Antilope

Advancing eHealth Interoperability

Quality Label and Certification Processes

Karima Bourquard
Director of Interoperability
IHE-Europe

cip competitiveness and innovation framework programme 2007–2013

IHE EUROPE Integrating the Healthcare Enterprise

SEVENTH FRAMEWORK PROGRAMME

Testing and Certification Objectives

To design a European quality label or certification process that supports eHealth interoperability in Europe.

These processes shall operate in harmony with country specific quality label or certification processes

Main benefits:

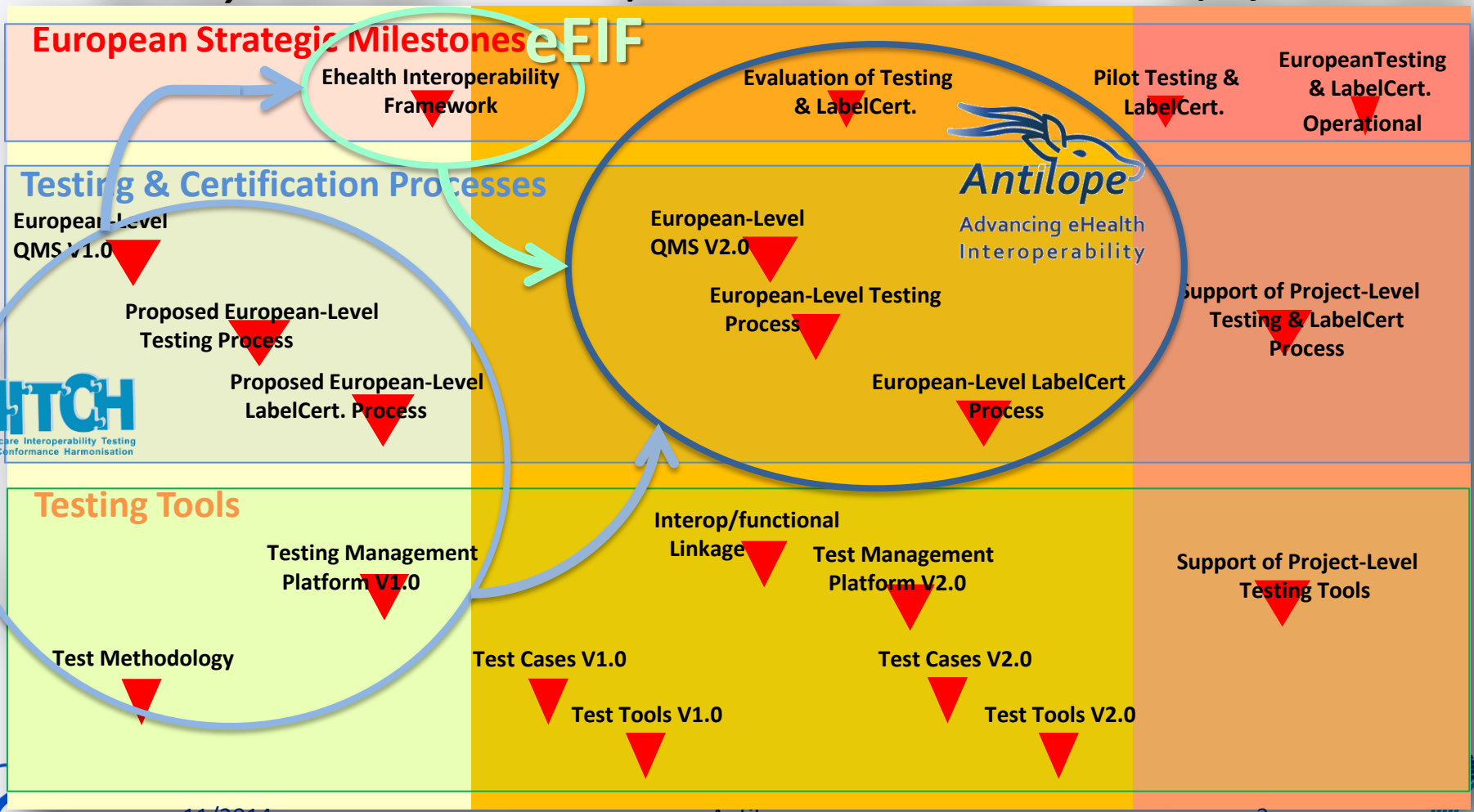
For Healthcare providers

- A harmlonized European market for the eHealth solutions
- Better integration between solutions
- Ability to exchange electronically medical data between Regions and Nations

For Industry

- One recognized quality label or certification process in Europe
- Avoid duplication between the national and regional testing processes
- Factor and mutualize specifications elements and corresponding testing tools

HITCH Roadmap



Key Recommendations

Stimulate the creation of European market based on the evolving European eHealth Interoperability Framework associated with a modular European Conformance Assessment Program

Harmonize the quality label and certification processes in Europe and among countries and regions

Propose a European interoperability quality label and certification process that allows for flexible national or regional approaches

Testing, Quality labelling and certification processes

Functional Model

Quality Label and Certification processes - Definitions

QL & C processes

- Requirements, activities and tasks to support an entity in organizing high quality interoperability assurance or certification

Conformity assessment

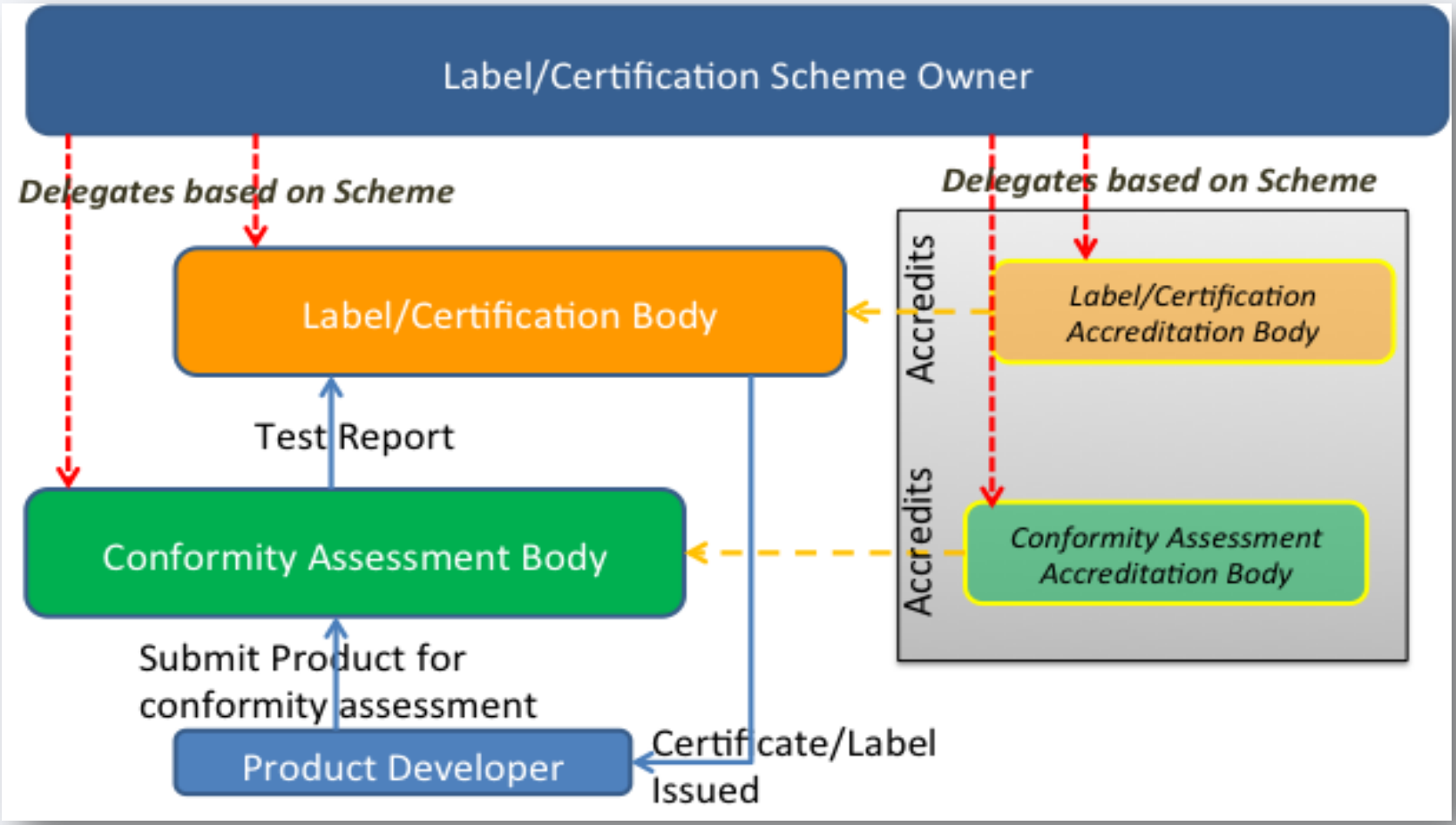
- demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (ISO/IEC 17000)

Functions

A certification or quality label process requires:

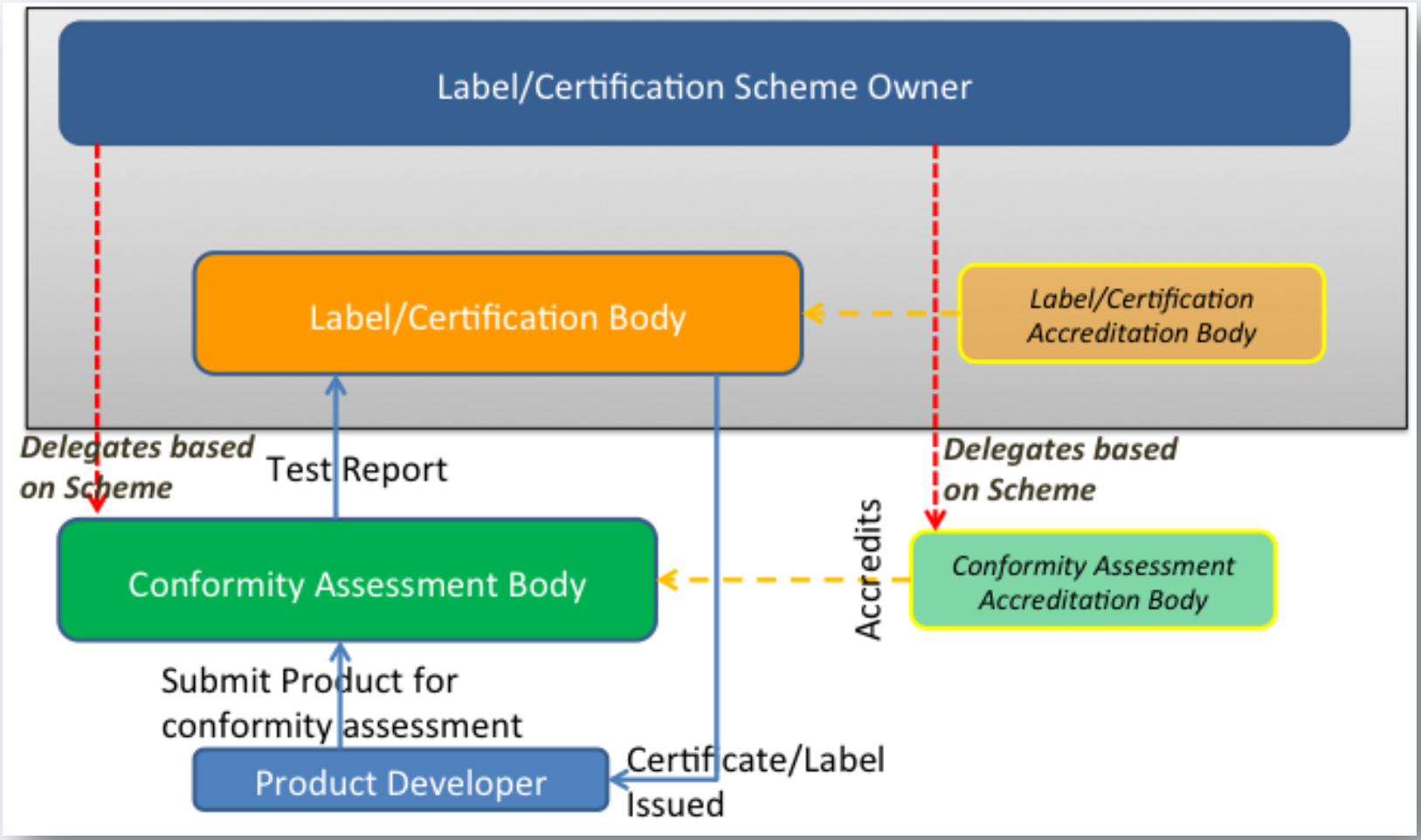
- A *Certification/Label Scheme Owner*: a party that sets the Certification or a quality label program or system;
- A *label/Certification Body*: a party that issues the quality label or certificate on the basis of the conformity assessment performed by a conformity assessment body;
- A *Conformity Assessment Body*: a party that assesses the conformity of products, services and/or suppliers (often called a testing laboratory)

Quality label and Certification Functional Model



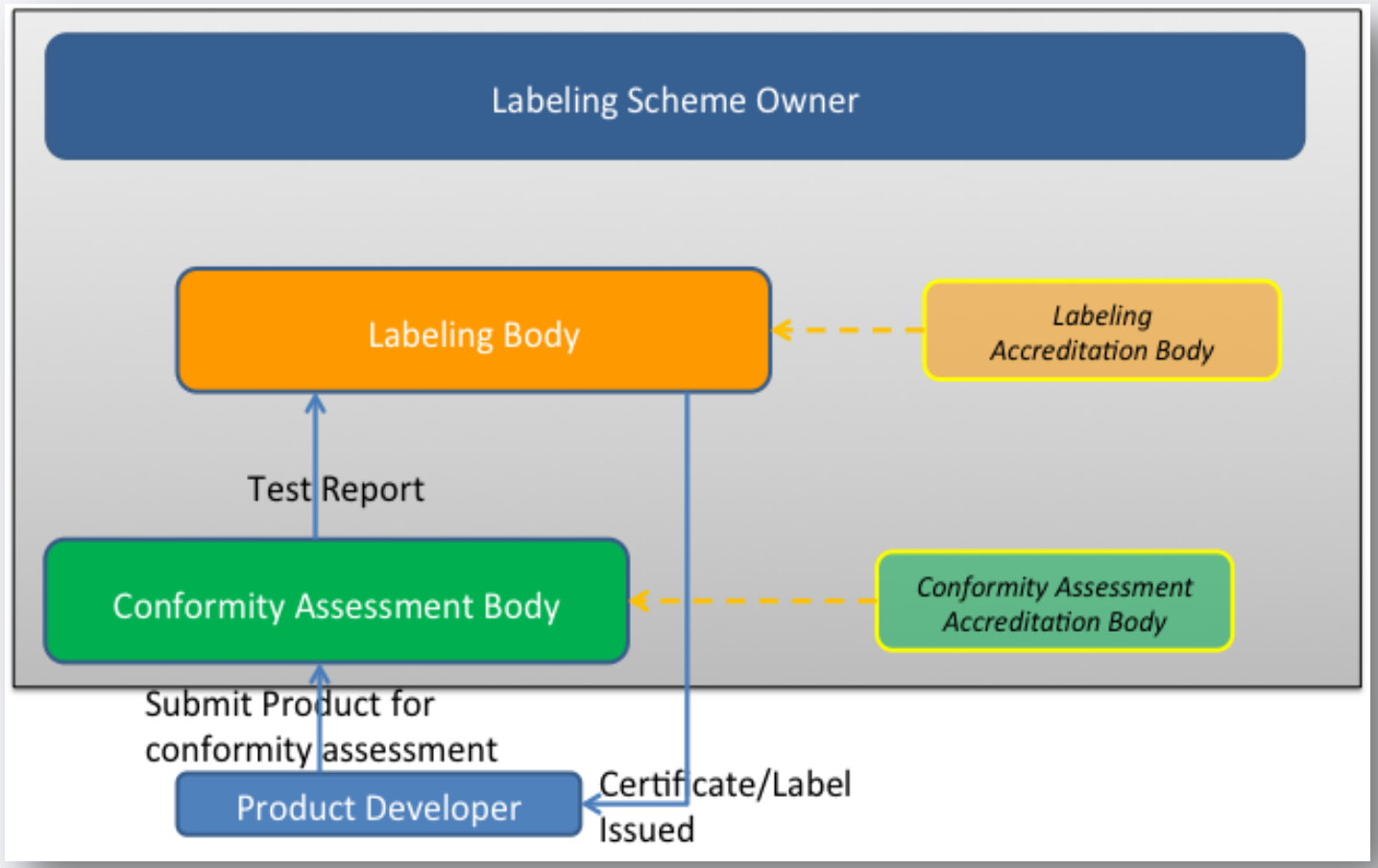
Implementation: Model 1

Labeling by eHealth project using accredited testing lab(s)



Implementation: Model 2

Labeling & testing by eHealth project (no third party accreditation)



Case Studies

Case study – 1 : DMP in France

Step 1

Registration of the Vendor to the process (ASIP Santé)
Registration and published candidates for DMP compatibility

Step 2

Access to the test environment
Access to the support
Pre-Homologation: upload files and validation of the tests

Step 3

Homologation and testing validation
Update and bugs resolution
Final decision by the committee and publication of the results

Label (Homologation) Process

Mapping Services/Standards and Profiles

Transactions DMP pour LPS		Technique : Standards ou protocole utilisés
ACCES SECURISE AU DOSSIER		
TD0.1	Authentification sur le DMP	SAML / TLS
	n DMP et vérification de l'autorisation	HL7-V3
	orisation	(ws)
	utorisés	(ws)
	extuel	--
	NISTRATIVE DU DOSSIER D'UN PATIENT	
TD1.1	Création d'un DMP	HL7-V3
	DMP	
	tives d'un DMP	
	P	
	atient	(ws)
	és/bloqués sur un DMP	(ws)
	documents d'un DMP	IHE XDS-b
CONSULTATION		
TD3.1	Recherche de documents sur un DMP	
TD3.2	Consultation d'un document sur un DMP	
TD3.3	Gestion des attributs d'un document	
AUTRES SERVICES DU DMP		
TD4.1	Notifications	(ws)
TD4.2	Correspondance entre PS et Patient	(ws)
TD4.3	Traces d'un DMP	(ws)
TD4.4	Traces d'un PS sur le DMP	(ws)
TD4.5	Recherche de patient sur le DMP sans INS	IHE-PDQ
TD4.9	Paramètres fonctionnels du SI-DMP	(ws)

Case study – 2 : epSOS project

eEIF

UC1 , UC2a UC2b

Nr	Level	Use case	Profiles
1	Cross-border	epSOS project : e-Prescription and e-Dispensation for cross-border information sharing for citizens travelling in Europe	• IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA* • Pharmacy: PRE*, DIS*
2a	Cross-border	epSOS project : patient summaries for cross-border information sharing for citizens travelling in Europe	• IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA* • Patient Care Coordination: XPHR*
2b	Cross-border	epSOS project - patient having access to his or her patient summary.	• IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA* • Patient Care Coordination: XPHR*

IHE Profiles

epSOS Specifications

IHE Gazelle

Test Plans

Testing Tools

epSOS Testing Process

- New PN
- New NCP

pre-PAT

Projectathon (PAT)

Fail

Pass

- Improvement of an existing service
- Newly added service
- PN who achieved a PAT, and then switched its NCP

Pre-Pilot Testing (PPT)

PPT-slot | PPT-slot | PPT-slot | PPT-slot | PPT-slot

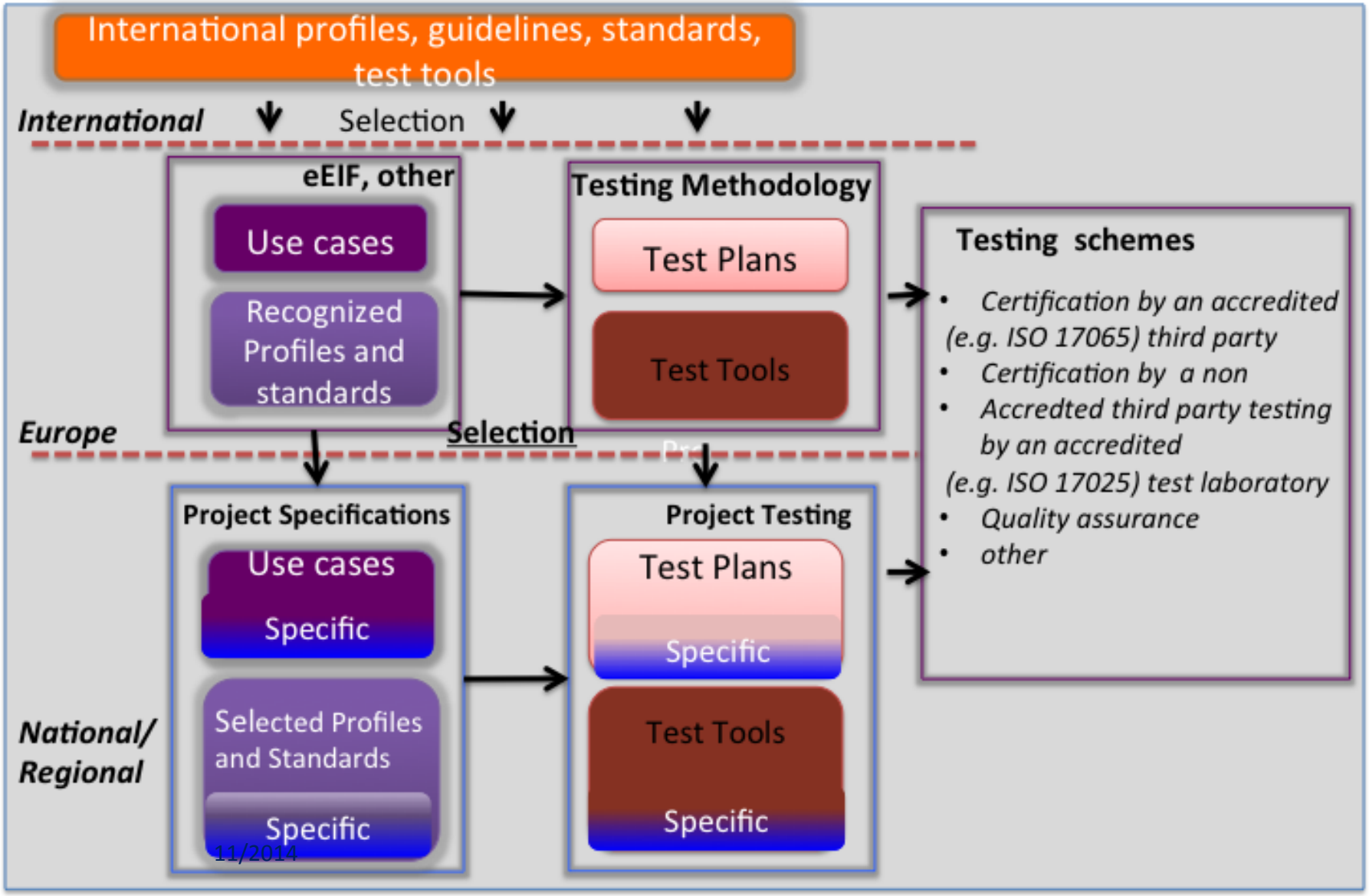
Fail

Pass

Production

Harmonisation of the quality label or certification processes in Europe

The Quality Label and Certification processes (1/2)



In Europe: Three key steps

1	Define the Interoperability Conformance Assessment Scheme closely related with the eEIF
2	Promote creation of accredited Conformance Assessment Bodies in Europe
3	Develop Suitable Organisation for the QL&C process

At the National and Regional levels

1	National and Regional Project leverage profiles recognized by eEIF and use flexibility with needed national extensions
2	Ensure that the European level certification may be used as an entry criteria at the national level
3	Organise acceptance and the recognition of profiles candidates in the eEIF based on local use cases

Guidelines and recommendations

How to deploy QL & C processes In your organisation, region, or Nation ?

4 STEPS

Step 1 Define your needs

Step 2 Setting up

Step 3 Execute and report

Step 4 Assess and Communicate

Step 1: Define your needs on Quality Label or Certification

- **Input**
  - National/regional project using use cases, standards and profiles desscribed in the eEuropean Interoperability framework (eEIF - Antilope WP1) or other needs
  - List of existing Test tools and test plans (Antilope WP3)
- **Activities**
  - Analyse the gaps between the eEIF and the needs
  - Specify the needs of QL or C regarding the specifications and requirements
  - Specify the Conformance Assessment Program scheme for the project
- **Output**
  - *Conformance Assessment Program scheme (CAPS)*
  - *Specifications of the tooling needs*

Step 2 Setting up the QL or C context

- **Input**
  - step 1 output
- **Activities**
  - Select existing test tools and test plans and describe what are missing
  - Specify the tender for the development of the new test tools by following the recommendations of Antilope WP3 (open source recommended)
  - Define the organisation: Is scheme owner,QL or C body the same organisation or two organisations and what are their level of recognition ?
  - Specify the testing process and procedures (WP2 QMS, ISO standards)
  - Select the Conformance Assessment Bodies and their QL or C level
- **Output**
  - *Organisation in place*
  - *Selection of CABs*
  - *Selection of organisations or companies that will develop new test tools and test plan*

Step 3: Execute and Report

- **Input** from the previous steps
- **Activities**
  - Recruit candidates for the QL or C
  - Check whether the candidates have their EU label or certificate
  - Execute the test process
  - Validate and report the results
  - Publish the results
- **Output**
  - *Validation report, passed candidates*

Step 4: Assess and Communicate

- **Input** from all the previous steps
- **Activities**
  - Evaluate the entire process (including the selection of specific profiles, test tools and test plan that can be shared at the European or International level)
  - Communicate on the existence of new use cases, profiles, test plans and test tools and add them in the inventory database
  - Communicate on the results of the QL or C process
- **Output**:
  - *Communication plan*
  - *Assessment Report*
  - *Interoperability Framework to be communicated*

SEVENTH FRAMEWORK PROGRAMME

Next steps and conclusion

- **Next steps:**
  - Collecting all the feedbacks from the summits and other conferences: January to June
  - New vesion to be submitted to the SEPs (experts)
  - Validation by the Core Group in November
  - Final drafts of the deliverables on January 2015
- Few feedbacks received due to the complexity of the topic where expertise is needed
- Benefit:
  - Align with ISO standards
  - Mutualisation and harmonisation in Europe
  - One QL&C processes at the EU level where derivation is described

Next activity: define the Conformity Assessment Scheme (iSPECIFICON)

For more information,

please refer to document D*4*.1.

available on the Antilope website

http://www.antilope-project.eu/