Validation – Concept and principles at EASA

Caroline VUILLIN, Chief PCM for Validations

Beijing, September 2017

EASA
European Aviation Safety Agency

CAAC

Legal framework 1/2

- EU Legislation (e.g. EASA Basic Regulation) and Implementing Rules)
- Bilateral Aviation Safety Agreements

- Implementing EU Legislation
- Oversight of national organisations
  - Production
  - Maintenance
  - OPs/Licencing
  - Training
  - ATM
  - Aerodromes

Member States

EASA
European Aviation Safety Agency

- Rulemaking
- Oversight of Member States
- Product certification & Design Organisation Approval
- Safety of non-EU operations
- Approval of non-EU organisations
  - Production
  - Maintenance
  - Training
  - ATM

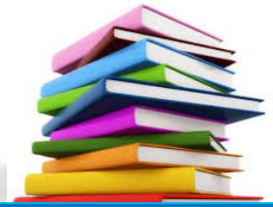
Legal framework 2/2

For EU products and EU approvals/certificates

DOA

For non-EU products and non EU approvals/certificates

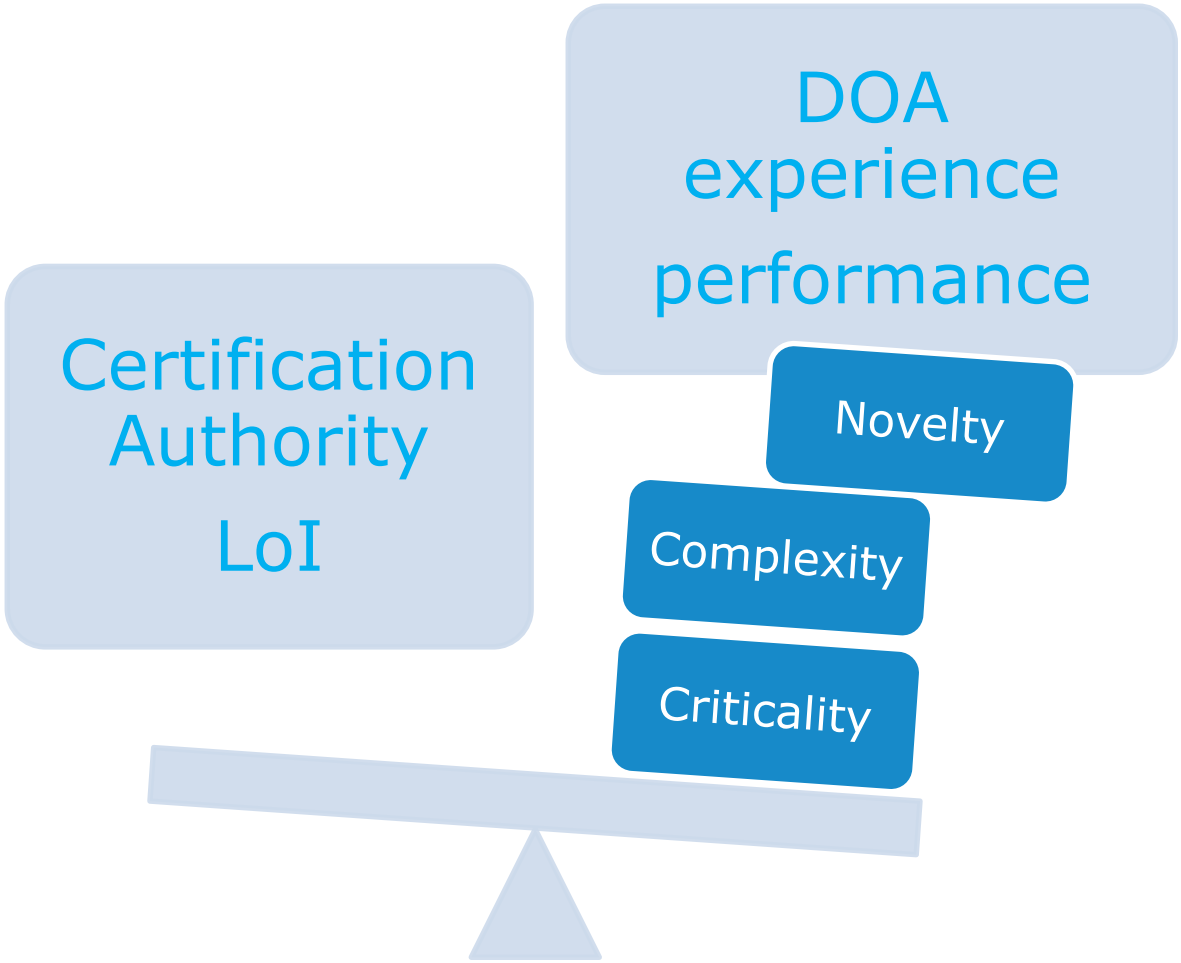
Recognition of foreign system possible



- Bilateral Agreements
- Working arrangements

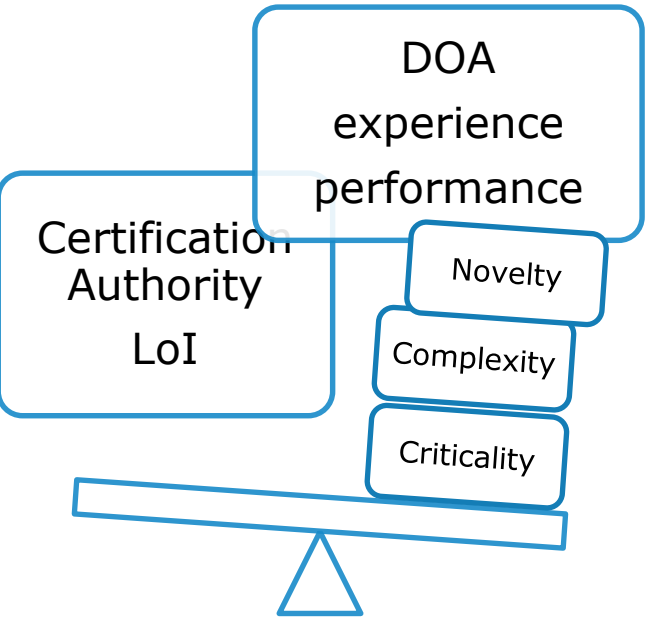
As per article 8 of Regulation 748/2012

Background – Strategy for validation



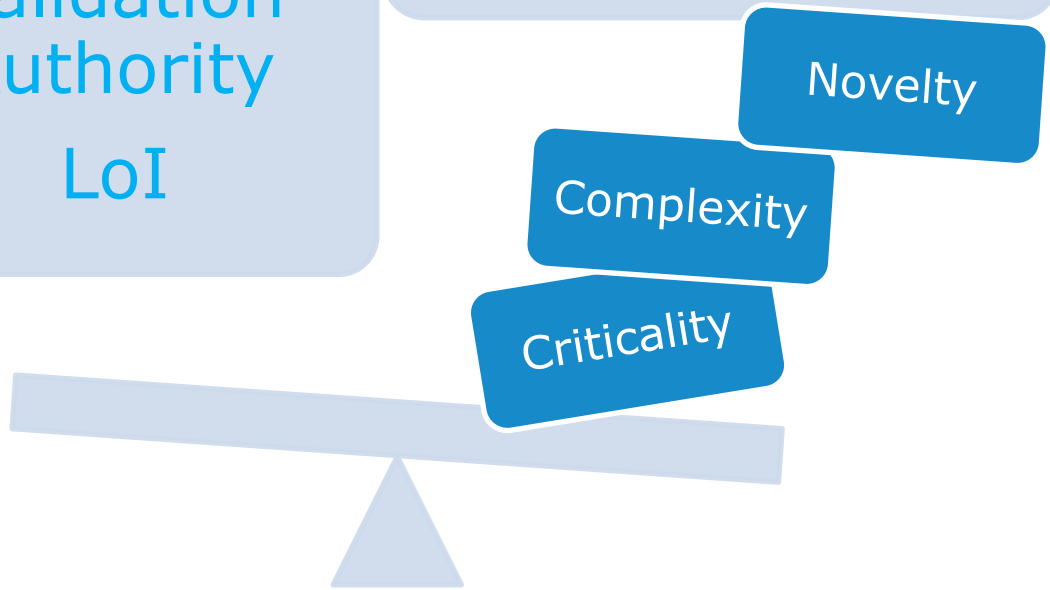
Background – Strategy for validation

- Same approach For Validations



Validation Authority LoI

Certifying Authority experience and mutual confidence



Bilateral Agreements

- Build upon mutual confidence that the two regulatory systems are equivalent
- Build upon experience of 2 Authorities working together as Certifying and Validation Authorities
- Simplified process, up to mutual recognition

Bilateral Agreements

- Avoidance of redundant compliance demonstration activities:
  - Authorities can focus their resources on tasks with higher safety relevance
  - Industry save resources

- Predictability: precise and documented processes for validation allow both Authorities and Industry to better plan (and therefore optimise) the use of their resources at the onset of a validation exercise

Bilateral Agreements

CA=Certifying Authority
VA= Validating Authority

CAAC

EASA
European Aviation Safety Agency

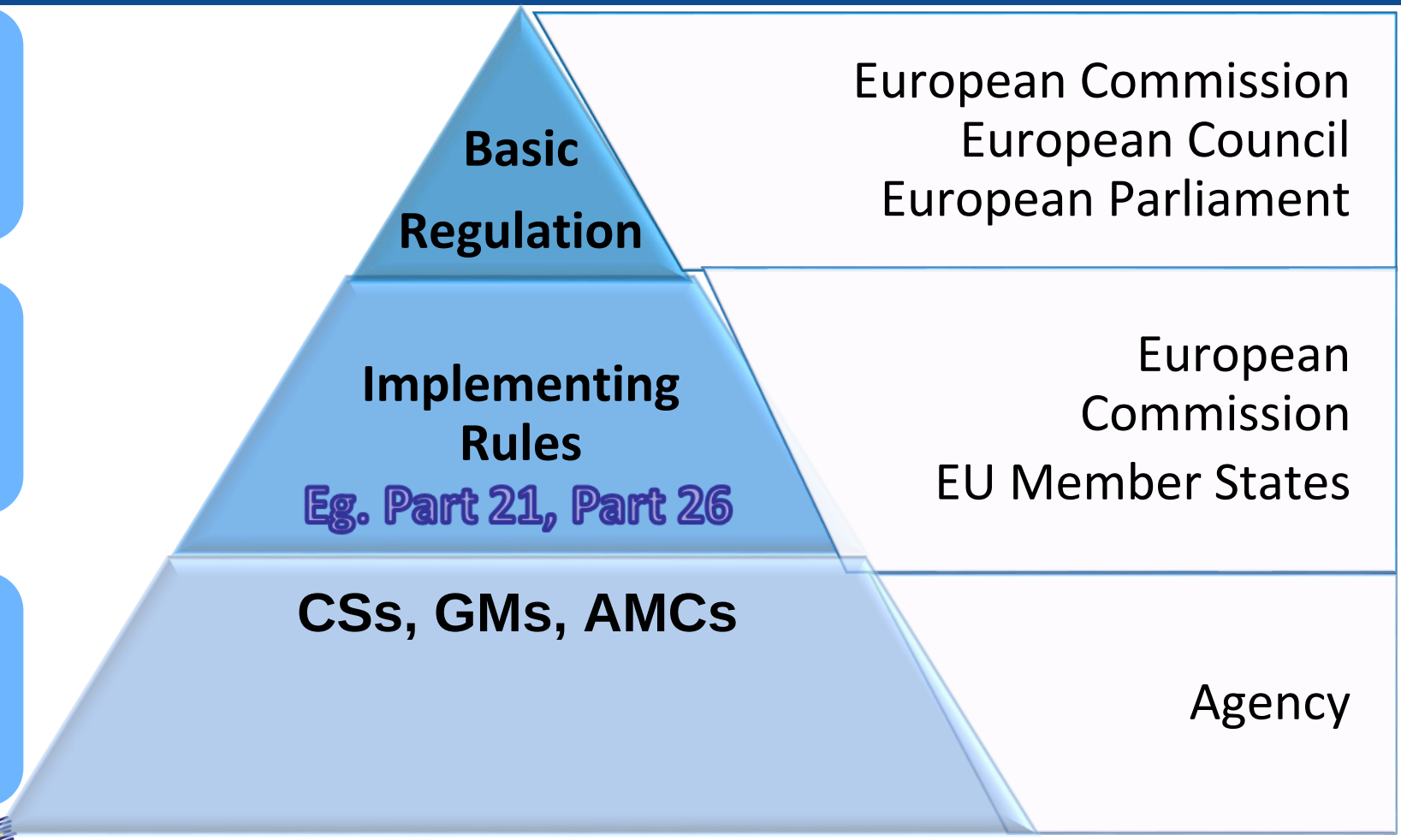
- Where airworthiness standards and interpretation are identical, the VA normally relies on the CA to maximum extent possible
- CA provides support for the validation to the VA
- VA focusses its activities on:
  - issues where there are known significant differences in airworthiness standards, Means of Compliance, interpretations (validation items) and the VA has not much experience on them
  - safety risks Items based on analysis of novelty, criticality, complexity.

Structure of EU rules

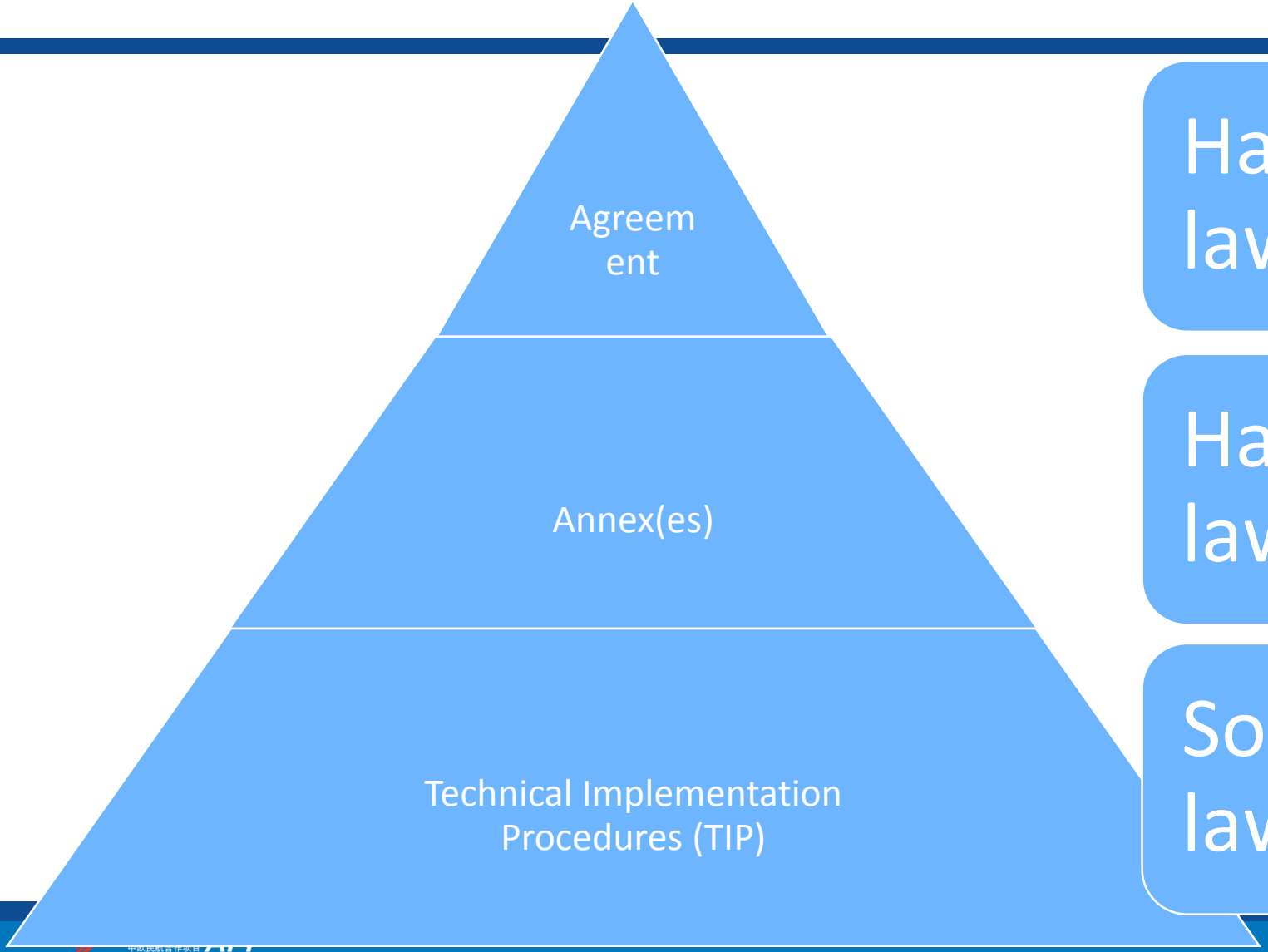
Hard law

Hard law

Soft law



Structure of EU Bilateral Agreements



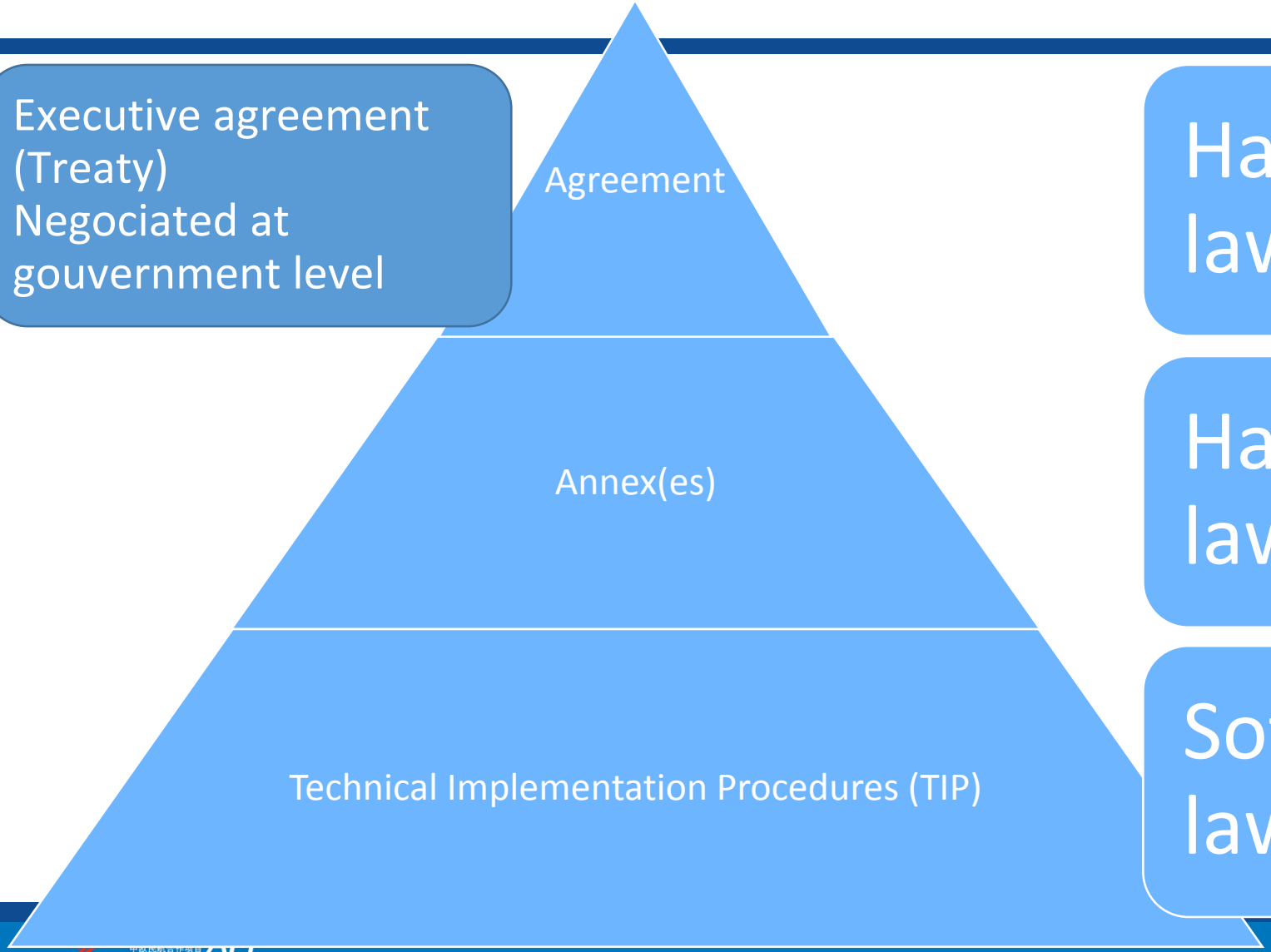
Hard law

Hard law

Soft law

Structure of EU Bilateral Agreements

Executive agreement (Treaty)
Negociated at gouvernment level

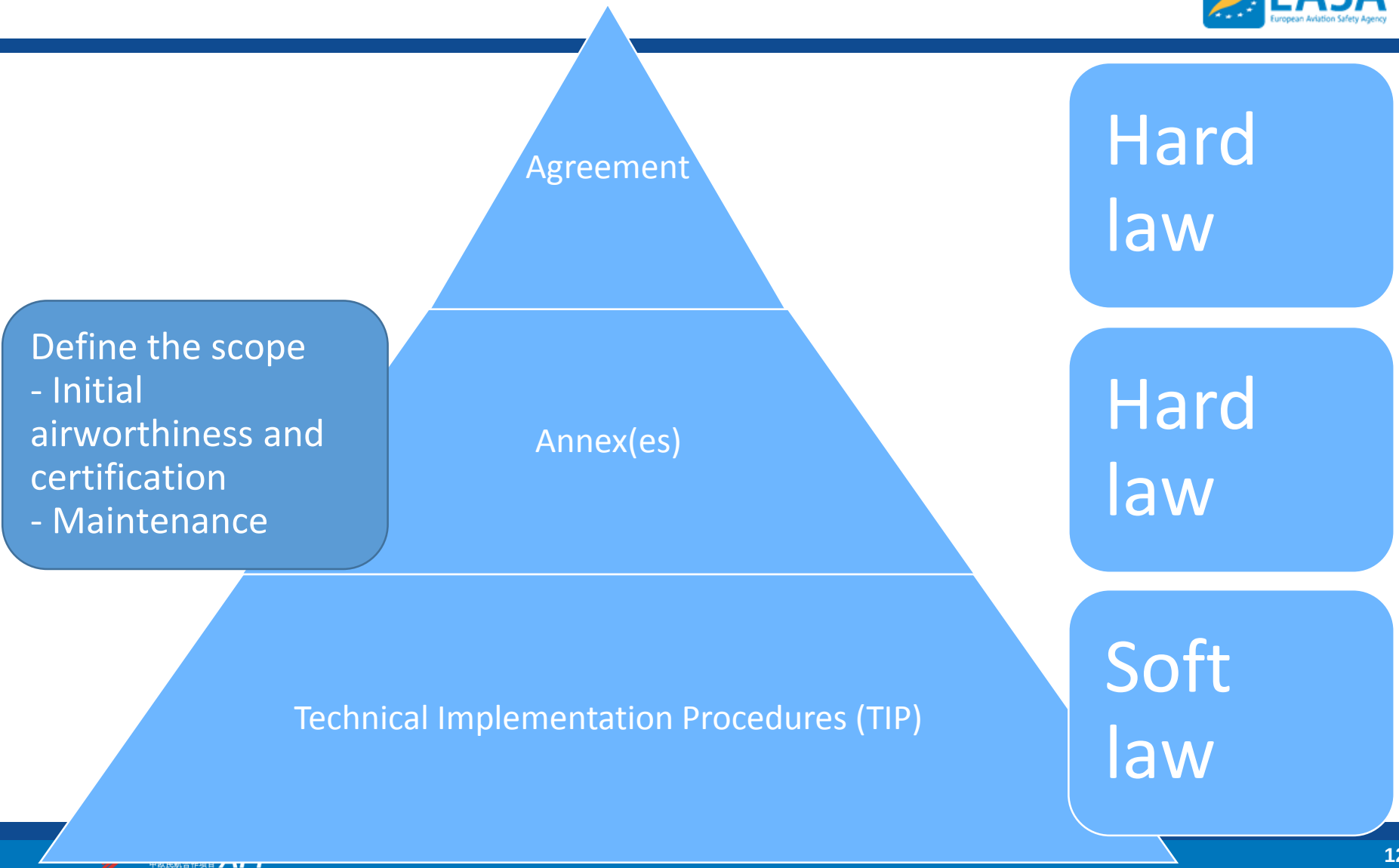


Hard law

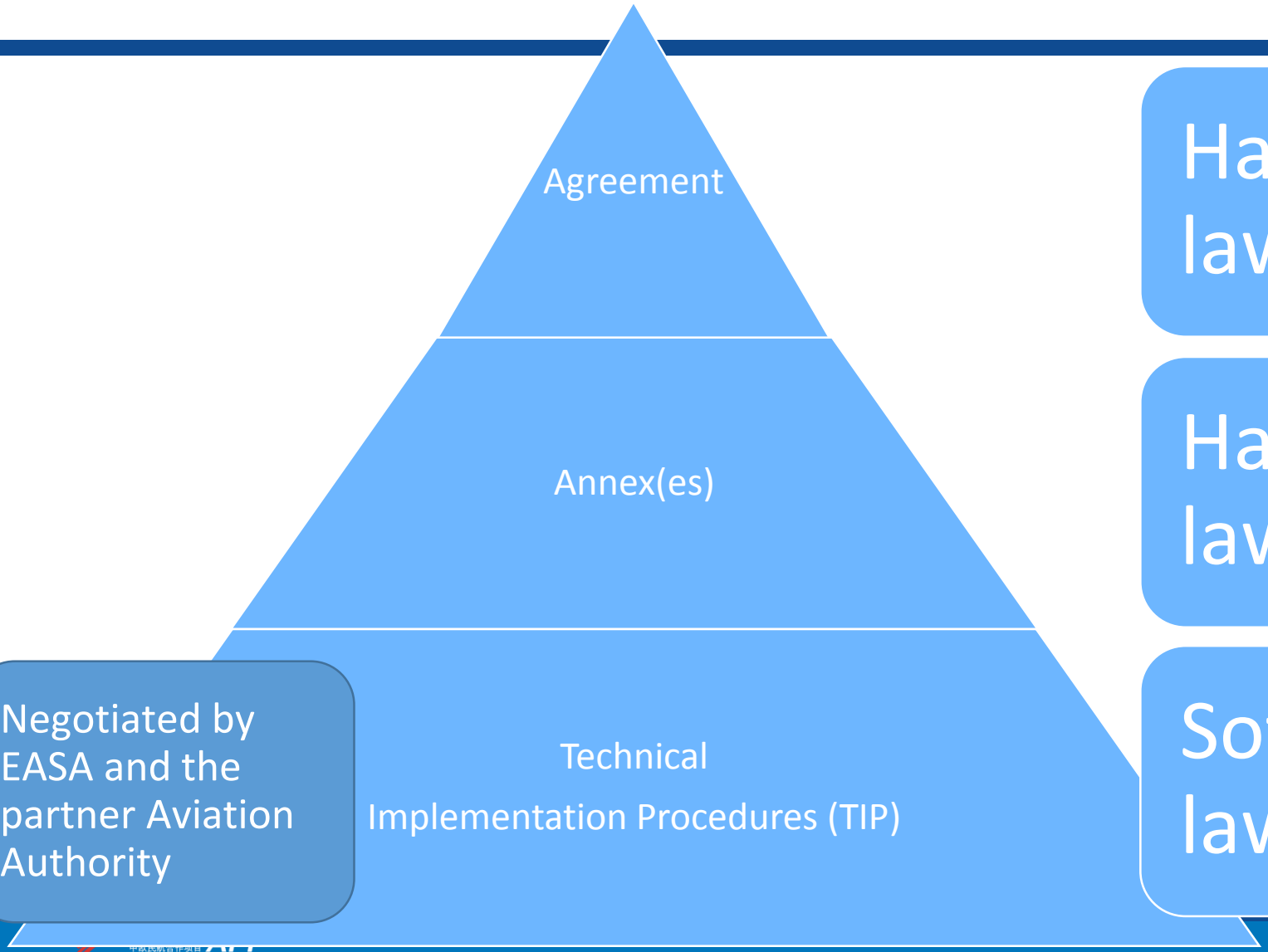
Hard law

Soft law

Structure of EU Bilateral Agreements



Structure of EU Bilateral Agreements



Hard law

Hard law

Soft law

Negotiated by EASA and the partner Aviation Authority

BASAs with EU

European Commission has the mandate to negotiate further BASAs with China and Japan

Validation process

In the context of bilateral agreement

Implementation of a Technical Implementation Procedure (TIP)

Validation process – 4 phases

I
- Familiarisation with the project, certification team composition, organisation and establishment of the initial Type Certification (TC) basis

II
- Agreement of the Certification Programme and determination of level of technical involvement

III
- Compliance determination

IV
- Final report and issuance of the approval

Validation process – Phase I- Familiarization

General familiarization of the product

- Good understanding of the design
- Team composition (size and disciplines involved)
- Validation schedule

Organization of the work

- Project Information Document

Establishment of the applicable standards

- Significant differenecs
- Generic Validation Items
- Project Validation Items

Identification of initial Validation Items

Validation process – Phase I- Familiarization

- Initial Certification basis
  - Starting point:

    Reference date for a validation is usually the date of application to the Certifying Authority

  - Then, the applicable Certification Standards and CRIs/IPs when the existing standards are not appropriate

  - Identification of the significant differences in airworthiness standards between the CA and the VA

Validation process – Phase I- Familiarization

- **Significant Differences** result from the comparison between the CA standards and the VA standards.
- A difference is significant when
  - it requires a Type Design change or
  - it requires a change in approved manuals
  - It requires additional or different demonstration of compliance
  - It imposes additional operational limits

- Differences in wording are not considered as significant differences

Validation process – Phase I- Familiarization

- **Significant Differences best practices:**
  - Comparison of airworthiness standards pairs is performed by Authorities and available for the applicants
  - Based on those comparisons, applicants develop the list of significant differences applicable to its project

Validation process – Phase I- Familiarization

Where the CS does not contain adequate or appropriate safety standards, because

- **novel or unsual design features**
- **use of the product unconventional**
- **unsafe conditions may develop**

Special Condition

The Agency reviews Certifying Authority material

Where an airworthiness provision cannot be complied with

- **+ compensated by factors**

ESF deviation

Validation process – phase I - Familiarization

- Certification basis is documented in Certification Review Item (CRI)
- Certification basis is notified to the applicant
- Effective for 5 years for large aeroplanes / rotorcraft; 3 years for all other cases

Validation process – Phase II – LOI

- The applicant needs to provide a validation programme
  - Giving the overall schedule of the validation
  - Defining the proposed means of compliance with the VA certification basis
  - Describing all activities planned for compliance demonstration

Review of the Certifying Authority materials (MOC, IM, ACs…)
The VA can 'adopt' the CA materials

Validation process – Phase II – LOI

Determination of Agency's level of involvement during validations

- Risk based assessment on the basis of the validation programme provided by applicant
- Assessing
  - Novelty + complexity of the design proposal
  - Experience with the applicant and with the Certifying Authority
  - Criticality of an unidentified non-compliance

Note: Significant Differences are not criteria for VA involvement

Validation process – Phase III – Compliance

- The applicant needs to
  - demonstrate compliance with the Validation certification basis
    - CA Certification basis+ significant differences
    - Use of VA MOCs ONLY if different from CA MOCs
  - record justification of compliance

Validation process – Phase III – Compliance

Agency's verification activities

- For tracking and recording of
  - substantial discussion on Means of Compliance or interpretation or
  - particular compliance demonstration issues or
  - significant discussion affecting the result of the validation process, or
  - Involvement

the Agency uses the format of Certification Review Items (CRI) or Certification Action Item (CAI)

Validation process – Phase III – Compliance

Agency's verification activities

- The applicant first needs to give their position on any CAI and CRI raised by the Validating Authority
- The Certifying Authority is requested to give their position on the CRIs and CAIs before closure

Validation process – Phase IV – TC

EASA closes the Certification basis CRI

EASA closes the Validation Item CRI

Validation process – Phase IV – TC

EASA experts provide Statement of Satisfaction

The applicant provides Declaration of Compliance against Validation Certification Basis

The Certifying Authority provides Statement of Compliance against the Validation Certification Basis

Validation process – Phase IV – TC

EASA produces a final certification Report

The final certification report is reviewed by EASA internal safety committee

TC is issued together with the Type Certificate Data Sheet and the Type Certificate Data Sheet for Noise

Continued Airworthiness process

In the context of bilateral agreement

Implementation of a Technical Implementation Procedure (TIP)

Continued Airworthiness for validated products

- Basic principles for Continued Airworthiness
  - EASA acts as the State of Registry on behalf of EU Member States
  - The Certifying Authority acts as State of Design authority for its products (resolves in-service safety issues related to Design)
  - The Certifying Authority shall provide applicable information necessary for the Validation Authority to ensure continued operational safety
  - The Validating Authority shall review and normally accept the corrective actions taken by the Certifying Authority in the issuance of its own mandatory corrective actions.

Continued Airworthiness for validated products

- Basic principles for Continued Airworthiness
  - The Validating Authority advises the Certifying Authority of malfunctions or defects and accidents/incidents which are believed to be potentially unsafe conditions occurring on the products and appliances which are imported.
  - The Validating Authority and Certifying Authority shall support each other in the investigations of accident or incident

Continued Airworthiness for validated products

- TIP benefits
  - Safety information exchange: the BASA/TIP allows Authorities to share safety information => promotes safety
  - Exchange of best practices: experts at various levels in both Authorities are exposed to different practices and can learn from each other => promotes safety and harmonization of regulatory systems

Working Arrangement

In the context of working arrangement

Signed between two Authorities

Validation of Foreign Certificates with no bilateral agreement in force

- When EASA acts as Validating Authority:
  - EASA can issue European design approval on the basis of the Implementing Rule 748/2012 (including Part 21)
  - For example: need for a DOA except when the other Authority's regulatory system is recognized as equivalent

As per article 8 of Regulation 748/2012

Working arrangement

- A working arrangement is an agreement between two authorities
- Procedures to facilitate the issuance of the EASA certificate, e.g.
  - assistance in determining airworthiness of products
  - providing technical evaluation assistance
- Under a working arrangement, Part-21 must be complied with

This project is funded by
the European Union

Caroline VUILLIN, Chief PCM for Validations

E-mail address: caroline.vuillin@easa.europa.eu

EASA
European Aviation Safety Agency

CAAC