



# Terms of Reference

## for rulemaking task RMT.0161

### Conformity assessment

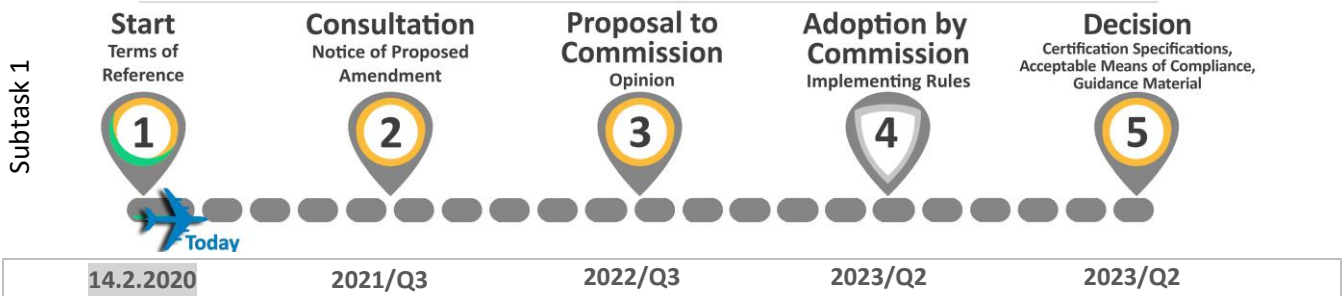
ISSUE 1

#### Issue/rationale

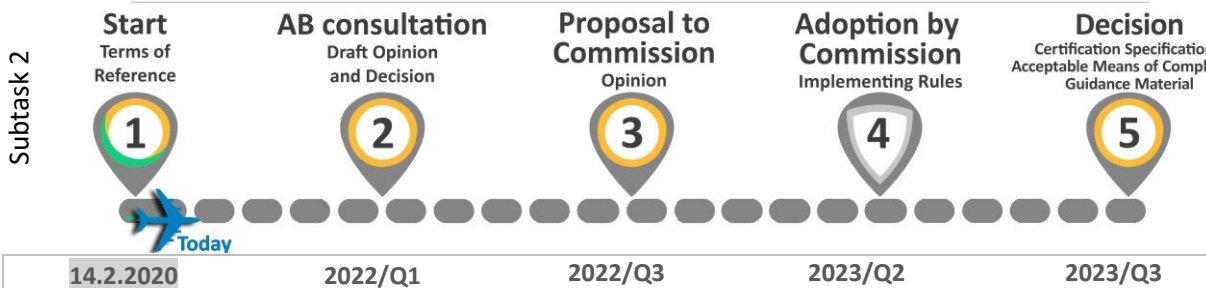
The development and introduction of new technologies and digitisation necessitate that safety-related aerodrome equipment and ground ATM/ANS systems and constituents demonstrate compliance with the relevant requirements for safety, performance, and interoperability in order to ensure the proper functioning of the European ATM network. Regulation (EU) 2018/1139 stipulates the use of harmonised and mutually recognised mechanisms to attest compliance and foresees the creation of a framework of detailed rules and provisions.

<b>Action area:</b>	ATM/ANS systems and constituents		
<b>Affected rules:</b>	Commission Implementing Regulation (EU) 2017/373; Commission Implementing Regulation (EU) 139/2014; Commission Implementing Regulation (EU) No 1079/2012; Commission Regulation (EC) No 262/2009; Commission Implementing Regulation (EU) No 1207/2011; Commission Regulation (EC) No 29/2009; Commission Regulation (EC) No 1032/2006; Commission Regulation (EC) No 633/2007; Commission Implementing Regulation (EU) No 1206/2011; Commission Regulation (EC) No 1033/2006		
<b>Affected stakeholders:</b>	Providers of ATM/ANS, Organisations involved in the design, production and maintenance of ATM/ANS systems and constituents, aerodrome operators, National Competent Authorities, EASA		
<b>Driver:</b>	Efficiency/proportionality	<b>Rulemaking group:</b>	Yes
<b>Impact assessment:</b>	Full (Subtask 1)	<b>Rulemaking Procedure:</b>	Standard (Subtask 1) Accelerated procedure (Subtask 2)

#### EASA rulemaking process milestones



#### EASA special rulemaking procedure milestones



## 1. Why we need to change the rules — issue/rationale

ATM/ANS<sup>1</sup> systems<sup>2</sup> and constituents<sup>3</sup> support the provision of services and functions, and provide data or information to and from the aircraft, as well as on the ground. Hence, it is very important that they be properly designed, manufactured, installed, maintained, protected against unauthorised interference, and operated in a manner that ensures that they are suitable for use.

The demonstration of suitability for use necessitates specific safety, performance, and interoperability requirements to be met. Therefore, the deployment of systems and their constituents which are used in the provision of ATM/ANS, as well as of safety-related aerodrome equipment<sup>4</sup>, necessitates the use of compliance demonstration processes to ensure that they meet the relevant requirements.

Conformity assessment involves a set of processes to demonstrate that a system or its constituents meet the relevant requirements, and, therefore, can be considered suitable for use. Hence, it provides confidence to stakeholders that a system and its constituents are suitable for use.

The provision of ATM/ANS is evolving to improve the capacity, efficiency, and safety of the European Air Traffic Management Network (EATMN) through the increasing application of data-based technologies and procedures that rely on digitalisation and an increased level of automation. Thus, ATM/ANS systems and their constituents are envisaged to be key to implementing these improvements.

Lack of an efficient and harmonised conformity assessment framework could result in the implementation of technologies that are not ready to support the anticipated improvements, as the ground system or its constituents may not behave as expected. A potential lack of performance or interoperability could undermine the confidence in operations that are supported by digital technologies and automation.

The existing conformity assessment processes are described in Regulation (EC) No 552/2004 and its implementing rules<sup>5</sup>. It should be noted that Regulation (EC) No 552/2004 ('Interoperability Regulation'), was repealed by Regulation (EU) 2018/1139 ('Basic Regulation'); however, a number of Articles and Annexes<sup>6</sup> related to conformity assessment remain applicable until 12 September 2023 at the latest, or until the European Commission adopts new rules on conformity assessment by means of delegated acts<sup>7</sup>. With regard to the implementing rules adopted on the basis of the Interoperability Regulation, they remain applicable, although the Basic Regulation requires that they be adapted by 12 September 2023<sup>8</sup>.

<sup>1</sup> ATM/ANS' ('air traffic management and air navigation services') means all of the following: the air traffic management functions and services as defined in Article 2(10) of Regulation (EC) No 549/2004 laying down the framework for the creation of the single European sky; the air navigation services defined in Article 2(4) of that Regulation, including the network management functions and services referred to in Article 6 of Regulation (EC) No 551/2004 on the organisation and use of the airspace in the Single European Sky, as well as services which augment signals emitted by satellites of core constellations of GNSS for the purpose of air navigation; flight procedures design; and services consisting in the origination and processing of data and the formatting and delivering of data to general air traffic for the purpose of air navigation.

<sup>2</sup> 'ATM/ANS system' means the aggregation of airborne and ground-based constituents, as well as space-based equipment, that provides support for air navigation services for all phases of flight.

<sup>3</sup> 'ATM/ANS constituent' means tangible objects such as hardware and intangible objects such as software upon which the interoperability of the European Air Traffic Management Network (EATMN) depends.

<sup>4</sup> 'Safety-related aerodrome equipment' means any instrument, equipment, mechanism, apparatus, appurtenance, software or accessory that is used or intended to be used to contribute to the safe operation of aircraft at an aerodrome

<sup>5</sup> Namely Regulation (EC) No 1033/2006, (EC) No 1032/2006, (EC) No 633/2007, (EC) No 262/2009, (EC) No 29/2009, (EU) No 73/2010, (EU) No 1206/2011, (EU) No 1207/2011, and (EU) No 1079/2012, which are known as the rules for interoperability.

<sup>6</sup> In particular, Articles 4, 5, 6, 6a, and 7 of the Interoperability Regulation and the Annexes III and IV thereto.

<sup>7</sup> Please see Article 139(2) and Article 139(4) for more information.

<sup>8</sup> See Article 140(2) of the the Basic Regulation.



It should be stressed that the Basic Regulation also contains various requirements for the formal attestation of compliance<sup>9</sup>, although their application would require the development of detailed rules and provisions adopted by means of implementing and delegated acts<sup>10</sup>. Therefore, new implementing measures need to be established to define the conditions and procedures to support declarations<sup>11</sup> made by stakeholders or certificates<sup>12</sup> issued by the competent authorities, e.g. the situations in which certificates or declarations are required, the actual allocation of responsibilities, what technical requirements the system or constituent should conform to, etc.

Moreover, the Basic Regulation also foresees the use of detailed specifications<sup>13</sup> to further develop and ensure compliance with its essential requirements<sup>14</sup>. Hence, the conformity assessment framework would require the establishment of these common technical requirements by EASA.

*Note: Hereinafter, any reference made to ‘ground systems and constituents’ should be understood to refer to both ground ATM/ANS systems and constituents, and safety-related aerodrome equipment.*

## 2. What we want to achieve — objective

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation and complemented by Article 4, in which a number of principles are described to guide the measures taken under said Regulation. Furthermore, the Basic Regulation applies to design, production, maintenance, and operation of systems and constituents used in the provision of ATM/ANS in the *single European sky* (SES) airspace, as well as personnel and organisations involved in these activities, except when these are performed or made available by the military.

This rulemaking task focuses on the development of a harmonised conformity assessment framework for ground systems and their constituents. In fact, the similar approach taken for ATM/ANS systems and constituents, and safety-related aerodrome equipment in the Basic Regulation, indicates that a common framework for both domains could be adopted, regardless of whether or not aerodrome equipment performs ATM/ANS services and functions. This framework will contribute to allow implementation to take place in a safe, efficient, and harmonised manner and minimise the risk of unwanted behaviours, especially those that are a consequence of interoperability problems, failures, disruptions and, in general, any shortfall in the expected performance. Moreover, the proposed implementing measures on conformity assessment should:

- minimise any undesirable implementation issues that may compromise operational functionalities and promote technical interoperability through the use, where available, of detailed specifications;
- promote the internal market by ensuring fair competition, while facilitating the free movement of ground systems and constituents through mutual recognition of certificates or declarations, without further requirements or evaluation, in all Member States;
- facilitate the development and implementation of new technologies by stakeholders;

<sup>9</sup> See, in particular, Article 42, Article 45, and Article 35.

<sup>10</sup> See Article 43, Article 47, and Article 36 for detailed information.

<sup>11</sup> ‘Declaration’ means any written statement made under the sole responsibility of a legal or natural person to confirm that the applicable requirements relating to a legal or natural person, ATM/ANS system, or ATM/ANS constituent are complied with.

<sup>12</sup> ‘Certificate’ means any certificate, approval, licence, authorisation, attestation or other document issued as the result of a certification attesting compliance with the applicable requirements.

<sup>13</sup> Produced in consistency with the procedures for the issuance of EASA documentation (see Article 115 of the Basic Regulation for further information).

<sup>14</sup> The requirements for safety-related aerodrome equipment are included in Point 1.3 of Annex VII, while those applicable to ATM/ANS systems and their constituents are contained in Annex VIII



- optimise the use of resources during the demonstration of compliance and minimise the administrative burden; and
- maximise the synergies with the existing processes to introduce changes to functional systems<sup>15</sup>.

The framework should consider formal attestation of compliance mechanisms in accordance with the following:

- organisations involved in the design, production, or maintenance of ATM/ANS systems and constituents may be allowed to declare their capability and the availability of the required means to discharge their responsibilities, or, where so prescribed, hold a certificate<sup>16</sup>;
- either providers of ATM/ANS or the organisation involved in the design, production, or maintenance of ATM/ANS systems and constituents may be allowed to declare that those systems and constituents comply with the detailed specifications that apply to them, or, where so prescribed, ATM/ANS systems and constituents undergo a certification<sup>17</sup> process<sup>18</sup>;
- organisations involved in the design, production and maintenance of safety-related aerodrome equipment may be allowed to declare that such equipment complies with the detailed specifications that apply to it or, where so prescribed, hold a certificate in respect of the equipment<sup>19</sup>.

Furthermore, the proposed framework should provide<sup>20</sup>:

- the conditions for the establishment (and notification to an applicant<sup>21</sup>) of the detailed specifications for the purpose of harmonising the implementation and operation of ground system and constituents, while ensuring compatibility with airborne and satellite constituents, where applicable;
- the rules, procedures, and conditions that apply to certification and declaration, as well as situations in which declarations will be permitted or certificates are to be granted, either for organisations or for ground systems and constituents;
- the privileges and responsibilities of the holders of certificates and of the organisations that make declarations.

Finally, the framework should provide requirements for the competent authority:

- to receive and assess the applications, and, where applicable, to issue or renew certificates;
- to receive declarations; and
- to conduct the associated oversight and enforcement activities.

Additionally, the rulemaking task should adapt the implementing rules adopted on the basis of the Interoperability Regulation to the Basic Regulation, particularly, to make them consistent with the new conformity assessment framework.

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<sup>15</sup> Specific requirements for the introduction of these changes are prescribed in Regulation (EU) 2017/373.

<sup>16</sup> See Article 42 of the Basic Regulation.

<sup>17</sup> 'Certification' means any form of recognition based on an appropriate assessment, that a legal or natural person, ATM/ANS system, ATM/ANS constituent complies with the applicable requirements, through the issuance of a certificate attesting such compliance.

<sup>18</sup> See Article 45 of the Basic Regulation.

<sup>19</sup> See Article 35 of the Basic Regulation.

<sup>20</sup> See Articles 43, 47, and 36 of the Basic Regulation.

<sup>21</sup> The notion of applicant is valid for certification processes. In those cases, the detailed specifications could be published as certification specifications.

Recognising that detailed specifications are an input to conformity assessment that must be established by EASA, the task needs to establish the aforementioned detailed specifications on the basis of the technical requirements included in said implementing rules and the existing Community specifications<sup>22</sup>.

### 3. How we want to achieve it

#### 3.1. The framework (Subtask 1)

The draft implementing measures will propose a robust conformity assessment framework, which:

- a) determines clear criteria whereby certificates may be required, together with the corresponding procedures and conditions for issuing, maintaining, amending, limiting, suspending, or revoking such certificates;
- b) stipulates clear criteria whereby declarations may be required, including the rules and procedures to make such declarations;
- c) enables the establishment and notification of the detailed specifications that will ensure compliance with the essential requirements;
- d) promotes the use of commonly agreed standards and acknowledges presumption of conformity with the essential requirements by recognising these standards or part of them in the detailed specifications;
- e) specifies the conformity assessment procedures that can be applied to demonstrate that a system or constituent is fit for purpose, i.e. demonstration of compliance with the relevant requirements;
- f) ensures harmonised and proportionate oversight and enforcement activities;
- g) places requirements for continuous monitoring of technical performance after the deployment into operation and during the whole lifecycle;
- h) specifies measures to ensure safety and continuity of operations when a system or constituent proves not to be fit for purpose;
- i) clarifies the roles of the stakeholders involved in conformity assessment, and the participation of competent personnel;
- j) ensures coordination and integration with the processes followed when notifying changes to a functional system and the related safety arguments;
- k) provides recognition of existing EC declarations issued, as well as a smooth transition to the future framework;

The development of the above conformity assessment framework would be addressed by means of Subtask 1, in accordance with the timeline shown on the front page of this Terms of Reference.

The regulatory requirements set out in Commission Regulation (EU) No 139/2014 and Commission Implementing Regulation (EU) 2017/373 currently constitute the main tools to facilitate compliance with most of the essential requirements concerning aerodromes and ATM/ANS, as per the Basic Regulation. The above-mentioned framework will complement those requirements by proposing implementing measures concerning ground systems and constituents.

<sup>22</sup> See Article 4 of the Interoperability Regulation for more information about the establishment and use of Community specifications.



A regulatory impact assessment (RIA) will be developed using qualitative and/or quantitative data in line with evidence-based policy making, and focusing on major and complex items.

### 3.2. Interoperability (Subtask 2)

In order to adapt and establish a comprehensive set of detailed specifications, RMT.0161 will review the existing EU rules for interoperability and the associated Community specifications. This Subtask will identify relevant technical requirements that can be formally recognised as detailed specifications, within the new framework established by Subtask 1. Subtask 2 will set the foundations of the future detailed specifications for certification/declaration of ground systems and constituents. The publication of additional detailed specifications needs to be developed gradually and is subject to other rulemaking tasks (see also Chapter 6 for more information).

## 4. What are the deliverables

According to the established Subtasks described in Section 3, the following deliverables will be issued:

Subtask 1. Conformity assessment framework<sup>23</sup>:

- a) A Notice of proposed amendment (NPA), including amendments to Commission Implementing Regulation (EU) 2017/373 and Commission Regulation (EU) No 139/2014, as well as associated acceptable means of compliance (AMC) and guidance material (GM);
- b) A Comment-response document (CRD) to the NPA referred to above;
- c) An Opinion with implementing and delegated acts, including amendments to Commission Implementing Regulation (EU) 2017/373 and Commission Regulation (EU) No 139/2014; and
- d) A Decision with AMC and GM related to the above-mentioned acts.

Subtask 2. Interoperability regulations<sup>24</sup>:

- a) An Opinion with implementing and delegated acts, including the amendment/repeal of Commission Implementing Regulation (EU) No 1079/2012, Commission Regulation (EC) No 262/2009, Commission Implementing Regulation (EU) No 1207/2011, Commission Regulation (EC) No 29/2009, Commission Regulation (EC) No 1032/2006, Commission Regulation (EC) No 633/2007, Commission Implementing Regulation (EU) No 1206/2011, Commission Regulation (EC) No 1033/2006;
- b) A Decision amending Executive Director Decision 2017/001/R of 8 March 2017 issuing AMC and GM to Commission Implementing Regulation (EU) 2017/373;
- c) A Decision on new Certification Specifications (CSs) for ground systems and constituents.

## 5. How we consult

In addition to the NPA public consultation, focused consultations may be organised, as required, prior to the publication of Subtask 1 and Subtask 2 deliverables. The focused consultations will be duly announced to the interested parties and may include the following:

- meetings with affected stakeholders;
- data collection via surveys or per email with affected stakeholders;

<sup>23</sup> Standard EASA rulemaking procedure.

<sup>24</sup> Special EASA rulemaking procedure.



- workshops;
- conferences (including teleconferences); and
- written consultation or ad-hoc meetings with the EASA Advisory Bodies.

## 6. Interface issues

The advent of new technologies is expected to require the creation of detailed specifications to support the implementation of ground system capabilities and functionalities, e.g. deployment of common projects for the realisation of the ATM Master Plan<sup>25</sup>. Detailed specifications will set out the applicable requirements for systems, and, as far as practicable, consider conformity assessment processes as well, including, where applicable, tests, checks, inspections, calibration activities, etc.

In particular, this rulemaking task is expected to be supplemented by RMT.0682 on the implementation of the regulatory needs of the SESAR common projects<sup>26</sup>, which will allow the establishment of additional detailed specifications applicable to ground systems and their constituents, whenever necessary.

As regards the airborne constituents, RMT.0519 on regular update of CS-ACNS allows to set requirements and means of compliance for the aircraft manufacturing and modification industries with respect to ATM/ANS equipment to be installed on board the aircraft. In this case, RMT.0161 contributes to ensure interoperability between the airborne and ground equipment and to the total system performance.

## 7. Profile and contribution of the rulemaking group

A rulemaking group (RMG) will be established to support EASA with this rulemaking task. The RMG members will support with the drafting of EASA deliverables (draft regulations, and AMC/GM/CS material), and may also assist with:

- the review of the comments received during the NPA public consultation;
- the focused consultations;
- the collection of relevant data to support the concerned proposals.

The RMG should be composed of experts representing providers of ATM/ANS, ground system and constituent manufacturers, aerodrome operators, and national competent authorities.

As regards the specific expertise required, the RMG members should have a deep knowledge of industry best practices and technological solutions applied to design, manufacture, and maintenance of ground systems and constituents, as well as system integration, putting into operation and common processes for demonstration of compliance.

## 8. Reference documents

### 8.1. Affected regulations

- Commission Implementing Regulation (EU) 2017/373 of 1 March 2017 laying down common requirements for providers of air traffic management/air navigation services and other air traffic management network functions and their oversight, repealing Regulation (EC) No 482/2008,

<sup>25</sup> The ATM Master Plan outlines the essential operational changes that enable the *single European sky* (SES) objectives to be achieved.

<sup>26</sup> This rulemaking task is described in EPAS 2020-2024.



Implementing Regulations (EU) No 1034/2011, (EU) No 1035/2011 and (EU) 2016/1377 and amending Regulation (EU) No 677/2011<sup>27</sup>;

- Commission Regulation (EU) No 139/2014 of 12 February 2014 laying down requirements and administrative procedures related to aerodromes pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council;
- Commission Implementing Regulation (EU) No 1079/2012 of 16 November 2012 laying down requirements for voice channels spacing for the single European sky<sup>28</sup>;
- Commission Regulation (EC) No 262/2009 of 30 March 2009 laying down requirements for the coordinated allocation and use of Mode S interrogator codes for the single European sky<sup>29</sup>;
- Commission Implementing Regulation (EU) No 1207/2011 of 22 November 2011 laying down requirements for the performance and the interoperability of surveillance for the single European sky<sup>30</sup>;
- Commission Regulation (EC) No 29/2009 of 16 January 2009 laying down requirements on data link services for the single European sky<sup>31</sup>;
- Commission Regulation (EC) No 1032/2006 of 6 July 2006 laying down requirements for automatic systems for the exchange of flight data for the purpose of notification, coordination and transfer of flights between air traffic control units<sup>32</sup>;
- Commission Regulation (EC) No 633/2007 of 7 June 2007 laying down requirements for the application of a flight message transfer protocol used for the purpose of notification, coordination and transfer of flights between air traffic control units<sup>33</sup>;
- Commission Implementing Regulation (EU) No 1206/2011 of 22 November 2011 laying down requirements on aircraft identification for surveillance for the single European sky<sup>34</sup>;
- Commission Regulation (EC) No 1033/2006 of 4 July 2006 laying down the requirements on procedures for flight plans in the pre-flight phase for the single European sky<sup>35</sup>.

## 8.2. Affected decisions

- Executive Director Decision 2017/001/R of 8 March 2017 issuing Acceptable Means of Compliance and Guidance Material to Commission Implementing Regulation (EU) 2017/373.

<sup>27</sup> OJ L 62/1, 8.3.2017

<sup>28</sup> OJ L 320, 17.11.2012

<sup>29</sup> OJ L 84, 31.3.2009

<sup>30</sup> OJ L 305, 23.11.2011

<sup>31</sup> OJ L 13, 17.1.2009

<sup>32</sup> OJ L 186, 7.7.2006

<sup>33</sup> OJ L 146, 8.6.2007

<sup>34</sup> OJ L 305, 23.11.2011

<sup>35</sup> OJ L 186, 7.7.2006





### 8.3. Reference documents

- 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<sup>36</sup>;
- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC<sup>37</sup>;
- Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council<sup>38</sup>;
- Commission Notice - The 'Blue Guide' on the implementation of EU products rules 2016<sup>39</sup>;
- 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<sup>40</sup>

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<sup>36</sup> OJ L 212, 22.08.2018

<sup>37</sup> OJ L 218, 13.8.2008

<sup>38</sup> OJ L 316, 14.11.2012

<sup>39</sup> OJ C 272, 26.7.2016

<sup>40</sup> OJ L 153, 22.5.2014

