose
Article 35 Identification numbers	AI models with systemic risk281
and lists of notified bodies243	Article 52 Procedure
Article 36 Changes to	
notifications 244	Section 2 – Obligations for providers
Article 37 Challenge to the	of general-purpose AI models 288
competence of notified bodies247	Article 53 Obligations for providers
Article 38 Coordination of	of general-purpose AI models288
notified bodies	Article 54 Authorised representatives
Article 39 Conformity assessment	of providers of general-purpose AI
bodies of third countries249	models 294

Section 3 – Obligations of providers	Section 2 - National competent		
of general-purpose AI models with	authorities		
systemic risk 296	Article 70 Designation of national		
Article 55 Obligations of providers	competent authorities and single		
of general-purpose AI models with	points of contact337		
systemic risk296			
Article 56 Codes of practice299	Chapter VIII - EU database for		
	high-risk AI systems341		
Chapter VI - Measures in support	Article 71 EU database for high-risk		
of innovation303	AI systems listed in Annex III341		
Article 57 AI regulatory			
sandboxes303	Chapter IX – Post-market		
Article 58 Detailed arrangements	monitoring, information sharing		
for, and functioning of, AI	and market surveillance 343		
regulatory sandboxes311			
Article 59 Further processing of	Section 1 – Post-market		
personal data for developing certain	monitoring343		
AI systems in the public interest in	Article 72 Post-market monitoring		
the AI regulatory sandbox316	by providers and post-market		
Article 60 Testing of high-risk AI	monitoring plan for high-risk		
systems in real world conditions	AI systems343		
outside AI regulatory sandboxes320			
Article 61 Informed consent to	Section 2 – Sharing of information		
participate in testing in real world	on serious incidents		
conditions outside AI regulatory	Article 73 Reporting of serious		
sandboxes 324	incidents346		
Article 62 Measures for providers			
and deployers, in particular SMEs,	Section 3 – Enforcement		
including start-ups325	Article 74 Market surveillance		
Article 63 Derogations for	and control of AI systems in the		
specific operators326	Union market		
	Article 75 Mutual assistance,		
Chapter VII - Governance 327	market surveillance and control		
	of general-purpose AI systems361		
Section 1 – Governance at	Article 76 Supervision of testing in		
Union level	real world conditions by market		
Article 64 AI Office327	surveillance authorities		
Article 65 Establishment and	Article 77 Powers of authorities		
structure of the European Artificial	protecting fundamental rights364		
Intelligence Board328	Article 78 Confidentiality366		
Article 66 Tasks of the Board330	Article 79 Procedure at national		
Article 67 Advisory forum332	level for dealing with AI systems		
Article 68 Scientific panel of	presenting a risk		
independent experts			
Article 69 Access to the pool of			

experts by the Member States 336

Article 80 Procedure for dealing with	Chapter X - Codes of conduct
AI systems classified by the provider	and guidelines395
as non-high-risk in application of	Article 95 Codes of conduct for
Annex III	voluntary application of specific
Article 81 Union safeguard	requirements395
procedure375	Article 96 Guidelines from the
Article 82 Compliant AI systems	Commission on the implementation
which present a risk376 Article 83 Formal	of this Regulation398
non-compliance378	Chapter XI – Delegation of power
Article 84 Union AI testing	and committee procedure401
support structures	Article 97 Exercise of the
	delegation401
Section 4 – Remedies	Article 98 Committee procedure403
complaint with a market	Chapter XII – Penalties 405
surveillance authority380	Article 99 Penalties405
Article 86 Right to explanation	Article 100 Administrative fines
of individual decision-making381	on Union institutions, bodies,
Article 87 Reporting of	offices and agencies 410
infringements and protection	Article 101 Fines for providers of
of reporting persons	general-purpose AI models412
Section 5 – Supervision, investigation,	general-purpose AI models412 Chapter XIII – Final
Section 5 – Supervision, investigation, enforcement and monitoring in	Chapter XIII – Final
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose	Chapter XIII – Final
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions 415 Article 102 Amendment to Regulation (EC) No. 300/2008415
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions 415 Article 102 Amendment to Regulation (EC) No. 300/2008415 Article 103 Amendment to
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions 415 Article 102 Amendment to Regulation (EC) No. 300/2008415 Article 103 Amendment to Regulation (EU) No. 167/2013417
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions 415 Article 102 Amendment to Regulation (EC) No. 300/2008415 Article 103 Amendment to Regulation (EU) No. 167/2013417 Article 104 Amendment to
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions 415 Article 102 Amendment to Regulation (EC) No. 300/2008 415 Article 103 Amendment to Regulation (EU) No. 167/2013 417 Article 104 Amendment to Regulation (EU) No. 168/2013 418
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions
Section 5 – Supervision, investigation, enforcement and monitoring in respect of providers of general-purpose AI models	Chapter XIII – Final provisions

Article 111 AI systems already placed	Section B – Information to be
on the market or put into service and	submitted by providers of high-risk
general-purpose AI models already	AI systems in accordance with
placed on the market	Article 49(2)474
Article 112 Evaluation and	
review	Section C – Information to be
Article 113 Entry into force and	submitted by deployers of high-risk
application 432	AI systems in accordance with
	Article 49(3)474
Annex I – List of Union	
harmonisation legislation 435	Annex IX - Information to be
	submitted upon the registration
Annex II – List of criminal offences	of high-risk AI systems listed in
referred to in Article 5(1), first	Annex III in relation to testing
subparagraph, point (h)(iii)439	in real world conditions in
	accordance with Article 60 477
Annex III – High-risk AI systems	
referred to in Article 6(2) 441	Annex X – Union legislative acts
	on large-scale IT systems in the
Annex IV - Technical	area of Freedom, Security
documentation referred to	and Justice 479
in Article 11(1) 461	
	Annex XI – Technical
Annex V - EU declaration of	documentation referred to in
conformity 465	Article 53(1), point (a) — technical
	documentation for providers of
Annex VI - Conformity assessment	general-purpose AI models 483
procedure based on internal	
control 467	Section 1 – Information to be
	provided by all providers of
Annex VII - Conformity based on	general-purpose AI models483
an assessment of the quality	
management system and an	Section 2 – Additional information
assessment of the technical	to be provided by providers of
documentation 469	general-purpose AI models with
	systemic risk
Annex VIII - Information to be	•
submitted upon the registration of	Annex XII – Transparency
high-risk AI systems in accordance	information referred to in
with Article 49 473	Article 53(1), point (b) – technical
	documentation for providers of
Section A – Information to be	general-purpose AI models to
submitted by providers of high-risk	downstream providers that
AI systems in accordance with	integrate the model into their
Article 49(1)473	AI system485
	-,

Annex XIII – Criteria for the	
designation of general-purpose	
AI models with systemic risk	
referred to in Article 51	487
Index	. 489
About the authors	499
About Globe Law	501
and Business	