



EASA

European Aviation Safety Agency

STC Validation Process with Foreign Authorities - Highlights

Charles LEBOEUF
Chief PCM - Validation Process
04.06.2017

STC WORKSHOP
June 4th/5th 2018

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TE.GEN.00409-001



STC Validation process - *International highlights for 2017*

- EASA/ANAC TIP: Approval of revision 3 (February 2017)
 - Introduction of Operational Suitability Data
- EASA/TCCA TIP: Approval of revision 3 (September 2017)
 - Clarification of reporting channels
 - Applicability of TIP to Norway, Switzerland and Iceland
- EASA/FAA TIP: Approval of revision 6 (September 2017)
 - Introduction of a new classification for design changes
 - Introduction of Basic TC concept
 - Reciprocal acceptance of all TSOA/ETSOA
 - Reciprocal acceptance of all repair design
- EU/China Bilateral Aviation Safety Agreement negotiations





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STC Validation Process with USA - EASA/FAA Type Rev.6

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What drove the EU/US TIP change ?

- The parties agreed to **reduce Validating Authority level of involvement**
 - Based on mutual confidence and the continued maintenance of such confidence with the Certifying Authority
- Objective, under a **risk-based approach**, is to **maximize full acceptance** by the Validating Authority **without any technical review** or issuance of validation approval
- Objective is to have:
 - **More directly accepted approvals**
 - **Less changes** where the Validating Authority gets involved
 - **Less involvement in Major Changes** where the Validating Authority gets involved.



What drove the EU/US TIP change ?

EASA-FAA Certification Oversight Board Validation Improvement Roadmap - 2022



Certification Director

Date 29 February 2016



Director, Aircraft Certification Service

Date 29 February 2016



Main TIP Rev. 6 changes

No more Level 1/ Level 2 classification for Major Changes

No more different set of criteria for Basic/Non-Basic STCs

No more specific path for Changes to approved manuals

No more separate path for Environmental Testing and Approval Procedures.

Instead :

TCs, STCs, changes to TC, changes to STCs are all classified as basic or non basic under the same set of criteria.



Non Basic Classification Criteria

TIP Rev. 5 - (App C § 6.2) (Only STCs)

- Includes GVI (App C §4.5)
- Includes SSD (App C §3.2)
- Other Criteria:
 - Significant change
 - Change requiring SC, ESF, ELoS, Exemption, Deviation
 - Change requiring a MoC CRI/IP
 - Any other design change categorized as non-basic by CA

Only a restricted
part of those shall
become SEI

TIP Rev. 6 - (§ 3.5.3.2) (All Changes)

- 1) SEI (see complete definition §3.5.10.4)
- 2) New SC, ESF, ELoS, Exemption, Deviation
- 3) Significant change
- 4) AD criteria (Unilateral or VA is SoD)
- 5) New Moc
- 6) New Technology
- 7) Novel application of existing technology
- 8) Non simple acoustic or emission substantiation
- 9) Appreciable effect on OSD
- 10) Any other design change categorized as non-basic by CA



TIP rev 6 What changed?

➤ Modified non-basic criteria for STCs

to allow more projects to be processed under basic streamlined procedures:

- Now, applications for design changes affecting the certification basis “may” be classified as Basic:

Eg: if applicable SC, ESF/ELoS, Exemption/Deviation is not new (already in TCDS); elect to comply.

- Now, applications for design changes requiring a MoC CRI/IP “may” be classified as Basic:

Eg: if MoC is not new or different from that previously agreed by the EASA and the FAA.

- Now, changes effecting SSDs (even retained during original certification) may be classified as basic.



Non-basic Criteria Classifications (§ 3.5.3.2)

Criteria for **non-Basic classification** are triggered when the change includes:

- (1) Any item in the VA Safety Emphasis Item (SEI)
- (2) The EASA or FAA certification basis includes or is anticipated to include a new or amended:
 - FAA exemption or EASA deviation; Special condition; or Equivalent level of Safety (ELOS/ESF)
(that is not yet included in the TCDS)
- (3) A classification of significant has been made by EASA under 21.A.101
- (4) An AD is affected that was issued unilaterally by the VA or where VA is SoD for the TC

The list shall be reviewed!



Non-basic Criteria Classifications (§ 3.5.3.2)

Criteria for **non-Basic classification** are **triggered** when the change also includes:

- (5) Changes involving the use of a new or different applicable method of compliance from that previously agreed by the EASA and the FAA

Note: A method of compliance (MOC) would not be considered “new” or “different” if it had been applied previously in a similar context by both the EASA and the FAA

- (6) New technology exists
 - New technology is technology that is new to the VA as a whole, not just new to the VA team members
- (7) Novel applications of existing technology exists
 - Novel application of technology is where a particular technology is being used in a manner that causes the precepts of the technology to be questioned.



Non-basic Criteria Classifications (§ 3.5.3.2)

Criteria for non-Basic classification are triggered when the change also includes:

- (8) Non simple substantiation of acoustic or emission changes
 - A simple substantiation is when the compliance demonstration with the EASA has involved standard means of compliance and procedures which were already regularly agreed by the FAA and EASA in previous applicant's projects using the same test organization.
- (9) Changes that have an appreciable effect on any one of the Operational Suitability Data (OSD) constituents
 - (refer to EASA Guidance Material GM 21.A.91 to determine an appreciable effect)
 - Effective implementation of this specific criterion is currently under discussion between EASA and FAA



Non-basic Criteria Classifications (§ 3.5.3.2)

Criteria for **non-Basic classification** are triggered when the change also includes:

- (10) Any other design change designated as Non-Basic by the CA

**Extension of STCs to other models
may be considered basic if none
of the 10 criteria is triggered**



TIP Rev.6 - New Accepted Changes (§3.3.3)

➤ **All** TSO/ETSO articles are now accepted.

TIP Rev.6 eliminates the last four restricted articles held for validation under TIP Rev 5 including:

1. Active Unit Load Devices (TSO/ETSO-C90) – e.g. heated or cooled cargo containers
2. Integrated Modular Avionics (TSO-C153/ETSO-2C153)
3. Emergency parachutes (TSO/ETSO-C23)
4. Auxiliary Power Units (TSO-C77/CS-APU)



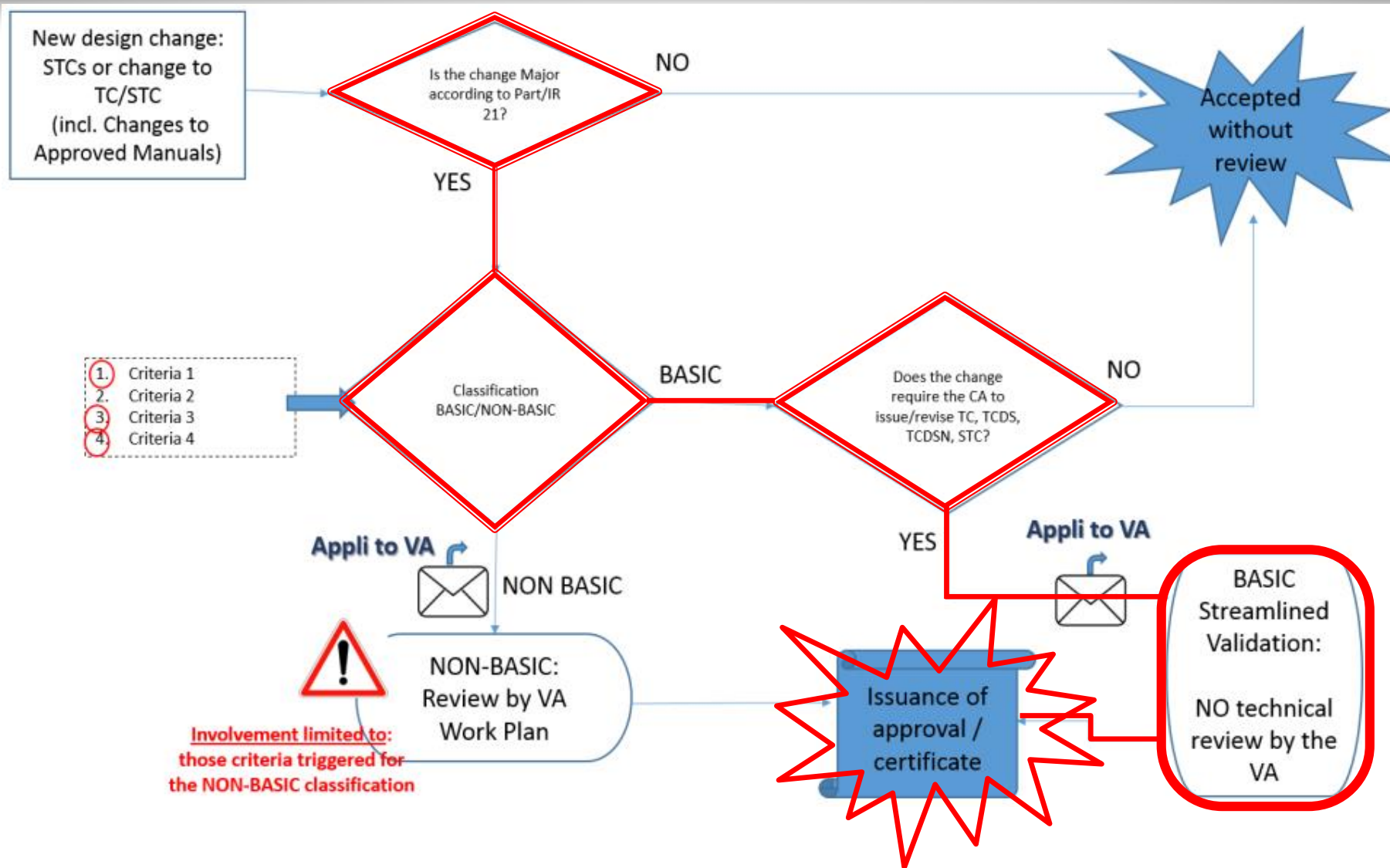
Main TIP 6 changes

All design approvals follow now one of three paths:

- Accepted
- Streamlined validation (Basic)
- Technical Validation (non-Basic)

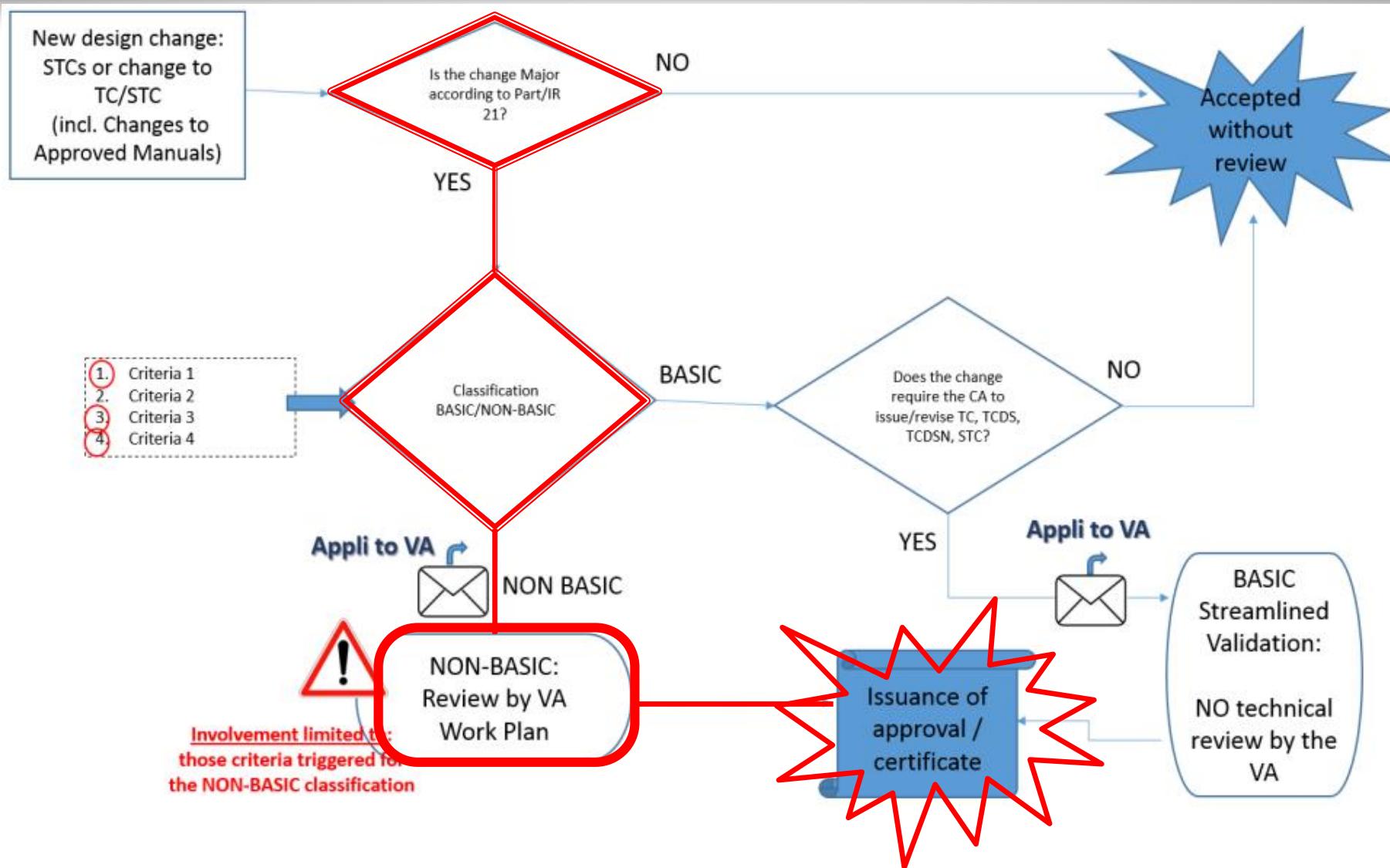


Decision Path for Design Change





Decision Path for Design Change





Validation of STCs: few questions

- **Can STCs be accepted according to TIP Rev 6?**
 - No, STCs are always validated, this means application to VA and approval always needed. The process can be:
 - For Basic STCs -> Streamlined Validation Process
 - For Non-Basic STCs -> Technical Validation Process
- **What about changes to STCs?**
 - Changes to STCs can be accepted when basic and not affecting the approval.
- **Is a CSV planned for Basic STCs?**
 - Yes, because „CA will classify an application for validation as *Basic or Non-Basic*“ therefore the CA must check the documentation of the applicant, classify according to the TIP and send the data package for validation (Streamlined or Technical).



Establishment of SEI (§3.5.10.4)

Safety Emphasis Items (SEI) list

- Are part of the Non-Basic classification criteria;
- Consist of items of VA interest for all products of a certain category.
- SEI lists developed and approved separately (but in coordination) by the FAA and EASA;
- Are available to the public on FAA and EASA websites;
- Shall be frequently revised with the goal of reducing the size of the list through targeted harmonization effort;
- SEI list revisions are approved by the management responsible for maintenance of the list.



Safety Emphasis Items definition (§3.5.10.4)

- New VA standards or certain SSDs where the VA or CA has limited past experience on the product or they have an important impact on the whole product or a critical feature, and engineering judgment is required to establish compliance.
- Airworthiness standards where the VA's and CA's IM, AC, MOC or GM differ or are insufficient, to an extent that those difference impact the level of safety and could result in VA required changes to the type design or approved manuals
- Items identified for special emphasis by the VA in a data-driven risk assessment analysis for the product class.
- Subjects linked to known safety conditions that the VA has identified, and for which the VA either has, or in the process of, taking airworthiness action.



Difference between SEI and former GVIs

- SEI does not include former „Commonly occurring Project VIs“.
- SEI may be SSD related, knowing that „the majority of SSD are well understood by both authorities, with full confidence given to the CA for determining compliance to those VA SSDs“.
- Advisory, MOCs or guidance material that differ or are insufficient can be SEI only if they have an impact in level of safety and could result in changes to type design or approved manuals.
- When the requirement is the same (i.e. no SSD), for different VA MoC, but not clearly having a safety repercussion or a design change, the VA must rely sufficiently on the quality of the CA system and accept this different MoC (if it really cannot, then it is an SEI).



Role of Significant Standards Differences

- The existence of an SSD is no longer a criteria for VA involvement
 - The existence of an SSD is not a criteria for the Non-Basic classification
 - Unless it is one of the SSDs translated into the SEI List
- Significant Standards Differences (SSD) are an integral part of the VA certification basis for validation. VA SSDs refer to VA airworthiness standards that either differ significantly from the CA standards or have no CA equivalent, as defined in EASA/FAA TIP Rev. 6 §3.5.13.
- The major role of SSDs is to allow the applicant to demonstrate, and the CA to verify, compliance with the VA's certification basis.

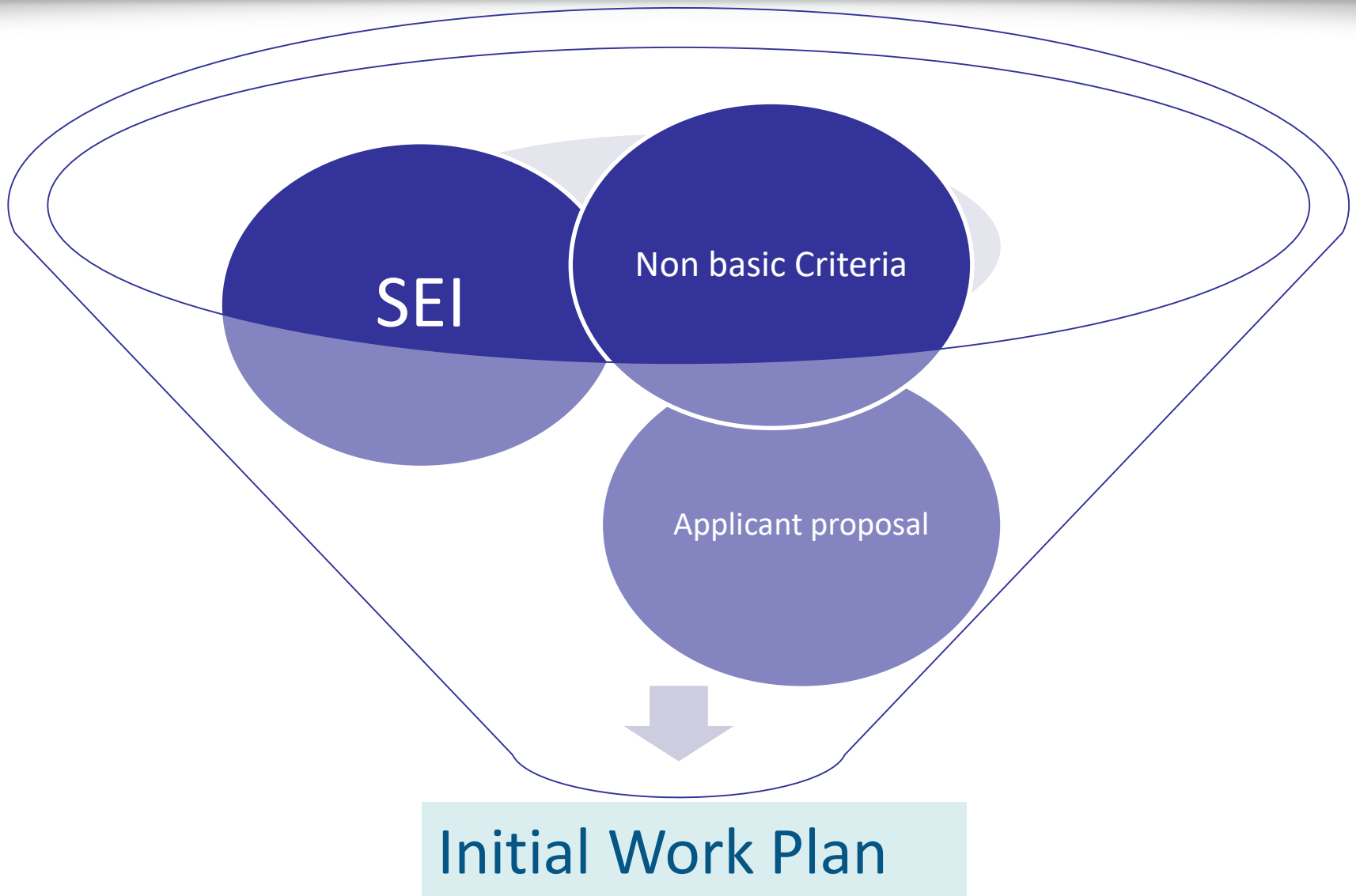


Establishing the Level of Involvement





Level of Involvement





The Validation Workplan (§3.5.9)

➤ What is a Work Plan?

- Document establishing the scope and depth of FAA involvement for non basic changes
- Used to document the FAA certification basis.

➤ Objective of the Workplan

- Limits the scope and depth of review of validation to only those items that triggered the Non-Basic classification.
- Eliminates/reduces the opportunity for FAA to review simply out of interest or unwarranted concern.
- Establishes a more disciplined procedure for FAA involvement.

➤ How is controlled the Workplan?

- Requires FAA project office management approval and oversight to TIP procedures.



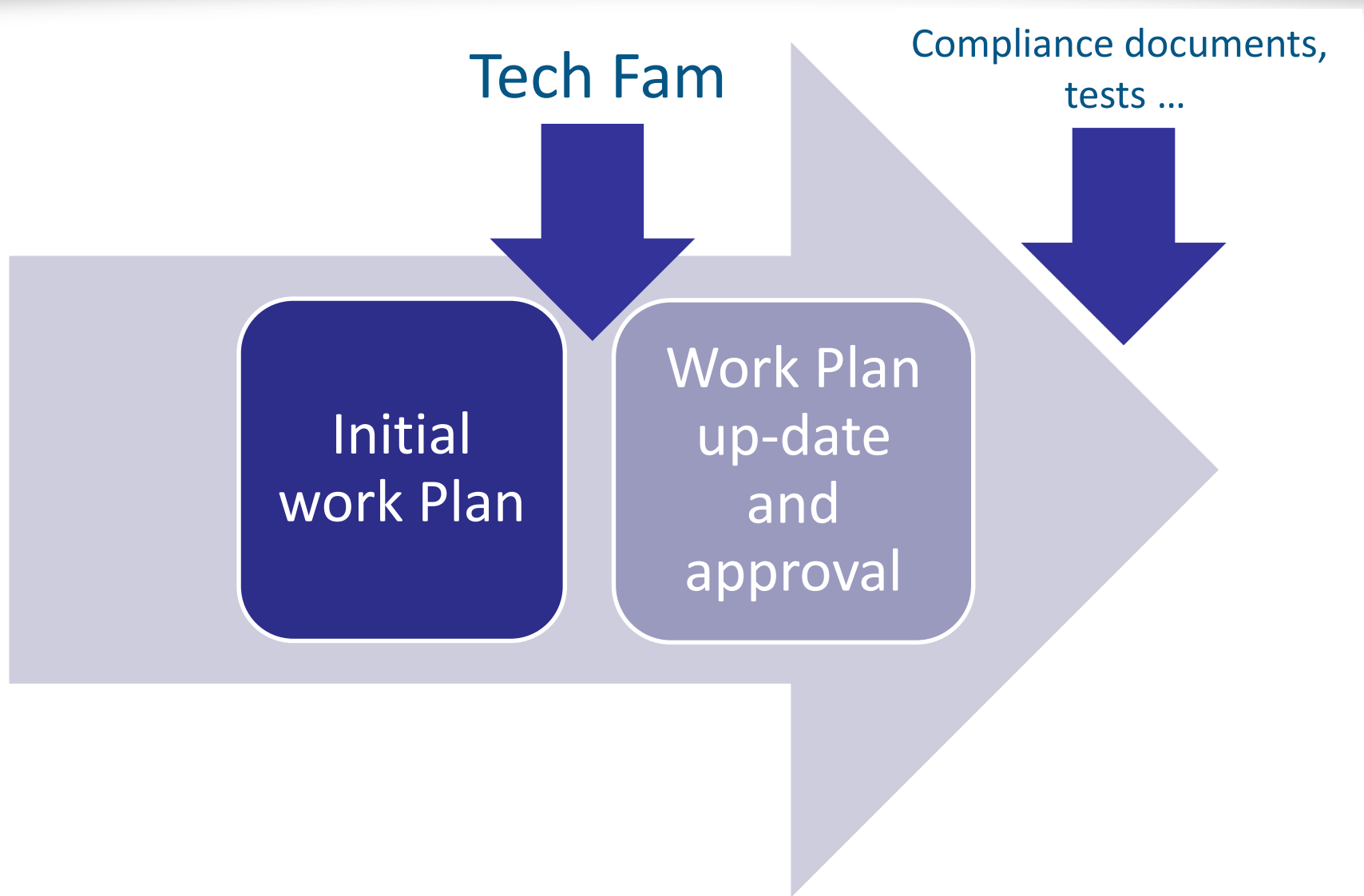
The Validation Workplan (§3.5.9)

- The initial Workplan is established by the FAA at the beginning of the project
 - Applicant Certification Plan
 - Non basic Criteria, SEI
 - Application package (ref. TIP §3.5.5.1)
 - General Familiarization if needed

- Final Workplan may necessitate technical familiarizations (as the VA gains knowledge during technical familiarization or as the design presented for validation, including methods of compliance, evolves over the course of the certification program).



Level of Involvement





The Validation Workplan (§3.5.9)

- The initial FAA work plan shall include:
 - A brief description of the product or change, as provided in the application package
 - A proposed initial FAA certification basis, including the following (if available at time of application):
 - Applicable FAA airworthiness standards
 - Applicable significant standards differences (SSD) and
 - Proposed exemptions, special conditions, or equivalent level of safety findings
 - A list of proposed areas of FAA level of review, bounded by the applicable Non-Basic criteria



The Validation Workplan (§3.5.9)

- The initial FAA work plan will also include (cont'd):
 - A proposal for technical familiarization activities necessary to achieve a final work plan with detailed level of involvement;
 - Identification of the responsible FAA project certification manager and any FAA team members identified based on review of the application

Note: these elements may be updated by the FAA over the course of the validation program



The Validation Workplan (§3.5.9)

- While the workplan is an **FAA document**, the FAA will share the approved plan with EASA and applicant
- If the FAA includes areas of involvement in the workplan that are not included in the Non-Basic criteria, the EASA will question those workplan elements using the resolution of conflicts process.
- The work plan documents the scope and depth of FAA level of involvement. All other areas shall not be subject to any FAA technical review beyond technical familiarization.
- This means that EASA will verify compliance on behalf of FAA against FAA Certification basis for all non-listed areas.



Work-plan Templates (§3.5.9)

- FAA Order 8110.52B gives a generic work-plan template
- EASA has developed a template which has been shared with FAA



What is expected from the Applicant?

- Must know the applicable VA regulations and how to show compliance with them
 - Thorough review of and compliance with SSD and SEIs
- Must provide the CA with a complete application
 - application package for transmittal to the VA according to §3.5.4.2 (streamlined) or §3.5.5.1 (Non-Basic), as applicable.
- Must determine the applicable non-basic criteria for their application
 - Which feeds directly into the initial VA work plan



***Do not hesitate to ask for support
to your favourite EASA PCM!***





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Thank you.

Questions ?

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STC Validation Process: EU/China BASA Highlights

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Content

- Background – Why BASAs?
- Recent developments
- High level description of Annex
- Next steps



What is a BASA?

- A BASA is a strong institutional link (international agreement) between the EU and a given Third Country that enables, as provided in the Annexes, the reciprocal acceptance of certificates and findings of compliance issued by the respective Competent Authorities.
- It allows derogation from EU law and creates rights and obligations for the EU (including EU-MS and the Industry).



Background – Why BASAs?

Improve aviation safety through:

- Increased cooperation between Aviation Authorities
- Sharing of information and best practices
- Resource allocation to highest added-value tasks (from risk management perspective) both for Authorities and Applicants

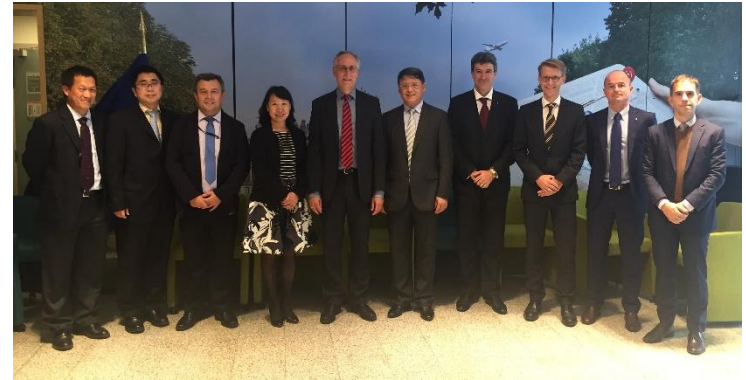
Support aviation industry by:

- Providing a sound regulatory framework to support transnational design/production industrial schemes
- Reducing un-necessary duplication of certification / validation tasks



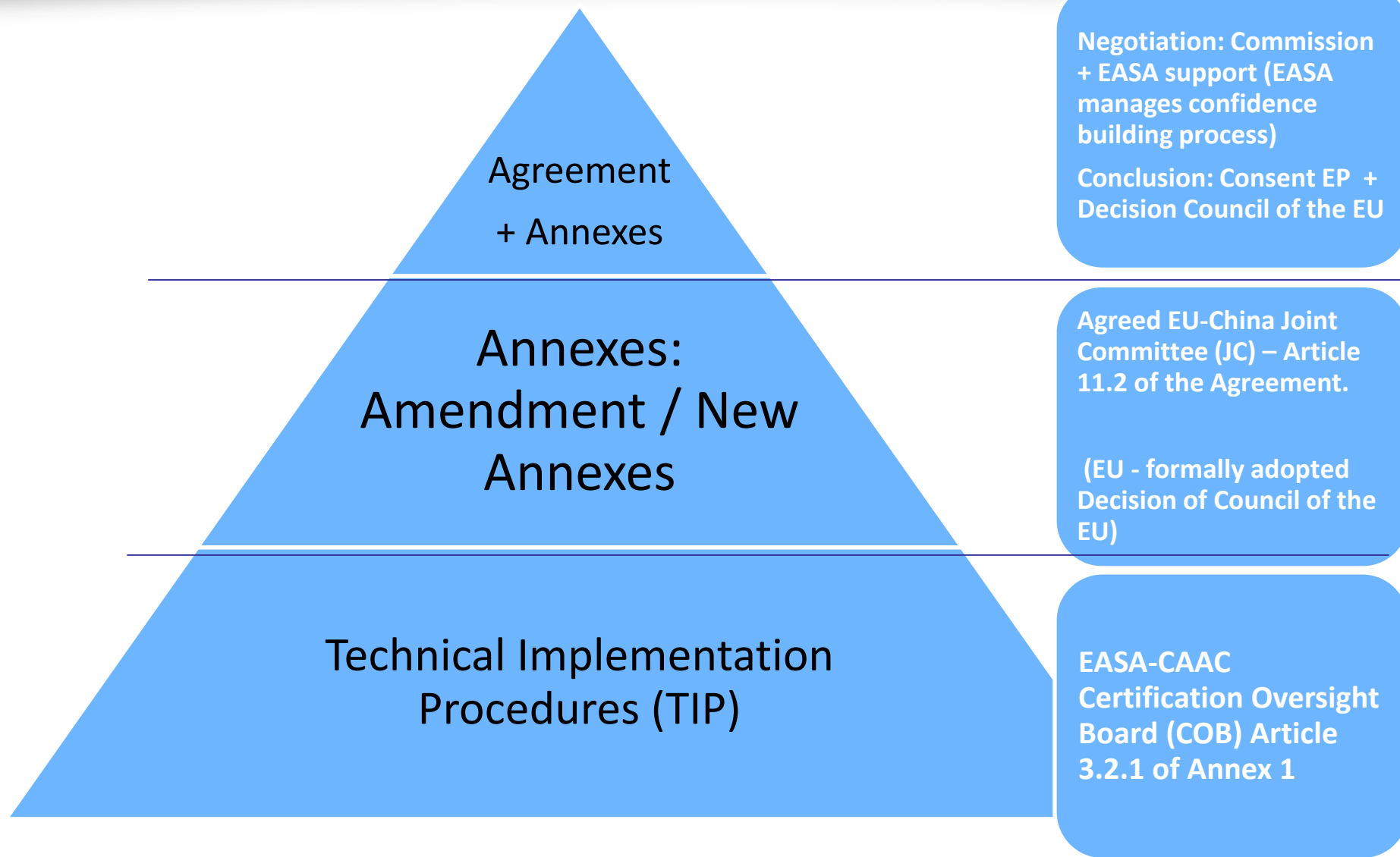
Recent developments

- 8 March 2016: Council Decision – Negotiation mandate to European Commission
- Four negotiation rounds:
 - December 2016 (Beijing)
 - March 2017 (Brussels)
 - June 2017 (Qingdao)
 - September 2017 (Brussels) – Executive Agreement and Annex 1 text finalised
 - Initialling of the Agreement in December 2017
- Technical Roadmap implementation milestones:
 - April 2015: conclusion of the Technical Roadmap Arrangement between EASA and CAAC
 - February 2017: Track 1 completion review (Cologne)
 - Track 2 implementation continuously





Agreement-Annex-TIP interfaces: Who is responsible for what?





High level description of Annex



Scope:

- Design and production (all aeronautical products)
- No temporary limitations

OSD / AEG within the scope



Principle of concurrent certification foreseen

Certain *ad hoc* cases





High level description of Annex



Automatic acceptance

Or



Validation:

- Level of Involvement principles
- Validation through an administrative process in some cases



High level description of Annex

Production:

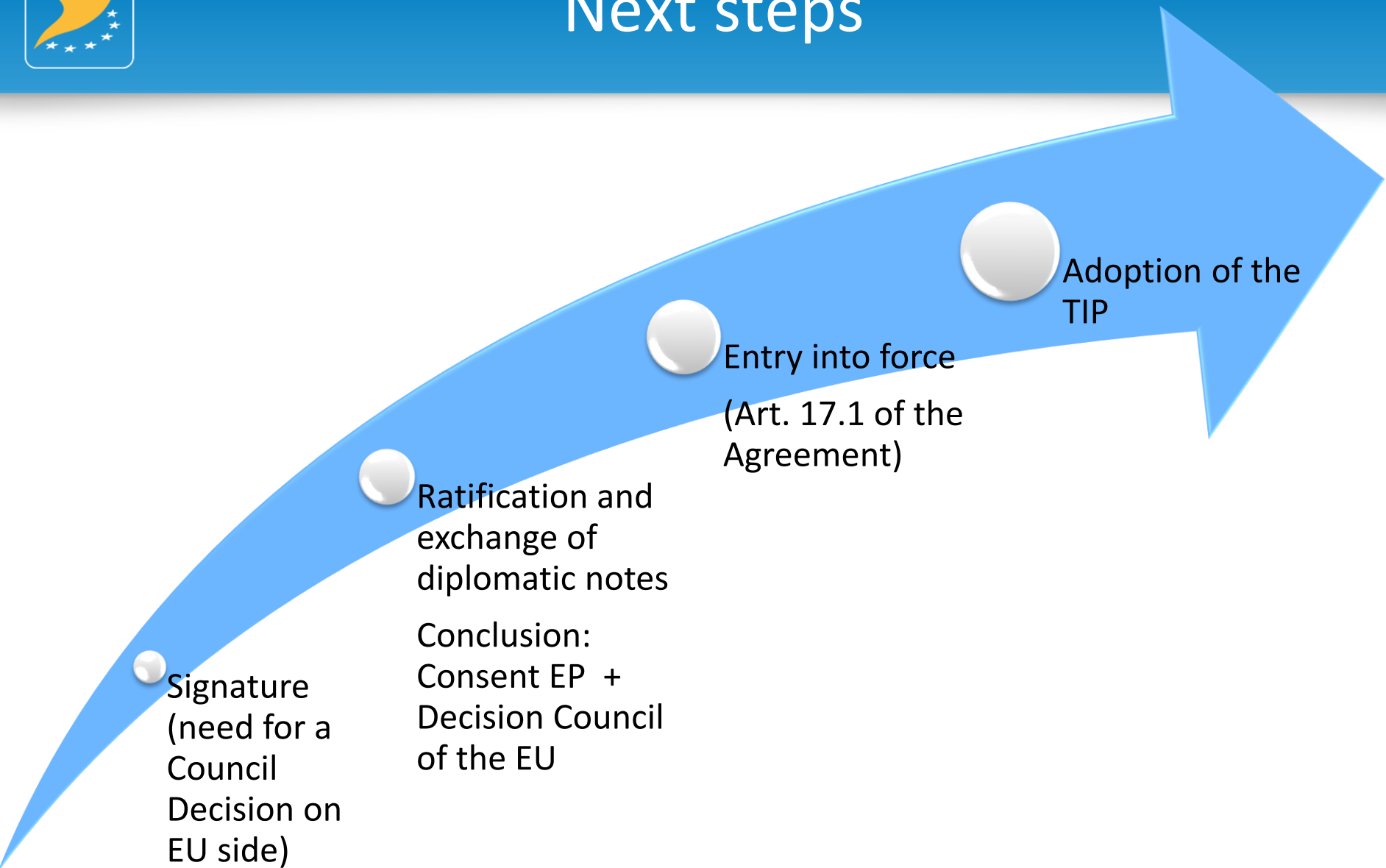
- Mutual acceptance of production systems and export forms under conditions
- Various production schemes covered

Relations between Authorities:

- Several provisions on cooperation
- Provisions on initial and recurrent mutual assessments



Next steps





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