



EASA

European Aviation Safety Agency

Rulemaking challenges in combining two fast developing fields:

Aviation and Medicine

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Your safety is our mission.

An agency of the European Union





Disclosure

- I have no actual or potential conflict of interest in relation to this program/presentation.



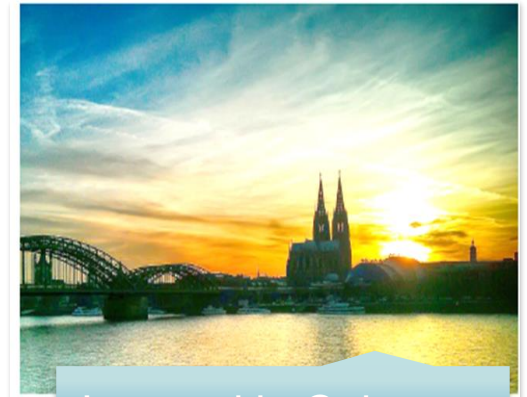
About EASA



Founded in 2003



Built on experience
from the JAA



Located in Cologne,
Germany



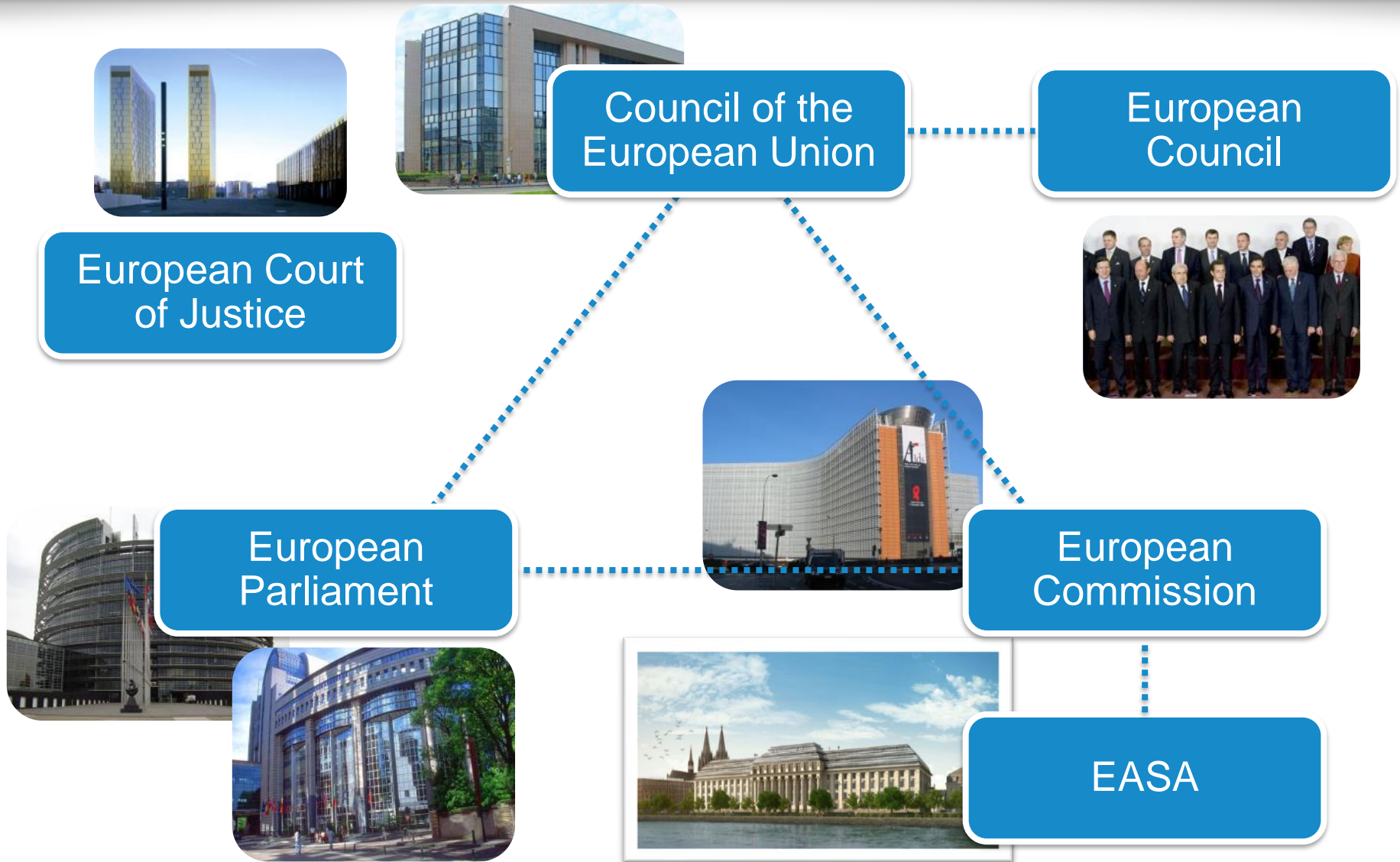
Staff of more than
800



Headed by
Mr Patrick Ky



The institutions



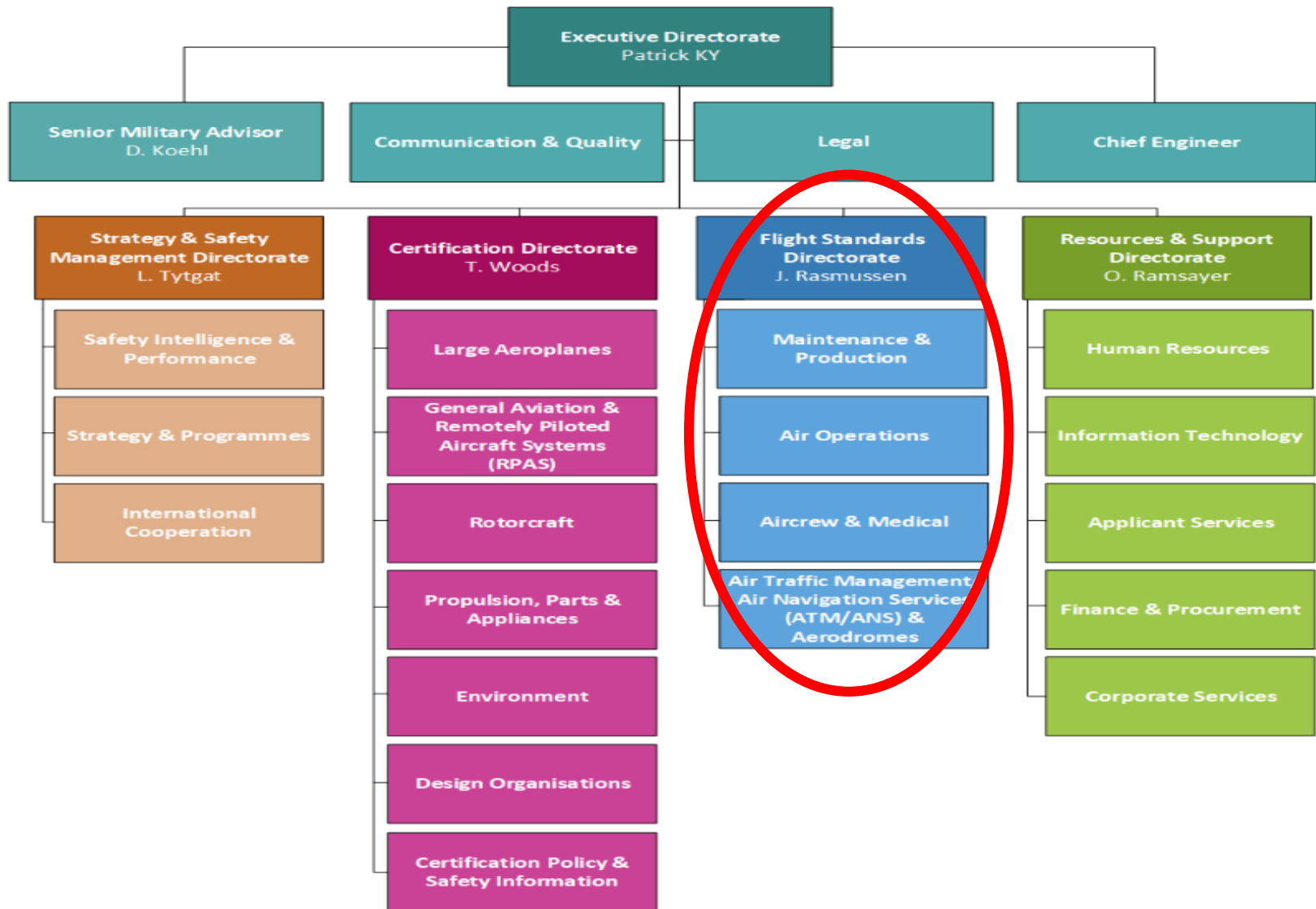


EASA member states and states with WA



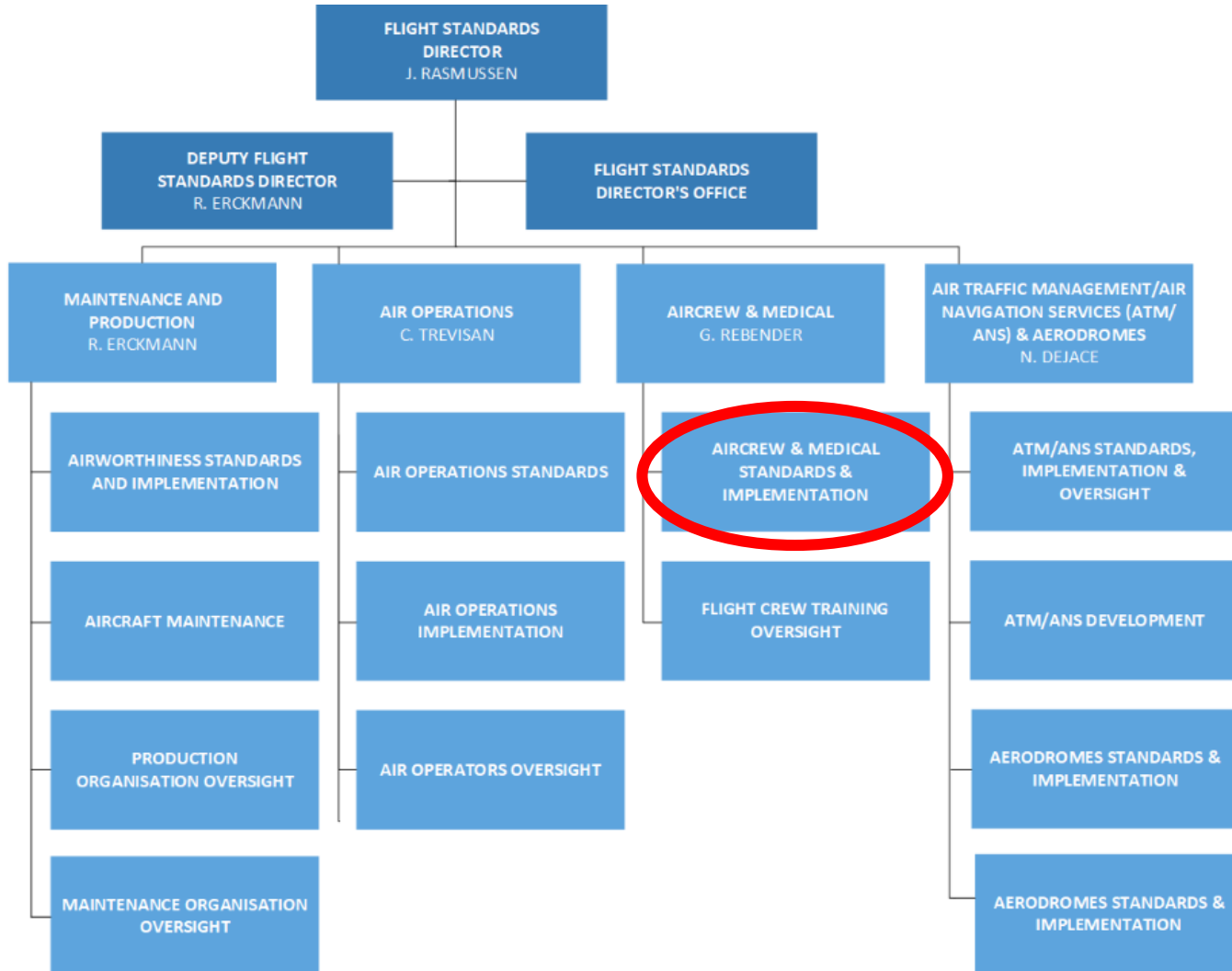


EASA Structure





EASA Structure





Aircrew and Medical department

Aircrew and Medical Standards and Implementation Section



Dr. Janis Vegers



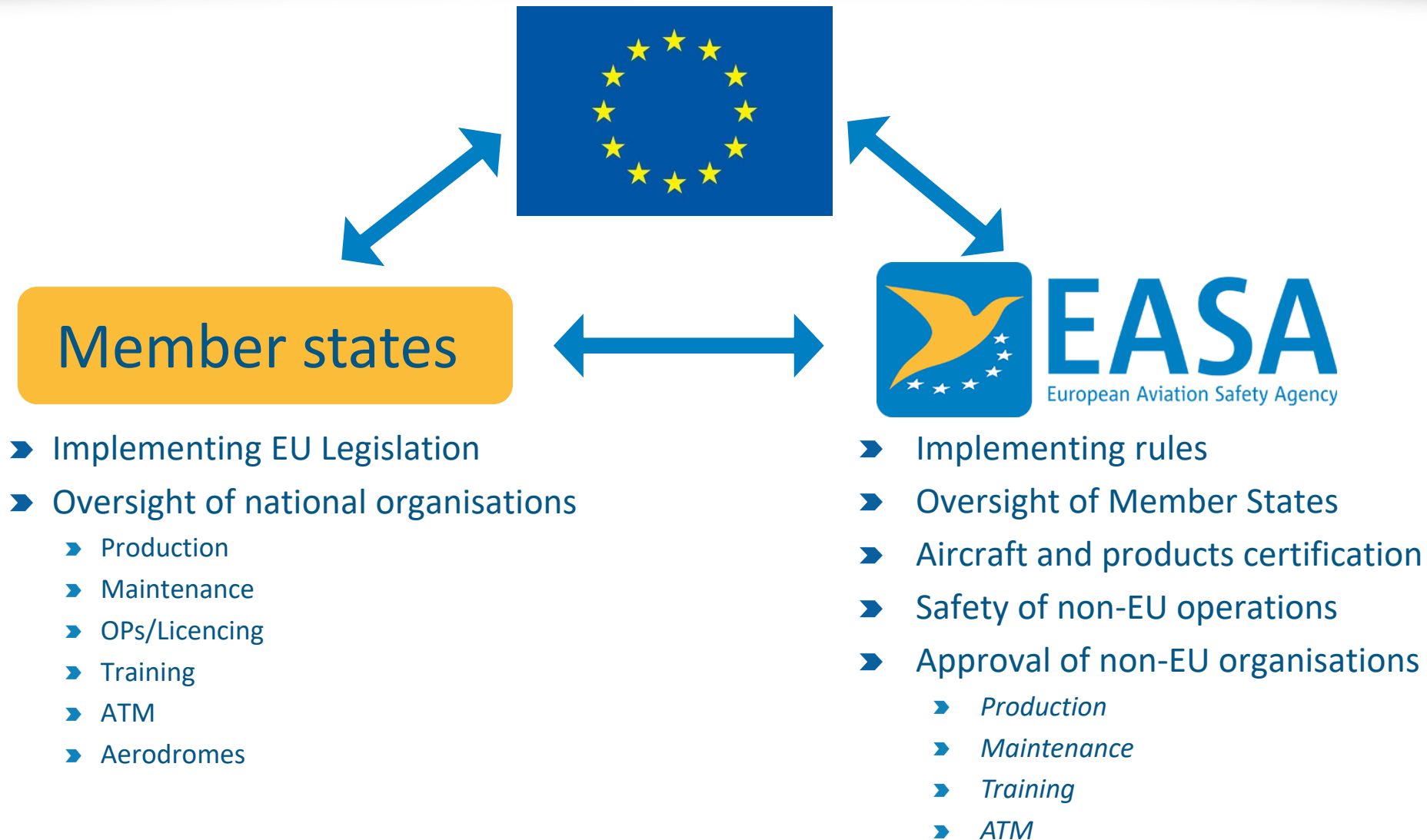
**Dr. Virgilijus
Valentukevicius**



**Dr. Cristian Ionut
Panait**



Partnership with EU Member States



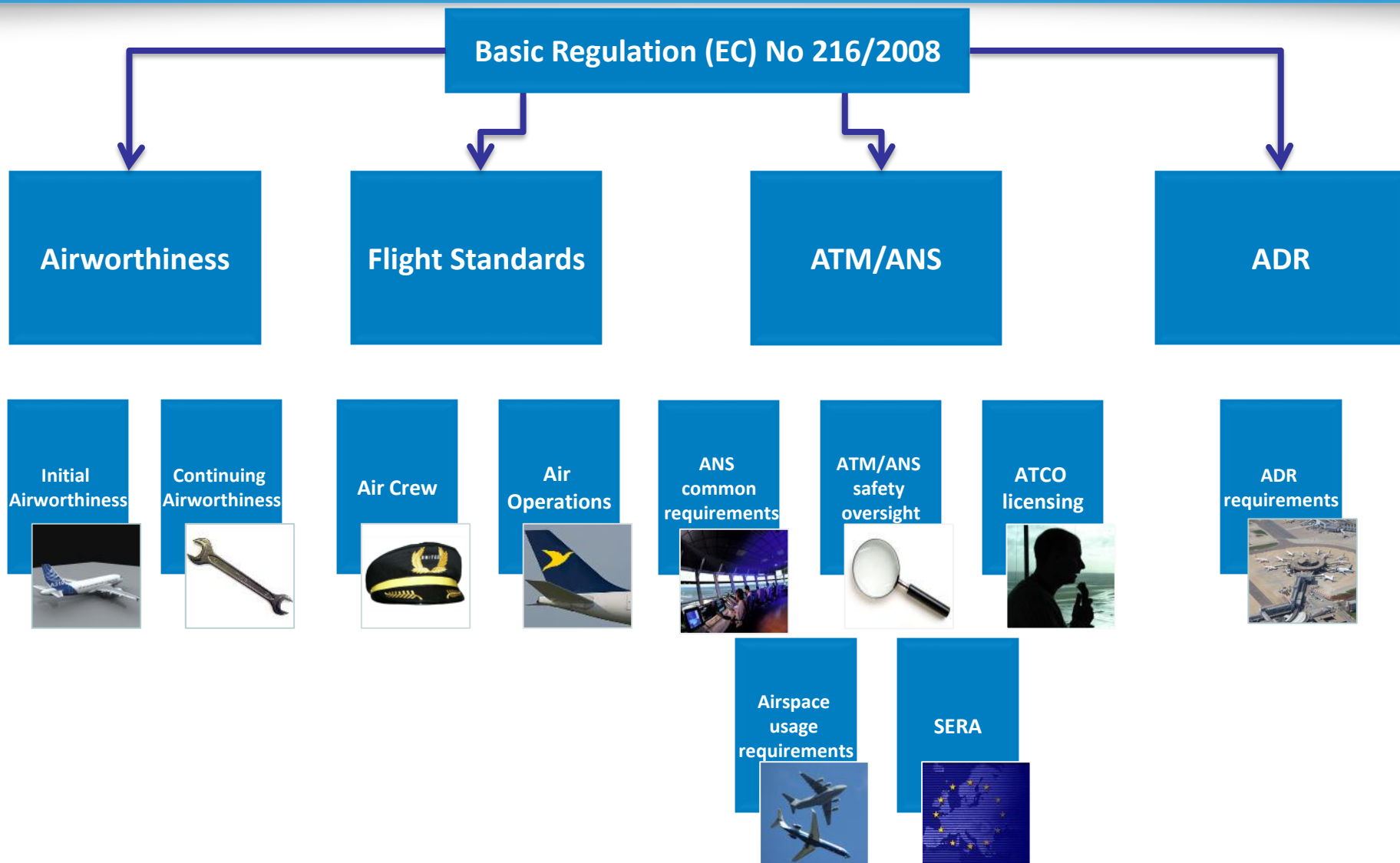


The EU aviation safety system





Current EASA Regulations

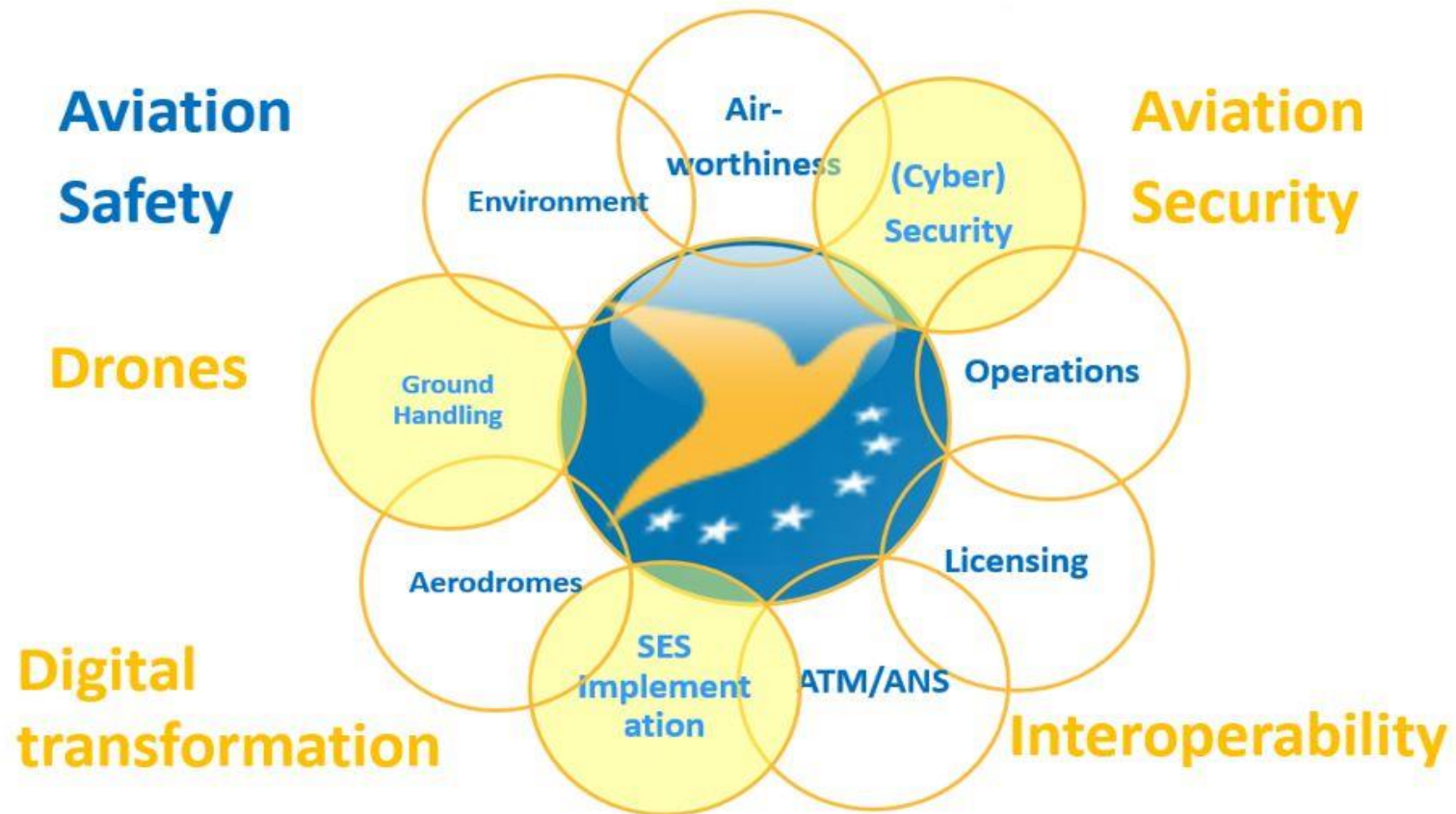




New Basic Regulation

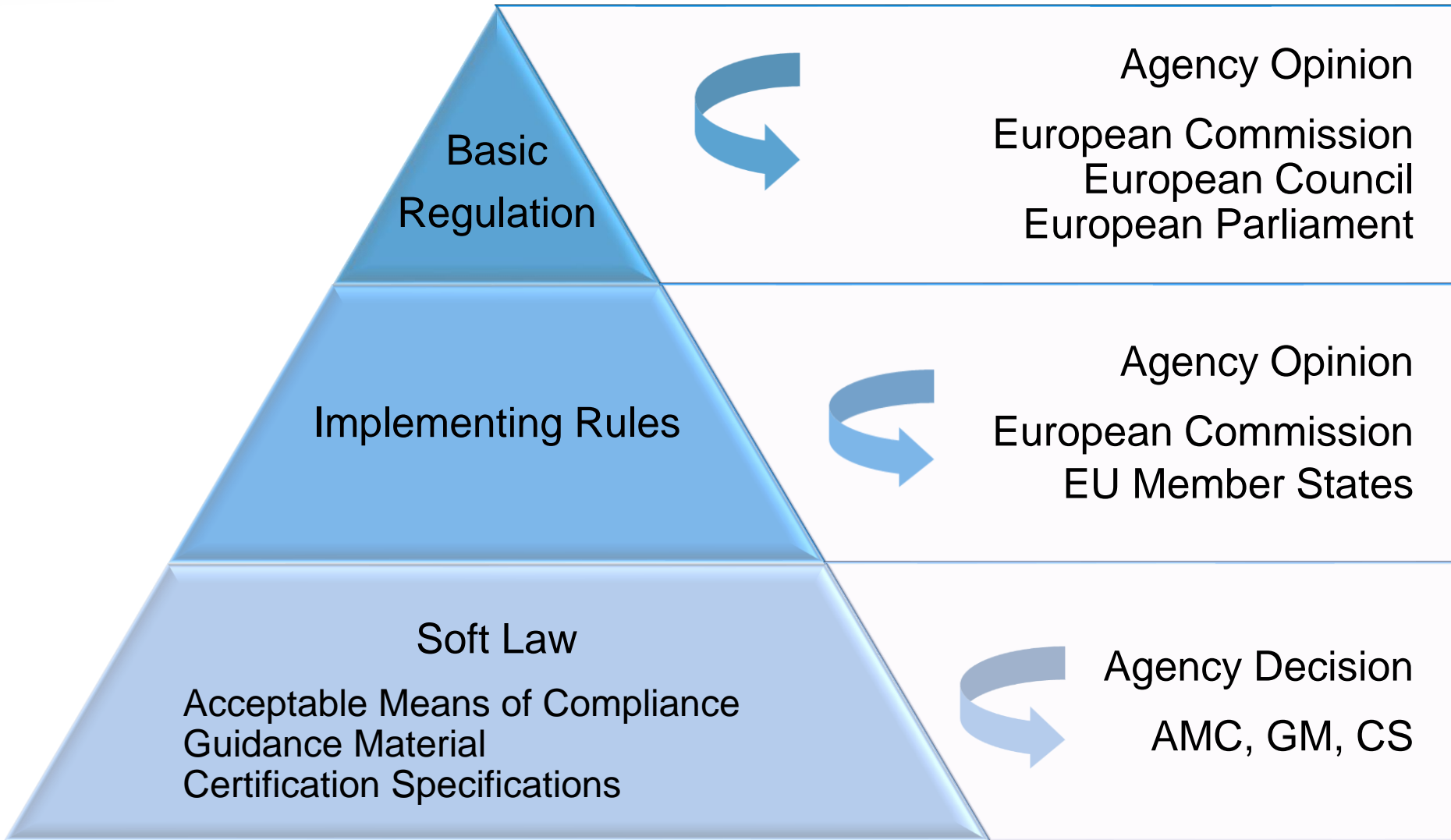
Regulation (EC) 216/2008 → Regulation (EU) 2018/ 1139

'old' BR → **NBR**



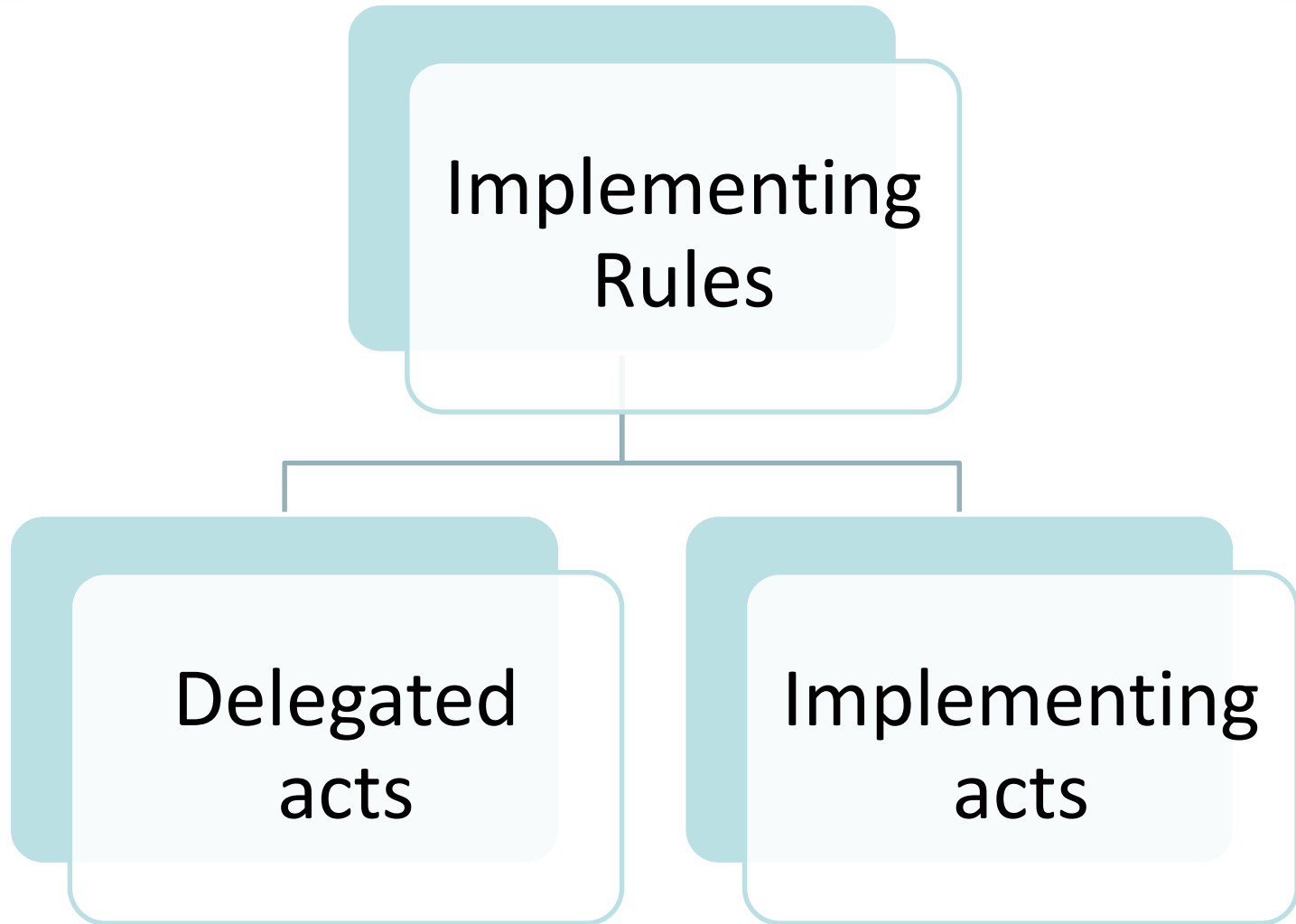


Regulatory Structure





Regulatory Structure - NBR





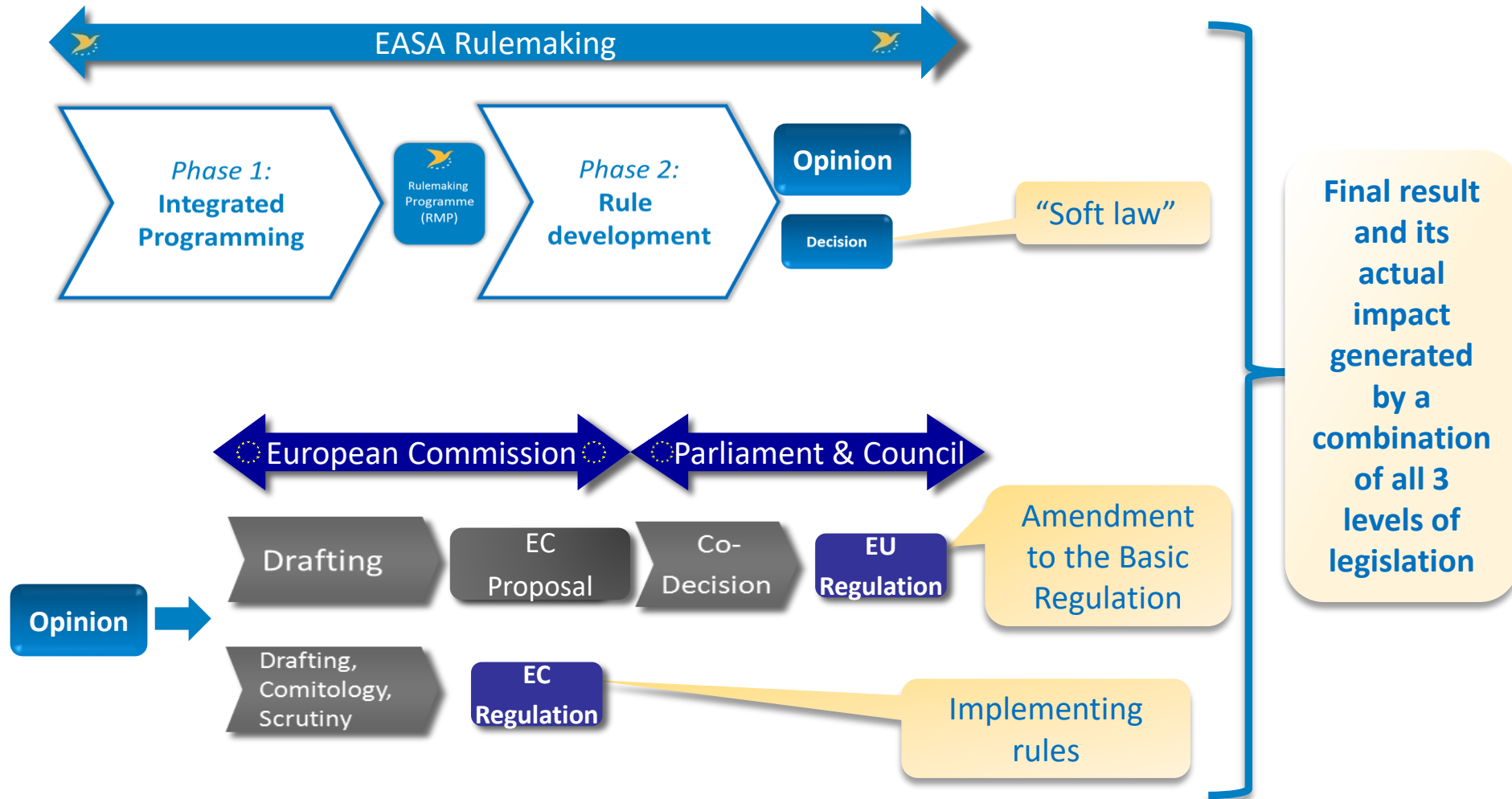
Roles EU aero-medical certification

- **Art.290-Delegated Acts:** The Commission has the power to adopt non-legislative acts of general application that supplement or amend certain non-essential elements of a legislative act.
 - Process: EASA Opinion – COM draft regulation; Consultation with MS experts; Inter-service consultation + 4-week feedback for MS; Adoption by EC-EP and Council can object.

- **Art.291-Implementing Acts:** Responsibility for implementing legally binding EU acts lies primarily with EU countries. However, some legally binding EU acts require uniform conditions for the implementation. In these cases, the Commission or the Council is empowered to adopt implementing acts. Always voted in the Committee.
 - Process: EASA Opinion – COM draft regulation; Consultation with MS experts; Inter-service consultation + 4-week feedback for MS; Draft IA – discussion and vote in Committee; Right of scrutiny – EP and Council; Adoption by EC.

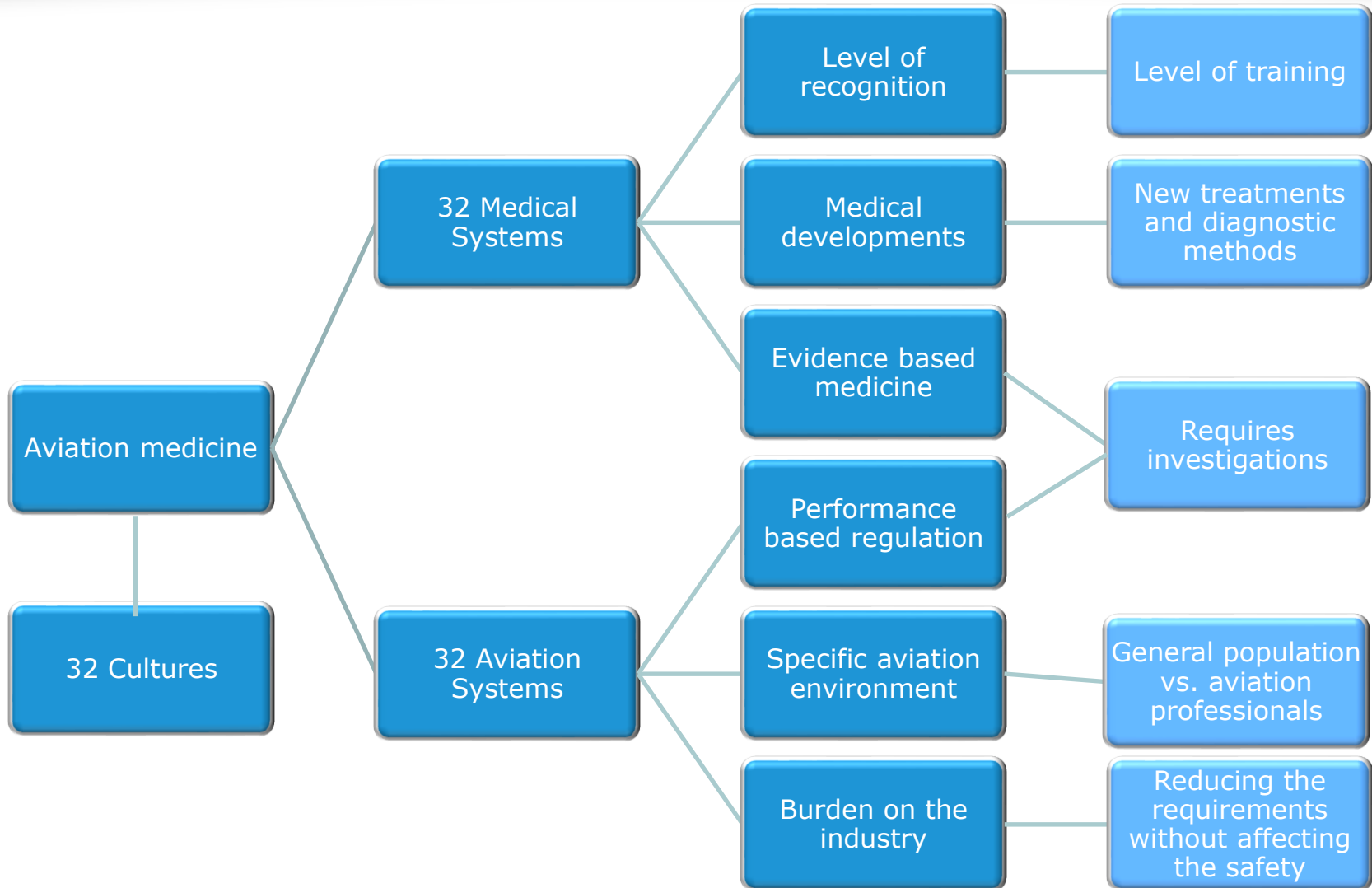


The EU regulatory process





Challenges for the EASA aviation medicine environment





Rulemaking Task RMT.0287

- Scope of RMT.0287 - to update Part-MED, Part-ARA and Part ORA IR and related AMC and GM
- The Task was split in two parts:
 - (a) update of Part-MED and related AMC and GM;**
 - (b) update of medical relevant requirements in Part-ARA and Part-ORA
- Objective - to review Part-MED to correct any editorial errors, consistency issues or gaps identified through implementation experience



Part-MED NPA and CRD

- NPA 2013-15 'Update of Part-MED'
 - Published on 26 July 2013
 - 392 comments
- CRD 2013-15 'Update of Part-MED'
 - Published on 25 September 2014
 - 42 reactions to the CRD
- Following the Germanwings accident the EASA lead Germanwings Taskforce issued 6 recommendations to address the safety concerns
- Q1 2016 – decision to harmonise the draft Part-MED requirements with Germanwings Taskforce recommendation



Part-MED: Achievements

- Safety is enhanced by improving fitness assessment and competency based training for AMEs
- Competency based criteria for renewal/ revalidation of AME Certificates provide flexibility for competent authorities to include previous performance of AMEs in the assessment
- Enhanced flexibility for class 2 medical certificate holders to support general aviation while maintaining the level of safety required
- Correcting editorial mistakes and ensuring consistency of wording for ease of implementation by the Member States



Part-MED Opinion

- Published on 15 August 2016
- Includes :
 - RMT.0287 Update of Part-MED
 - RMT.0700 Implementation of Germanwings Taskforce Recommendations
- Positive vote in May 2017 and February 2018
- Stopped during the Scrutiny procedure by the European Council
- Currently is put in the new format by the EC and will be presented for vote by the Member States



Rulemaking activity

- Updated Part-MED expected to be adopted early 2019
- RMT.0287(b) – Update of the medical relevant parts of Part-ARA and Part-ORA – NPA published 21.12.2017; 400+ comments received
- RMT. 0424 – Regular update of Part-MED –ToR published on 09 Oct. 2017
- RMT.0707 - Medical Regulation — Combine Part-MED and Part ATCO MED – ToR scheduled for 2018
 - To include RPAS operators in class 3 provisions
 - To include Flight test engineers in class 2 provisions
 - Possibly to amend pilot age restrictions
- EC and EASA agreed to make a stop for all new EASA opinions until the EC has cleared the backlog of existing opinions.



Rulemaking activity

- Safety promotion
- Implementation support
- Scientific studies – Pilot age limits – kick-off meeting
14th Nov 2017
- Future projects under consideration
 - Colour vision
 - HIV
 - Risk assessment tool



EASA

European Aviation Safety Agency

Thank you for your attention!



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