

Brussels, 21.4.2021 COM(2021) 206 final

ANNEXES 1 to 9

ANNEXES

to the

Proposal for a Regulation of the European Parliament and of the Council

LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS

{SEC(2021) 167 final} - {SWD(2021) 84 final} - {SWD(2021) 85 final}

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ANNEX I ARTIFICIAL INTELLIGENCE TECHNIQUES AND APPROACHES referred to in Article 3, point 1

- (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;
- (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;
- (c) Statistical approaches, Bayesian estimation, search and optimization methods.

ANNEX II

LIST OF UNION HARMONISATION LEGISLATION

<u>Section A – List of Union harmonisation legislation based on the New Legislative</u> 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and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) [as repealed by the Machinery Regulation];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).
- Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 6. 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 aircrafts 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.

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.
- 7. 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.

ANNEX IV TECHNICAL DOCUMENTATION referred to in Article 11(1)

The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:

- 1. A general description of the AI system including:
 - (a) its intended purpose, the person/s developing the system the date and the version of the system;
 - (b) how the AI system interacts or can be used to interact with hardware or software that is not part of the AI system itself, where applicable;
 - (c) the versions of relevant software or firmware and any requirement related to version update;
 - (d) the description of all forms in which the AI system is placed on the market or put into service;
 - (e) the description of hardware on which the AI system is intended to run;
 - (f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;
 - (g) instructions of use for the user and, where applicable installation instructions;
- 2. A detailed description of the elements of the AI system and of the process for its development, including:
 - (a) the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;
 - (b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;
 - (c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;
 - (d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);
 - (e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles 13(3)(d);

- (f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2;
- (g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness, cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).
- 3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;
- 4. A detailed description of the risk management system in accordance with Article 9;
- 5. A description of any change made to the system through its lifecycle;
- 6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied;
- 7. A copy of the EU declaration of conformity;
- 8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61, including the post-market monitoring plan referred to in Article 61(3).

ANNEX V EU DECLARATION OF CONFORMITY

The EU declaration of conformity referred to in Article 48, shall contain all of the following information:

- 1. AI system name and type and any additional unambiguous reference allowing identification and traceability of the AI system;
- 2. Name and address of the provider or, where applicable, their authorised representative;
- 3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider;
- 4. A statement that the AI system in question is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;
- 5. References to any relevant harmonised standards used or any other common specification in relation to which conformity is declared;
- 6. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate issued;
- 7. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

ANNEX VI CONFORMITY ASSESSMENT PROCEDURE BASED ON INTERNAL CONTROL

- 1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4.
- 2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.
- 3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Title III, Chapter 2.
- 4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 61 is consistent with the technical documentation.

ANNEX VII

CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION

1. Introduction

Conformity based on assessment of quality management system and assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5.

2. Overview

The approved quality management system for the design, development and testing of AI systems pursuant to Article 17 shall be examined in accordance with point 3 and shall be subject to surveillance as specified in point 5. The technical documentation of the AI system shall be examined in accordance with point 4.

- 3. Quality management system
- 3.1. The application of the provider shall include:
 - (a) the name and address of the provider and, if the application is lodged by the authorised representative, their name and address as well;
 - (b) the list of AI systems covered under the same quality management system;
 - (c) the technical documentation for each AI system covered under the same quality management system;
 - (d) the documentation concerning the quality management system which shall cover all the aspects listed under Article 17;
 - (e) a description of the procedures in place to ensure that the quality management system remains adequate and effective;
 - (f) a written declaration that the same application has not been lodged with any other notified body.
- 3.2. The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17.

The decision shall be notified to the provider or its authorised representative.

The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.

- 3.3. The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient.
- 3.4. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.

The proposed changes shall be examined by the notified body, which shall decide whether the modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.

4. Control of the technical documentation.

- 4.1. In addition to the application referred to in point 3, an application with a notified body of their choice shall be lodged by the provider for the assessment of the technical documentation relating to the AI system which the provider intends to place on the market or put into service and which is covered by the quality management system referred to under point 3.
- 4.2. The application shall include:
 - (a) the name and address of the provider;
 - (b) a written declaration that the same application has not been lodged with any other notified body;
 - (c) the technical documentation referred to in Annex IV.
- 4.3. The technical documentation shall be examined by the notified body. To this purpose, the notified body shall be granted full access to the training and testing datasets used by the provider, including through application programming interfaces (API) or other appropriate means and tools enabling remote access.
- 4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2. Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate.
- 4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the notified body shall also be granted access to the source code of the AI system.
- 4.6. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.

Where the AI system is in conformity with the requirements set out in Title III, Chapter 2, an EU technical documentation assessment certificate shall be issued by the notified body. The certificate shall indicate the name and address of the provider, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system.

The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated, and to allow for control of the AI system while in use, where applicable.

Where the AI system is not in conformity with the requirements set out in Title III, Chapter 2, the notified body shall refuse to issue an EU technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the EU technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, notably on the reasons for non-compliance.

4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements or its intended purpose shall be approved by the notified body

which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. The intended changes shall be assessed by the notified body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.

- 5. Surveillance of the approved quality management system.
- 5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly fulfils the terms and conditions of the approved quality management system.
- 5.2. For assessment purposes, the provider shall allow the notified body to access the premises where the design, development, testing of the AI systems is taking place. The provider shall further share with the notified body all necessary information.
- 5.3. The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which an EU technical documentation assessment certificate was issued.

ANNEX VIII

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF HIGH-RISK AI SYSTEMS IN ACCORDANCE WITH ARTICLE 51

The following information shall be provided and thereafter kept up to date with regard to high-risk AI systems to be registered in accordance with Article 51.

- 1. Name, address and contact details of the provider;
- 2. Where submission of information is carried out by another person on behalf of the provider, the name, address and contact details of that person;
- 3. Name, address and contact details of the authorised representative, where applicable;
- 4. AI system trade name and any additional unambiguous reference allowing identification and traceability of the AI system;
- 5. Description of the intended purpose of the AI system;
- 6. Status of the AI system (on the market, or in service; no longer placed on the market/in service, recalled);
- 7. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body, when applicable;
- 8. A scanned copy of the certificate referred to in point 7, when applicable;
- 9. Member States in which the AI system is or has been placed on the market, put into service or made available in the Union;
- 10. A copy of the EU declaration of conformity referred to in Article 48;
- 11. Electronic instructions for use; this information shall not be provided for high-risk AI systems in the areas of law enforcement and migration, asylum and border control management referred to in Annex III, points 1, 6 and 7.
- 12. URL for additional information (optional).

ANNEX IX UNION LEGISLATION ON LARGE-SCALE IT SYSTEMS IN THE AREA OF FREEDOM, SECURITY AND JUSTICE

1. Schengen Information System

- (a) Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).
- (b) Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 (OJ L 312, 7.12.2018, p. 14)
- (c) Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU (OJ L 312, 7.12.2018, p. 56).

2. Visa Information System

(a) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 767/2008, Regulation (EC) No 810/2009, Regulation (EU) 2017/2226, Regulation (EU) 2016/399, Regulation XX/2018 [Interoperability Regulation], and Decision 2004/512/EC and repealing Council Decision 2008/633/JHA - COM(2018) 302 final. To be updated once the Regulation is adopted (April/May 2021) by the co-legislators.

3. Eurodac

(a) Amended proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of 'Eurodac' for the comparison of biometric data for the effective application of Regulation (EU) XXX/XXX [Regulation on Asylum and Migration Management] and of Regulation (EU) XXX/XXX [Resettlement Regulation], for identifying an illegally staying third-country national or stateless person and on requests for the comparison with Eurodac data by Member States' law enforcement authorities and Europol for law enforcement purposes and amending Regulations (EU) 2018/1240 and (EU) 2019/818 – COM(2020) 614 final.

4. Entry/Exit System

- (a) Regulation (EU) 2017/2226 of the European Parliament and of the Council of 30 November 2017 establishing an Entry/Exit System (EES) to register entry and exit data and refusal of entry data of third-country nationals crossing the external borders of the Member States and determining the conditions for access to the EES for law enforcement purposes, and amending the Convention implementing the Schengen Agreement and Regulations (EC) No 767/2008 and (EU) No 1077/2011 (OJ L 327, 9.12.2017, p. 20).
- 5. European Travel Information and Authorisation System

- (a) Regulation (EU) 2018/1240 of the European Parliament and of the Council of 12 September 2018 establishing a European Travel Information and Authorisation System (ETIAS) and amending Regulations (EU) No 1077/2011, (EU) No 515/2014, (EU) 2016/399, (EU) 2016/1624 and (EU) 2017/2226 (OJ L 236, 19.9.2018, p. 1).
- (b) Regulation (EU) 2018/1241 of the European Parliament and of the Council of 12 September 2018 amending Regulation (EU) 2016/794 for the purpose of establishing a European Travel Information and Authorisation System (ETIAS) (OJ L 236, 19.9.2018, p. 72).
- 6. European Criminal Records Information System on third-country nationals and stateless persons
 - (a) Regulation (EU) 2019/816 of the European Parliament and of the Council of 17 April 2019 establishing a centralised system for the identification of Member States holding conviction information on third-country nationals and stateless persons (ECRIS-TCN) to supplement the European Criminal Records Information System and amending Regulation (EU) 2018/1726 (OJ L 135, 22.5.2019, p. 1).

7. Interoperability

- (a) Regulation (EU) 2019/817 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of borders and visa (OJ L 135, 22.5.2019, p. 27).
- (b) Regulation (EU) 2019/818 of the European Parliament and of the Council of 20 May 2019 on establishing a framework for interoperability between EU information systems in the field of police and judicial cooperation, asylum and migration (OJ L 135, 22.5.2019, p. 85).