




# **PROPOSED AI ACT WHAT ARE HIGH-RISK AI SYSTEMS?**

- Title I: General Provisions
- Title II: Prohibited AI Practices
- Title III: **High-risk systems**
- Title IV: Transparency obligations for certain systems
- Title V: Measures in support of innovation 
- Title VI: Governance
- Title VII: EU database for stand-alone high-risk AI systems
- Title VIII: Post-market monitoring, information sharing, market surveillance
- Title IX: Codes of Conduct
- Title X: Confidentiality and penalties

# **Chapter 1: Classification rules for high-risk AI systems**



# Chapter 1

## Art. 6.1

Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b),

- that AI system **shall be considered high-risk** where **both** of the following conditions are fulfilled:
  - a. *the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;*
  - b. *the product whose safety component is the AI system, or the AI system itself as a product,*
    - *is required to undergo a third-party conformity assessment*
    - *with a view to the placing on the market or putting into service of that product*
    - *pursuant to the Union harmonisation legislation listed in Annex II.*



**ANNEX II**  
**LIST OF UNION HARMONISATION LEGISLATION**

**Section A – List of Union harmonisation legislation based on the New Legislative Framework**

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on **machinery**, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) [as repealed by the Machinery Regulation];
2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the **safety of toys** (OJ L 170, 30.6.2009, p. 1);
3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on **recreational craft and personal watercraft** and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);
4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and **safety components for lifts** (OJ L 96, 29.3.2014, p. 251);
5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States **relating to equipment and protective systems intended for use in potentially explosive atmospheres** (OJ L 96, 29.3.2014, p. 309);
6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of **radio equipment** and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);
7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of **pressure equipment** (OJ L 189, 27.6.2014, p. 164);
8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on **cableway installations** and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);
9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on **personal protective equipment** and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);
10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on **appliances burning gaseous fuels** and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);
11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on **medical devices**, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);
12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on **in vitro diagnostic medical devices** and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

**Section B. List of other Union harmonisation legislation**

1. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on **common rules in the field of civil aviation security** and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72).
2. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of **two- or three-wheel vehicles and quadricycles** (OJ L 60, 2.3.2013, p. 52);
3. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of **agricultural and forestry vehicles** (OJ L 60, 2.3.2013, p. 1);
4. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on **marine equipment** and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146);
5. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the **interoperability of the rail system within the European Union** (OJ L 138, 26.5.2016, p. 44).
6. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of **motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles**, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1); 3. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on **type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users**, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1);
7. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on **common rules in the field of civil aviation** and establishing a European **Union Aviation Safety Agency**, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the **design, production and placing on the market of aircraft referred to in points (a) and (b) of Article 2(1) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned**.

# Chapter 1

## Art. 6.2



2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.

### **ANNEX III**

#### **HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)**

High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas:

1. **Biometric identification and categorisation of natural persons:**
  - (a) AI systems intended to be used for the 'real-time' and 'post' remote biometric identification of natural persons;
2. **Management and operation of critical infrastructure:**
  - (a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity.
3. **Education and vocational training:**
  - (a) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions;
  - (b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to educational institutions.
4. **Employment, workers management and access to self-employment:**
  - (a) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests;
  - (b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships.
5. **Access to and enjoyment of essential private services and public services and benefits:**
  - (a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well as to grant, reduce, revoke, or reclaim such benefits and services;
  - (b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use;
  - (c) AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid.
6. **Law enforcement:**
  - (a) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending or reoffending or the risk for potential victims of criminal offences;
  - (b) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person;

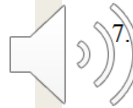
- (c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3);
- (d) AI systems intended to be used by law enforcement authorities for evaluation of the reliability of evidence in the course of investigation or prosecution of criminal offences;
- (e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups;
- (f) AI systems intended to be used by law enforcement authorities for profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences;
- (g) AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data.

#### **Migration, asylum and border control management:**

- (a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person;
- (b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State;
- (c) AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features;
- (d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status.

#### 8. **Administration of justice and democratic processes:**

- (a) AI systems intended to assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts.



A golden statue of Lady Justice, blindfolded and holding scales of justice in her left hand and a sword in her right hand, set against a blue sky background.

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- AI Act: enables, prohibits, restricts
  - *Reasonable?*
  - *Pertinent?*