

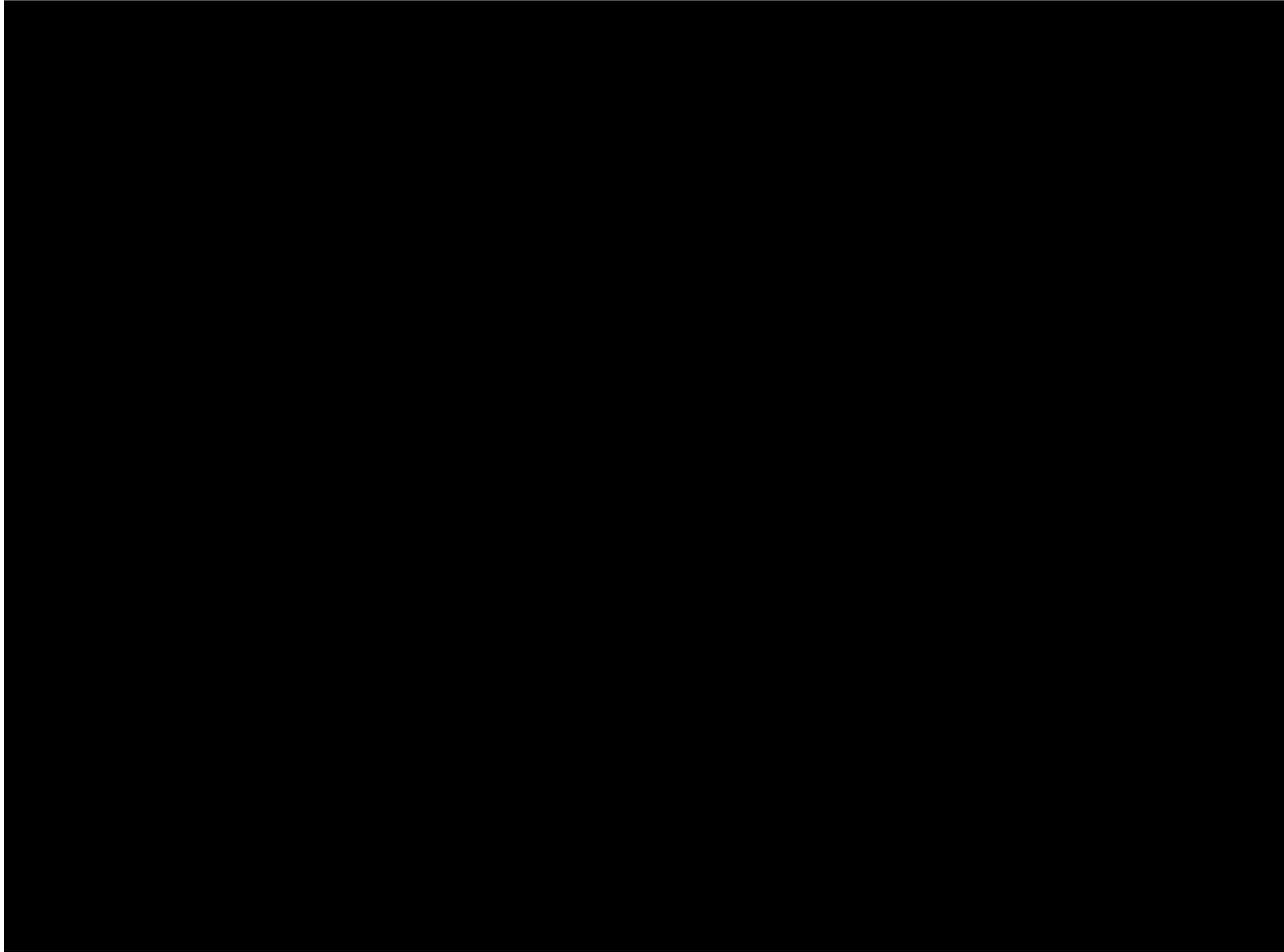
NIST

Global Standards Information



Conformity Assessment Basics and Trade Aspects

Blast Resistant Trash Receptacle Testing



Today's Discussion

- Terminology
- Types of Conformity Assessment
- How it Works
- Standards and Conformity Assessment in Regulation
- Market Access vs. Market Acceptance
- Pathways to Trade

Conformity Assessment

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



The Parties – who done it?

- 1st Party
- 2nd Party
- 3rd Party

1st Party – seller or manufacturer

2nd Party – purchaser or user

3rd Party – independent entity

Government – in regulation

Types of Conformity Assessment

1st Party

2nd Party

3rd Party

SDoC	ISO/IEC 17050
Testing	ISO/IEC 17025
Inspection	ISO/IEC 17020
Certification	ISO/IEC Guide 65
Registration	ISO/IEC 17021
Accreditation	ISO/IEC 17011

Supplier's Declaration of Conformity (SDoC)

1st Party

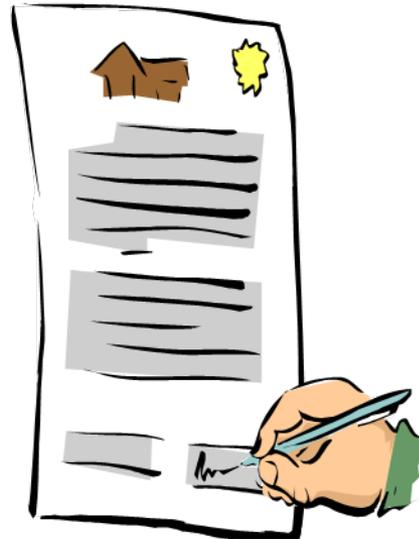
2nd Party

3rd Party

Characteristics

- Used when low product risk
- Penalties for noncompliant products
- Effective recall system

Examples



- ISO/IEC 17050



Testing

1st Party
2nd Party
3rd Party

Characteristics

Examples

- Measures Characteristics
- Representative samples are often used
- May be element of SDoC or certification system

- *ISO/IEC 17025*





Certification

1st Party
2nd Party
3rd Party

Characteristics

- Used when moderate – high product risk
- More expensive
- Surveillance

Examples



- *ISO/IEC GUIDE 65*

Accreditation

1st Party

2nd Party

3rd Party

Characteristics

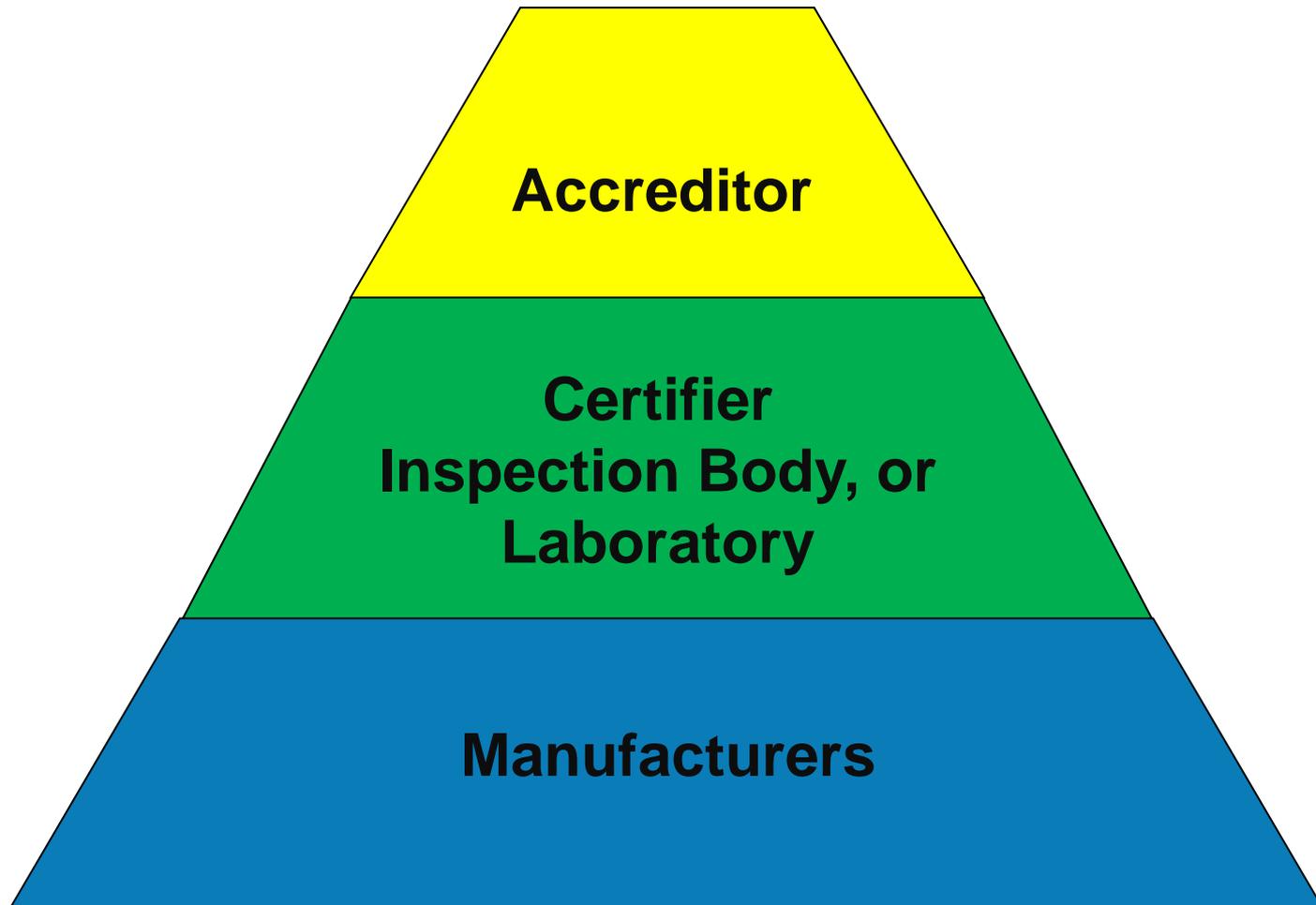
- Formal demonstration of competence to carry out specific tasks
- Provides confidence for purchasers, regulators and consumers

Examples



- *ISO/IEC 17011*

Who watches the watchers?

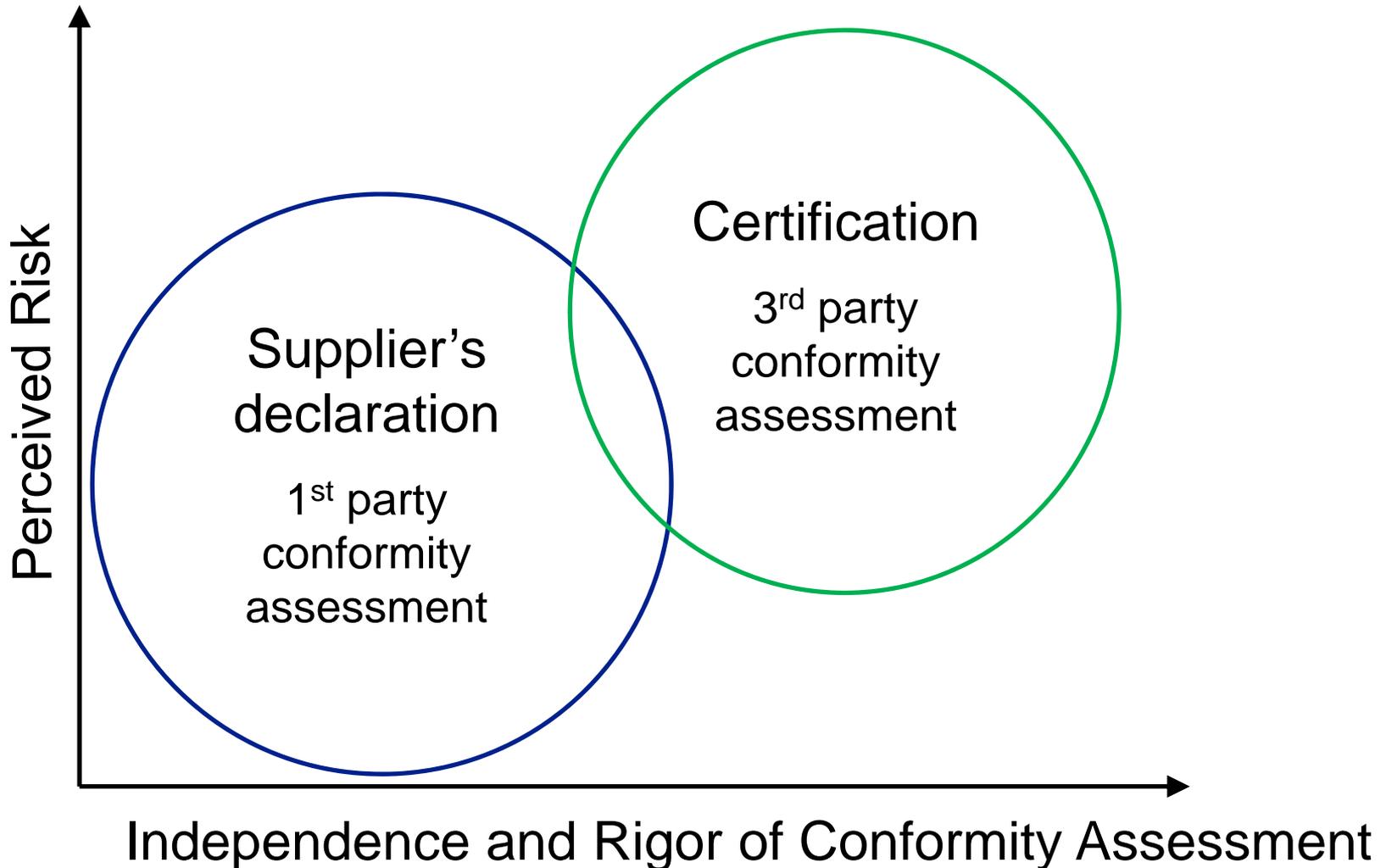




Factors in Conformity Assessment Systems

- Risks associated with non-compliance should be proportional to the rigor of the system design
 - ▶ Over-design costs too much
 - ▶ Under-design gives too little confidence
- Marketplace consequences (penalties) & effective recall allow less rigor

How much confidence is needed?



Regulatory System - USA

- Diversity in use of standards and conformity assessment by different government agencies and within government agencies
- Reliance on private sector standards, supported by the National Technology Transfer and Advancement Act and OMB Circular A119
- Regulation based on locale of use for many products with overlap. State and local regulation in addition to federal regulation
 - CPSC – homes, schools and places of public enjoyment
 - OSHA – the workplace
- Extensive use of supplier's declaration – formal and informal
- Moves to use of accredited private sector conformity assessment for regulatory purposes
 - FDA Accredited Persons Programs
 - FCC Telecommunications Certification Bodies
- In some sectors private sector programs preceded government regulation and are still effective – products for fire protection, roofing, electrical safety.
- Some regulatory systems not standards based – FDA 510(k) pre-market clearance
- Established national standards and unique safety concerns make harmonization with “international” standards (ISO and IEC) a challenge

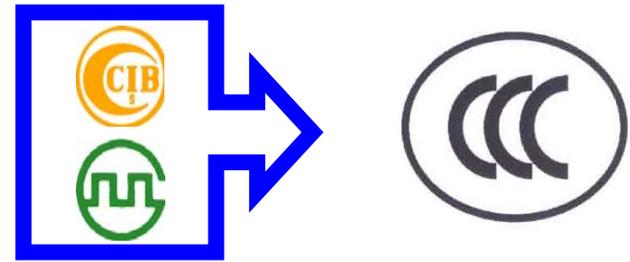


Regulatory System - EU



- “New Approach” based on European Commission Directives replaced member state regulations. New Approach motivated by desire to facilitate internal EU free trade and to create a market to compete with major trade countries such as U.S. - not to improve safety, health and environment
- European Commission develops directives with “essential requirements” – very few specific technical requirements
- European SDOs (CEN, CENELEC) develop European Norm (EN) standards to support essential requirements
- Compliance with appropriate EN Standards provides presumption of conformity with essential requirements – other approaches are technically allowed, but difficult
- CE marking placed on products declared to comply with essential requirements of directives – allows free movement of good within the European Union
- Generally, the CE marking is not a certification mark and is based by supplier’s declaration and required technical file
- For high risk sectors the use of Notified Bodies (3rd party conformity assessment organizations) is required before declaring conformity and placing the CE mark on a product
 - Examples: medical devices, electrical products for use in hazardous environments
- Post market surveillance left to member states with limited resources from European Commission

Regulatory System - China



- China's national standards referred to as "GB" Standards
 - Based on IEC/ISO Standards with Chinese National Differences
 - Safety and EMC Standards
- Products on compulsory list are required to be certified and bear the CCC Mark
- Type testing at a CNCA accredited laboratory and certification including annual factory surveillance by a CNCA accredited certifier is required
- Chinese government agency (CNCA) administers the system
- Only wholly owned Chinese organizations can be accredited certifiers at this time
- Previously China had two separate systems one for domestically produced products and a separate more onerous one for imports
- China's entry into the World Trade Organization (WTO) and compliance with the Agreement on Technical Barriers to Trade (TBT) motivated the development of one system for both

Market Access vs. Market Acceptance

Market Access



Product Meets the Legal Requirements

Market Acceptance



**Product Meets
Non-Regulatory Market
Expectations**

Mechanisms to Facilitate Trade - Examples

Supplier's Declaration of Conformity

Mutual recognition of laboratory accreditation

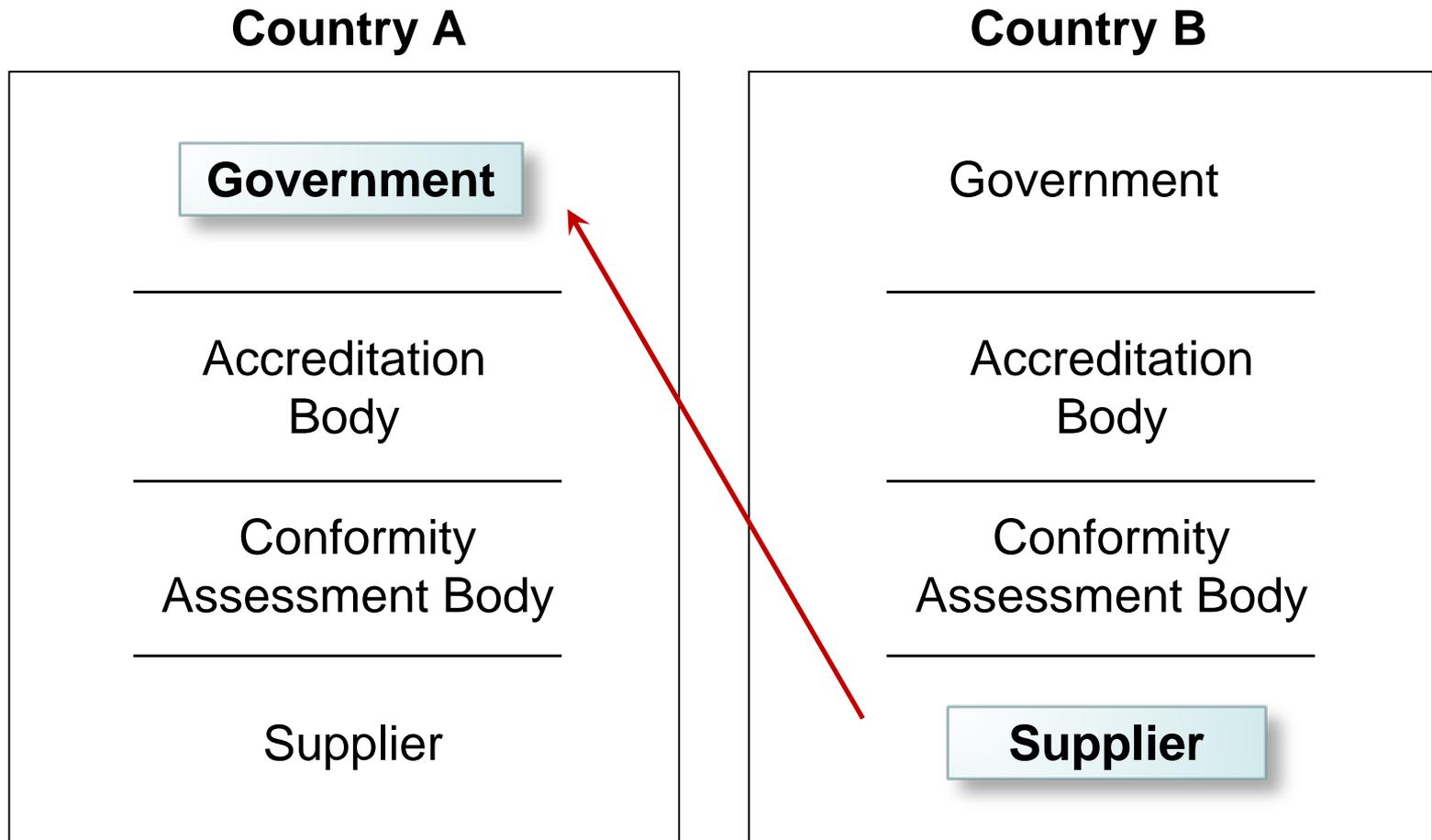
National treatment for conformity assessment organizations

Private sector data exchange agreements among certifiers

Government-to-Government Mutual Recognition
Agreements/Arrangements

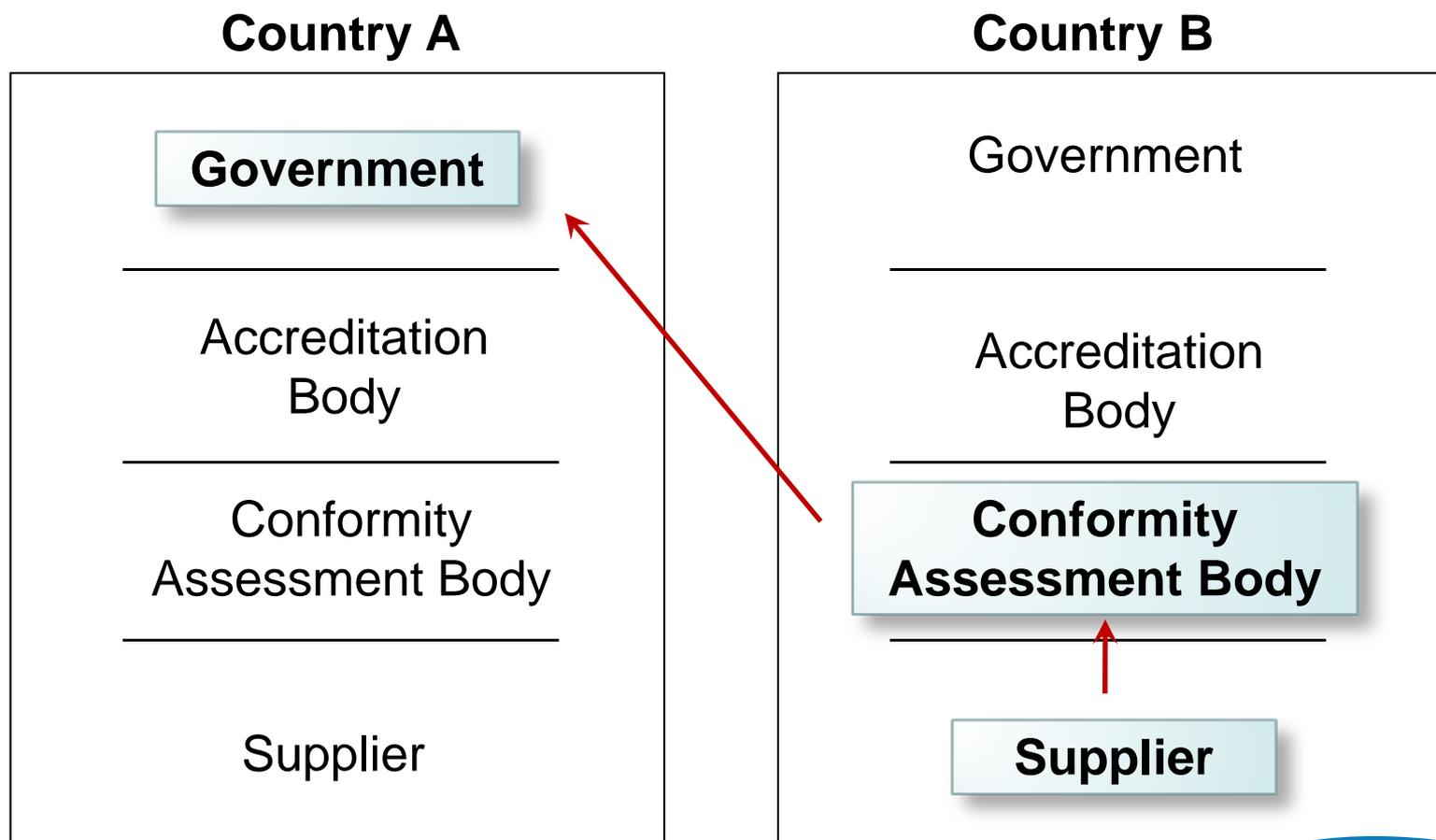
Pathways for International Trade

Supplier's Declaration of Conformity



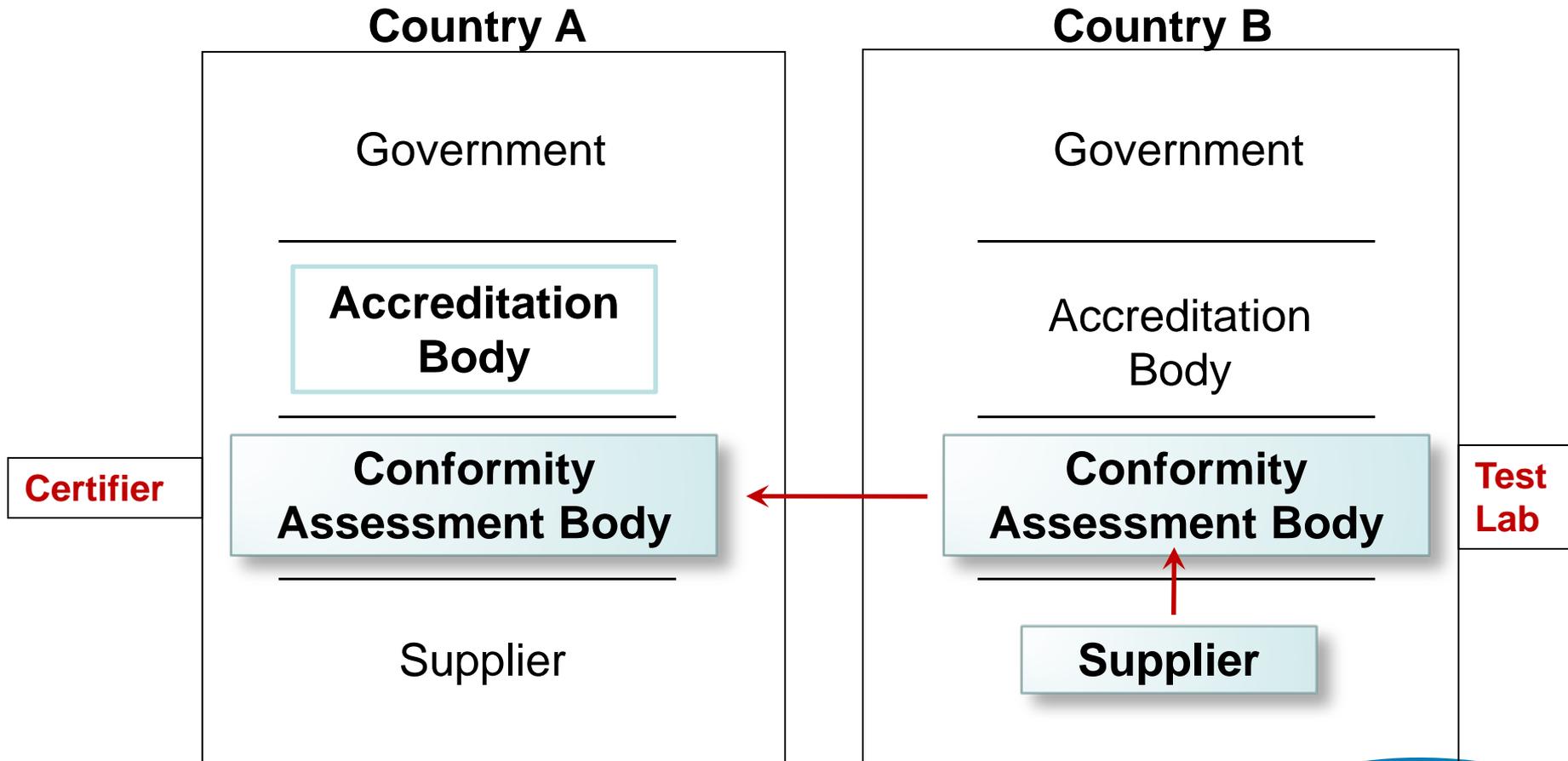
Pathways for International Trade

National Treatment Conformity Assessment



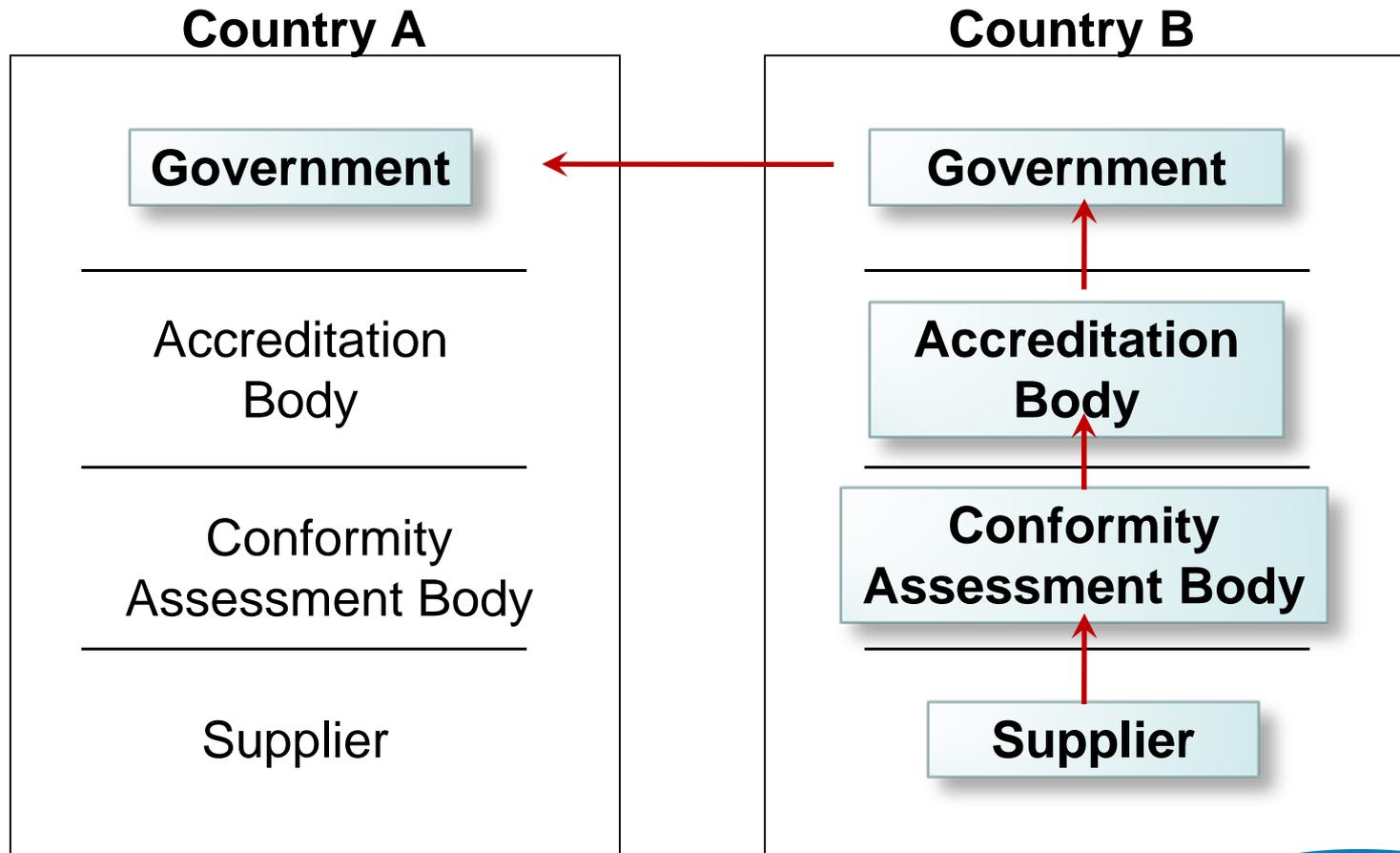
Pathways for International Trade

Data Exchange Agreements



Pathways for International Trade

G2G Mutual Recognition Agreements



Review

- Terminology
- Types of conformity assessment
- How it works
- Standards and conformity assessment in regulation
- Market Access vs. Market Acceptance
- Pathways to Trade

Thank You

Conformity Assessment

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