

# Evolution of the regulatory framework for conformity assessment

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# Conformity Assessment (CA)

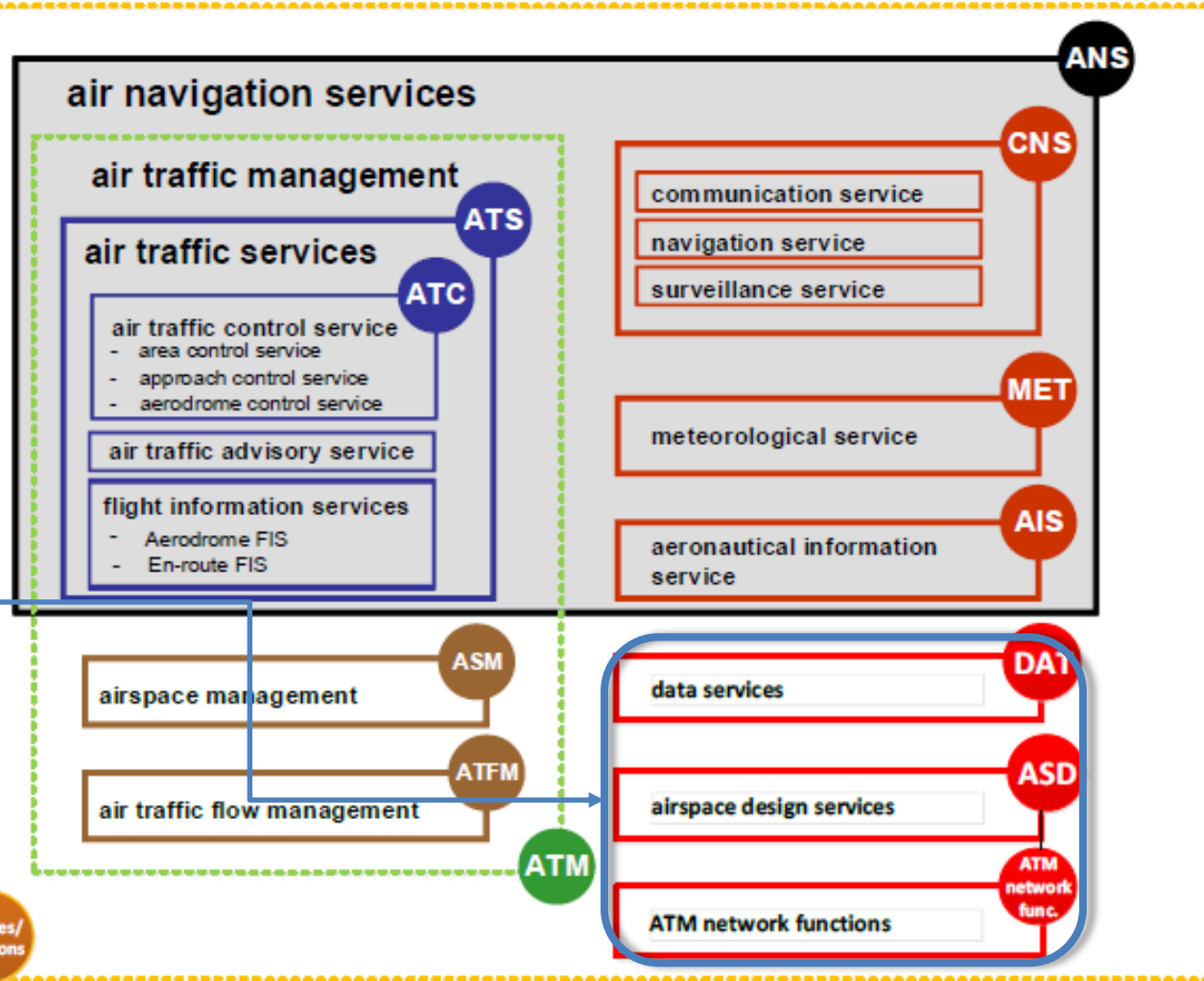
- Conformity assessment involves a set of processes to demonstrate that a system or its constituents meet the relevant requirements and, therefore, can be considered suitable for use
  - Compliance demonstration processes
  - Specific requirements for safety, security, performance and interoperability
  - Systems or constituents used in support of ATM/ANS
    - ATM/ANS system: aggregation of airborne and ground-based constituents, as well as space-based equipment
    - ATM/ANS constituent: objects such as hardware and software
  - Properly designed, manufactured, installed, maintained
  - Fit for purpose  $\Leftrightarrow$  Suitable for use

# Role of ATM/ANS systems

- ATM/ANS systems and constituents are part of the European ATM network (EATMN)
- Currently important, but in the future...
  - Key to implementing the **single digital** European sky and its goals
    - Wise Persons Group Report & Airspace Architecture Study
  - Essential to improve the capacity, efficiency and safety of the European Air Traffic Management Network (EATMN)
    - enhanced technologies and procedures that rely on digitalisation and an increased level of automation
    - improved functions and services, which are being defined in the 'ATM Master Plan'

# Support a number of ATM/ANS functions & services

Not explicitly mentioned in point 3.1 of Annex VIII



# Today's CA demonstration

- Regulation (EC) 552/2004 <==> Interoperability (IOP) Regulation
  - Repealed by Regulation (EU) 2018/1139, which now contains the essential IOP requirements, i.e. the essential requirements (ERs) for ATM/ANS systems that support the EATMN functions and services
  - Based on a number of Articles of and Annexes to the IOP Regulation that will continue to apply **until 12.9.2023 at the latest**
    - Articles 4, 5, 6, 6a, and 7 and Annexes III and IV
    - Mandatory issuance of EC declarations by both the manufacturer and the ANS provider, who are, respectively, responsible for constituent and system CA
    - Compliance with the ERs and **Regulation (EC) 552/2004 implementing rules**
  - These implementing rules remain applicable, although they need to be adapted to the Basic Regulation by 12.9.2023 i.a.w. Article 140(2)

# CA as per the Basic Regulation (BR)

- BR contains various requirements for CA in Art. 45 and 42
  - Contemplate certification or declaration as formal mechanisms for attestation of compliance
  - Apply to ATM/ANS systems and constituents, and organisations
  - Several options are offered without stated preferences
- Their effective application would require the development of a supporting framework i.a.w. Art. 47 and 43
  - By means of delegated and implementing acts
  - Establishment of clear rules to underpin declarations made by stakeholders or certificates issued by the competent authorities

# Affected stakeholders

## → Basic Regulation

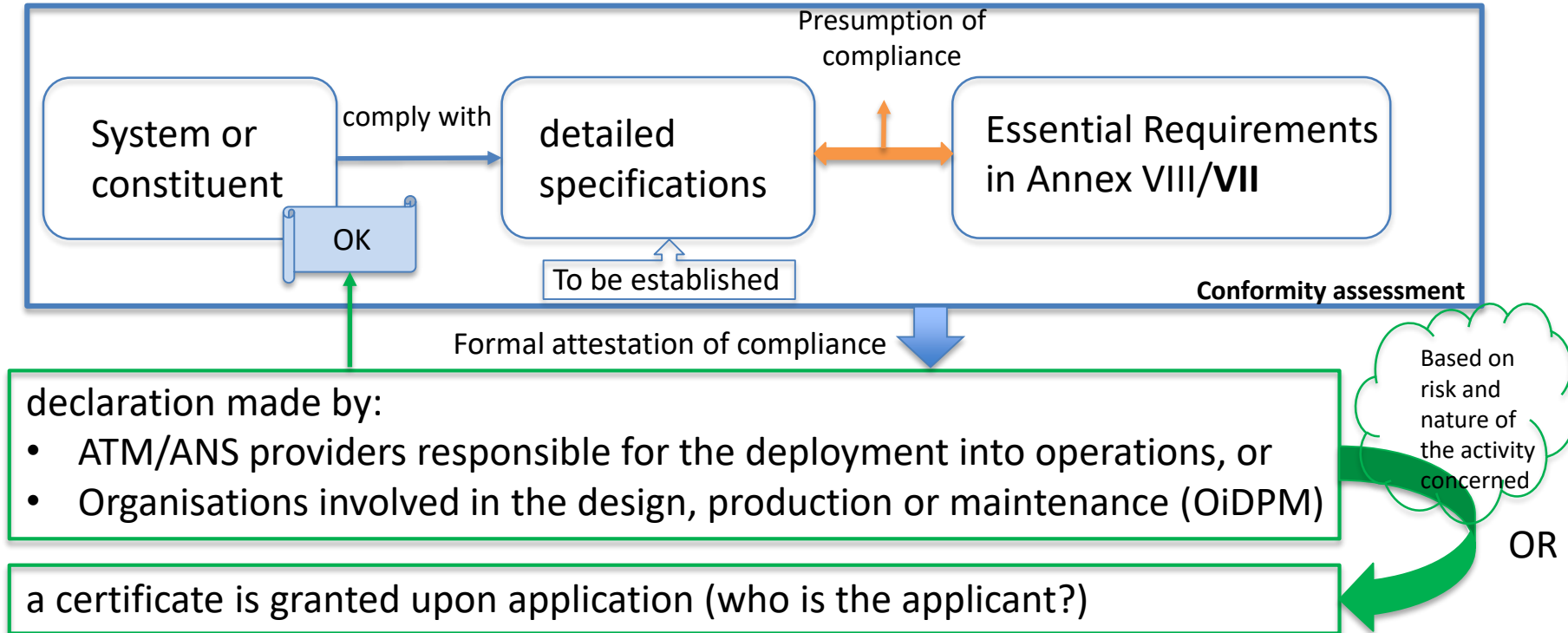
- ATM/ANS providers
- Organisations involved in the design, production and maintenance of ATM/ANS systems and constituents (OiDPM)
- Competent authorities, including EASA

## → Interoperability Regulation

- ANS providers (ANSPs)
- Manufacturers or its authorised representatives
- National supervisory authority and EASA

# ATM/ANS Systems & constituents – Art. 45

Where so provided:





# ATM/ANS Systems & constituents – Art. 47

- Detailed rules are necessary in order to stipulate
  - Conditions for the establishment of the detailed specifications
  - The situations in which certificates or declarations are to be required
    - considering the nature and risk of the particular activity concerned!
  - Establish the procedures and guidance to prepare a declaration or apply for a certificate, together with the conditions for:
    - issuing, maintaining, amending, limiting, suspending, revoking a certificate
    - accepting/rejecting a declarations
  - Clear responsibilities with regard to who is supposed to demonstrate compliance with the detailed specifications
  - Responsibilities and privileges associated with the granting/issuance of certificates/declarations

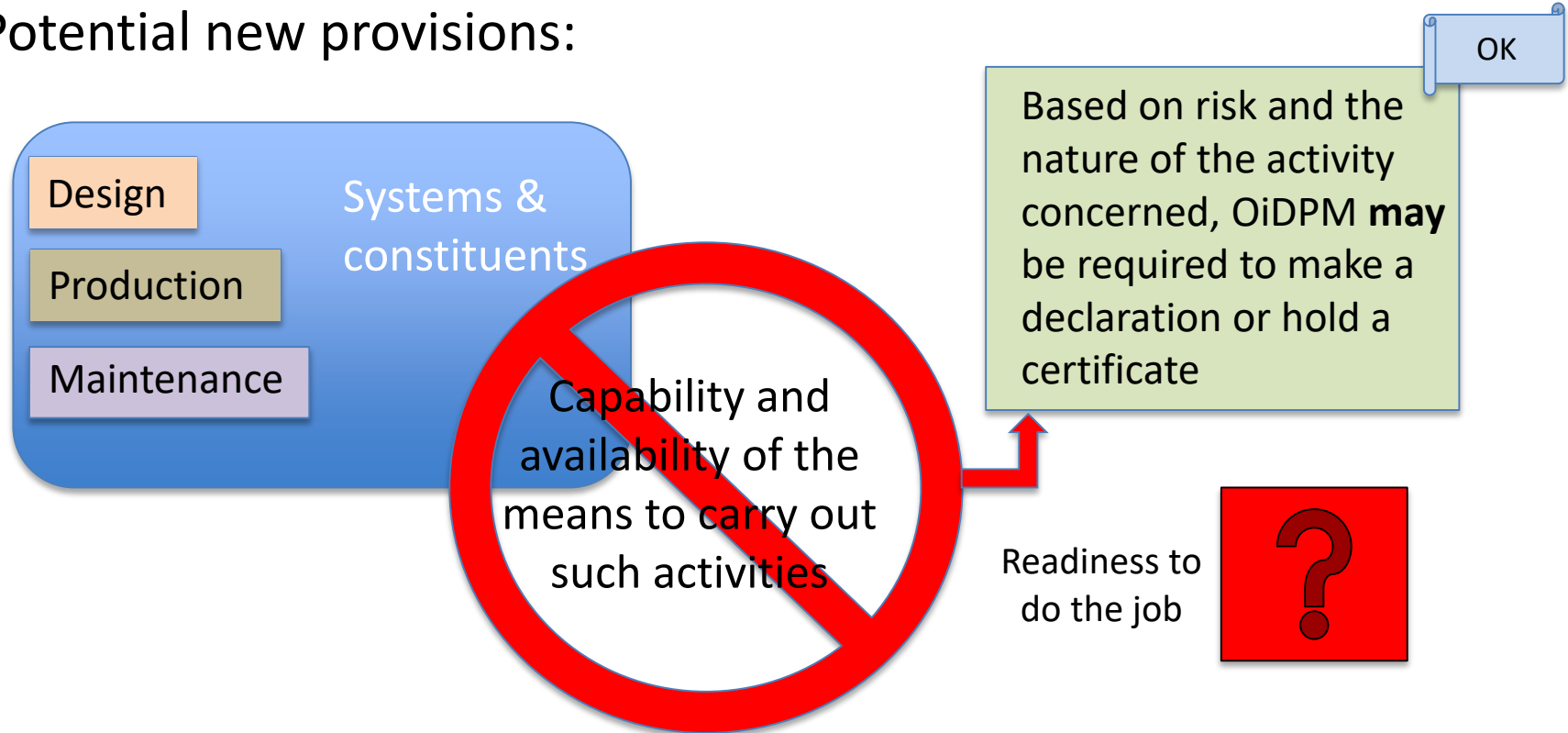
# Some considerations

Basic REG IOP REG

- DoC, DSU & DoV are no longer considered in the Basic REG
  - Issuance is mandatory for manufacturers and ANSPs i.a.w. Art. 5&6
  - Defined in Annex III and Annex IV, together with the detailed instructions to make these declarations and produce the supporting documentation, e.g. technical file
  - Voluntary use of Community specifications, which are defined in Art.4
- Declarations are not necessarily mandatory, but an option together with certification
- Declarations made in respect of constituents could be issued by the providers of ATM/ANS which put them into operation, whereas OiDPM of a system could also be permitted to issue the declarations in respect of systems
- Detailed specifications ensure compliance with the essential ERs

# OiDPM – Art. 42

Potential new provisions:



# OiDPM – Art. 43

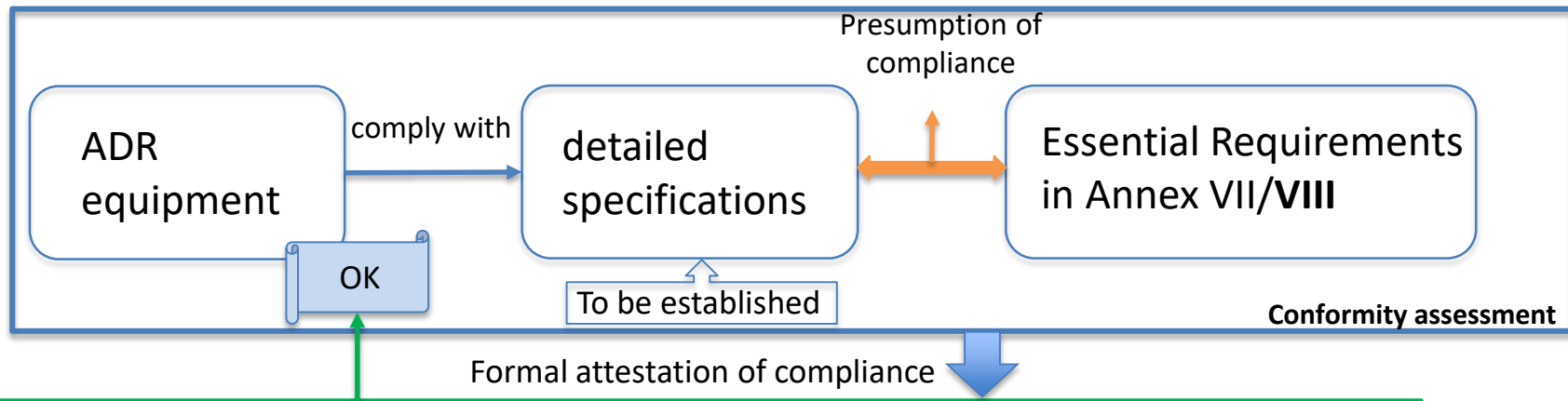
- Requirements for organisations not contemplated in the existing CA mechanisms => competence to do the job!
- To explore their use together with the possibilities that Article 45 offers for systems and constituents
  - e.g. there could be cases in which declarations made in respect of a system could become unnecessary due to the fact that the system has been designed/produced by (a) qualified organisation(s)
- Detailed provisions would be necessary in order to stipulate the
  - Situations in which either a certificate or a declaration is to be required
  - Rules and procedures for declaration by/and certification of organisations
  - Associated privileges and responsibilities

# Equipment at aerodromes (ADRs)

- Safety-related ADR equipment:
  - ‘Devices’ used or intended to be used to contribute to the safe operation of aircraft => also potentially used in support of ATM/ANS
- BR equally addresses suitability of this kind of equipment
  - Either through their inclusion in the aerodrome certificate, or
  - separately through the use of detailed specifications, as per Arts. 35 & 36
  - ERs in Point 1.3 of Annex VII and, if applicable, Annex VIII
  - Many similarities with the provisions that apply to ATM/ANS systems and constituents
- A common framework could be used!

# Safety-related ADR equipment – Art. 35

Potential provisions when not addressed under the ADR certificate:



Organisations involved in the design, production or maintenance (OiDPM):

- apply for a certificate in respect of the equipment, or
- make a declaration of compliance

Based on  
risk and  
nature of  
the activity  
concerned

# Safety-related ADR equipment – Art. 36

- Detailed provisions are necessary in order to stipulate
  - Conditions for the establishment of the detailed specifications
  - The situations in which certificates or declarations are to be required
    - considering the nature and risk of the particular activity concerned!
  - Establish the procedures and guidance to prepare a declaration or apply for a certificate, together with the conditions for:
    - issuing, maintaining, amending, limiting, suspending, revoking a certificate
    - accepting/rejecting a declarations
  - Responsibilities and privileges associated with the granting/issuance of certificates/declarations

# What we could achieve

- Development of a harmonised CA framework for ATM/ANS systems and their constituents, and ADR safety-related equipment
  - Minimize any undesirable implementation issues
  - Use common detailed specifications for the same systems
  - Mutual recognition of certificates issued or declarations made in the EU
  - Promote the EU market of products
- Improvement of what we have
  - Optimise the use of resources during the demonstration and minimise the administrative burden by means of commensurate requirements
  - Maximise the synergies with the existing processes to introduce changes to functional systems



# Thank you!

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