

SwissCham Event: Market Access for Products and Services in China Regulations & Standards

Beijing Capital Club

1 June 2010



Quality Partnerships LLC



*International expertise,
Local practice and
Clear understanding*

*Make Quality Partnerships your trustworthy choice for
obtaining speedily **market access licenses** in **China***

Quality Partnerships LLC (QP):

- incorporated in Switzerland
- offices in Beijing and Zurich

QP is dedicated to the improvement of **Quality Infrastructure**, namely:

- testing and certification
 - standardization
 - market surveillance
 - investments in this sector

QP assembles together **experts** with long term experience in those fields; QP experts are supported by a team of **professionals** with different backgrounds and common solid track record.

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General remark at beginning:

- Europe reference = EU legislation for common market
 - Applies for all EU and EFTA countries (texts with “EEA Relevance”), except for CH
 - “Autonomer Nachvollzug”: These type technical regulations have been adopted in CH to almost 100%
 - Not adopted in CH: Tools for common market surveillance, e.g. RAPEX information system, REACH chemicals registration system
- European Standards (EN standards) = SNV Standards
 - CH is full member of CEN/CENELEC/ETSI, means that all EN standards apply in CH
 - CH is member of CEPT agreement, means that all ETSI standards apply in CH

The Basic Difference:

- Access to European market is in general free – as long producer / importer can prove that product is safe
 - Compliance with harmonized standards gives presumption of conformity (New Approach Sectors)
 - CE marking is a self-declaration by producer
- Access to China market is restricted – in most cases a permit is needed to import / place products in market
 - Government permit is required for most products and services before being placed on market
 - For many consumer products CCC certificate is required

- Market Access is restricted – for most goods one or several pre-market approval schemes apply:
 - CCC Scheme according to catalogue published by CNCA, based on compulsory National Chinese Standards (GB)
 - Licensing Schemes controlled by various ministries, based on technical regulations, National, and Industry standards
- For mechanical and electrical goods an importation license is required which is linked to the port of entry
- For goods not listed in the CCC catalogue and for which no specific licensing applies, market access is free as long product complies with general rules for safety and environmental protection
- Some goods require marks and labels on a self-declaration basis
 - China Compulsory Energy label
 - China RoHS declaration for electronic products

Who is in charge for safe products?

- In Europe: Safety of products and services placed on market is the sole responsibility of producer / importer
 - Pre-access: Government controls for few high risk products only
 - Post-access: Market surveillance activities by member states
 - No expert controls (except dual use)
- In China: Shared responsibility government and producer
 - Pre-access: Producer must ensure that products are safe
 - Pre-access: On top of this – government gives permits for market entry based on quality criteria
 - Post-access: Market surveillance activity by provincial governments
 - Export permits for quality-sensitive products

a) Formal Legislation

- Legislation, e.g. standardization law, consumer protection law, energy saving law, food safety law, IP law, etc.
- Regulations, e.g. CCC market access scheme, regulations about indigenous innovation products, etc.
- Instructions for implementation of regulations, e.g. CCC implementation rules

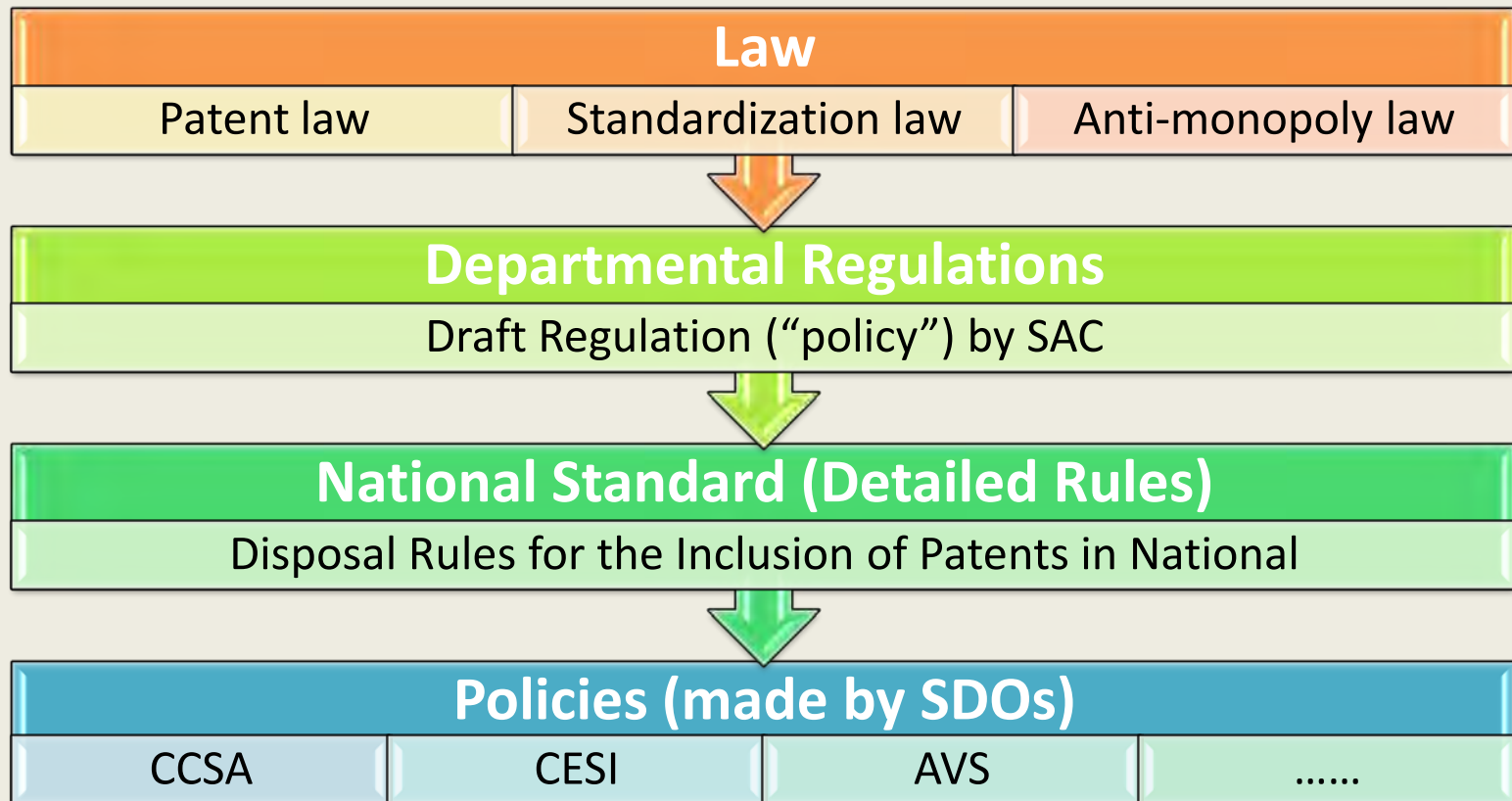
b) Co-Regulations (soft regulation)

- Compulsory standards (part of technical regulations, but adopted in informal process)
- Voluntary Chinese standards

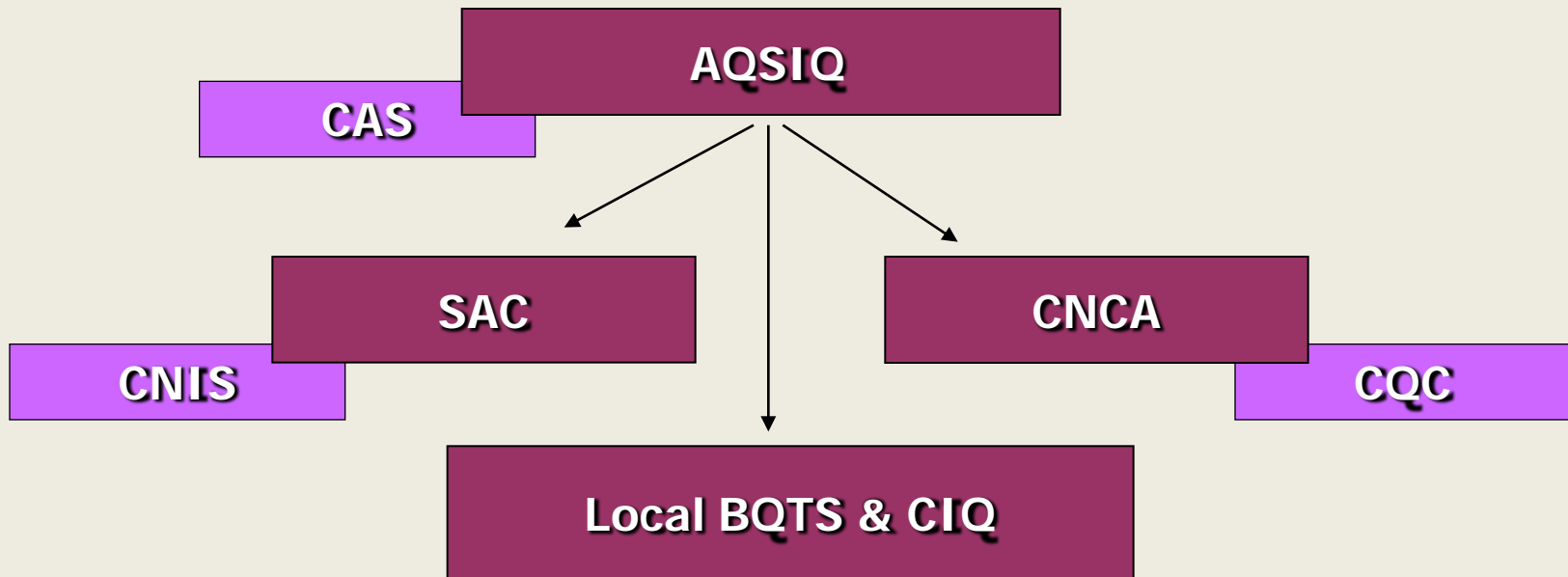
China Standardization System

- System matured, probably more standards than any other country on earth (over 100'000 standards, compared with 20'000 EN standards)
- China has a defined standardization strategy based on legal framework, clearly allocated resources
- SAC is in charge for management of the Chinese standardization system and owns China National Standards
- MIIT (Science & Technology Department) coordinating inter-national contacts for ICT standardization, especially towards ITU
- Chinese standardization in general lives up to the criteria of stakeholder participation and due process
- Close link between standardization and conformity assessment
- China aims at a fair share of chairmanships, secretariats of TC on ISO/IEC/ITU level

1. Standardization is a tool to disseminate scientific experience and accelerate technical innovation (“leapfrog technologies”)
2. Standardization is a tool to develop a strong domestic knowledge base and a related industry (“home-grown standards”)
3. National safety and security interests shall be reflected in the standardization system
4. Export of Chinese standards shall support Chinese trade policies, e.g. in the field of IPR in standards



- Consensual Technology Transfer
 - Standardization reflects “Best Practice”, allowing industry to integrate R&D and management experiences
 - IPRs locked into European standards are based on the “FRAND” principle, and thus publicly available against fee
- Forced or Induced Technology Transfer
 - Access to standard development in China in exchange for technical contribution, including technology disclosure and know-how transfer
 - Performance standards as basis for market access



AQSIQ = Administration for Import and Export Control (Ministry)

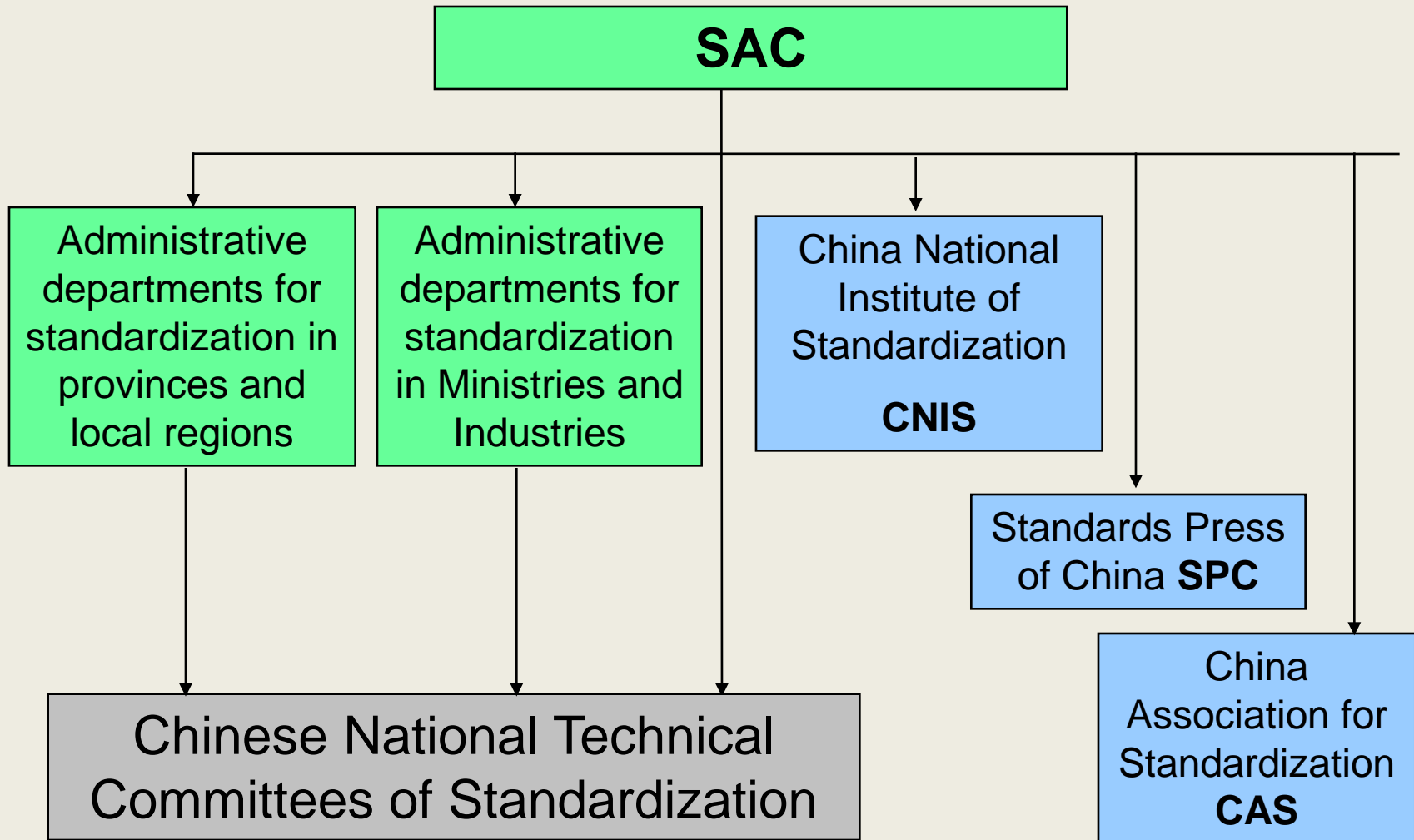
SAC = Standard Administration of China

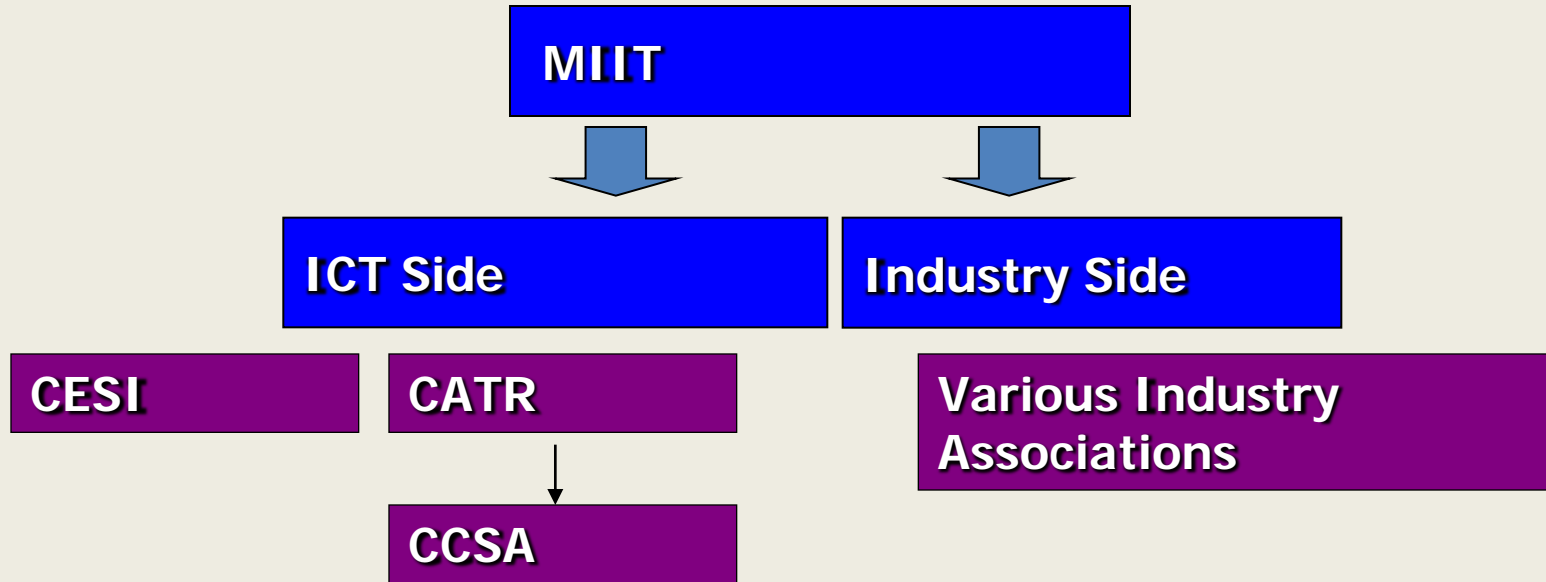
CNCA = China National Certification and Accreditation Administration

CNIS = China National Institute for Standardization

CQC = China Quality Centre

CAS = China Association for Standardization





MIIT = Ministry for Industry Information Technology
CESI = China Electronics Standardization Institute
CATR = China Academy for Telecom Research
CCSA = China Communication Standards Institute

Standardization Law Stipulates: Openness, Transparency, and Impartiality, however:

- Standards are provided by government for industry
- Stakeholder involvement (exception: foreigners...)
- Government mandates (compulsory)
- Due process & consensus driven
- Government is the ultimate arbiter
- Standard development bodies are government controlled organizations
- TC participation depending on SDO policy
- Principle of “National Treatment” not fully implemented
- Working group members appointed ad personam
- IPR policies – depending on SDO and TC
- Financing by government, co-sponsoring by industry

Quality control: Conformity Assessment and Market Surveillance (8)

Economic Operator's responsibility

PRE-MARKET ASSESSMENT

- **Products must fulfil
Essential
Requirements**
- **CE marking**



Member State responsibility

POST-MARKET CONTROL

- **Compliance with
Essential
Requirements**
- **Market surveillance
authorities**

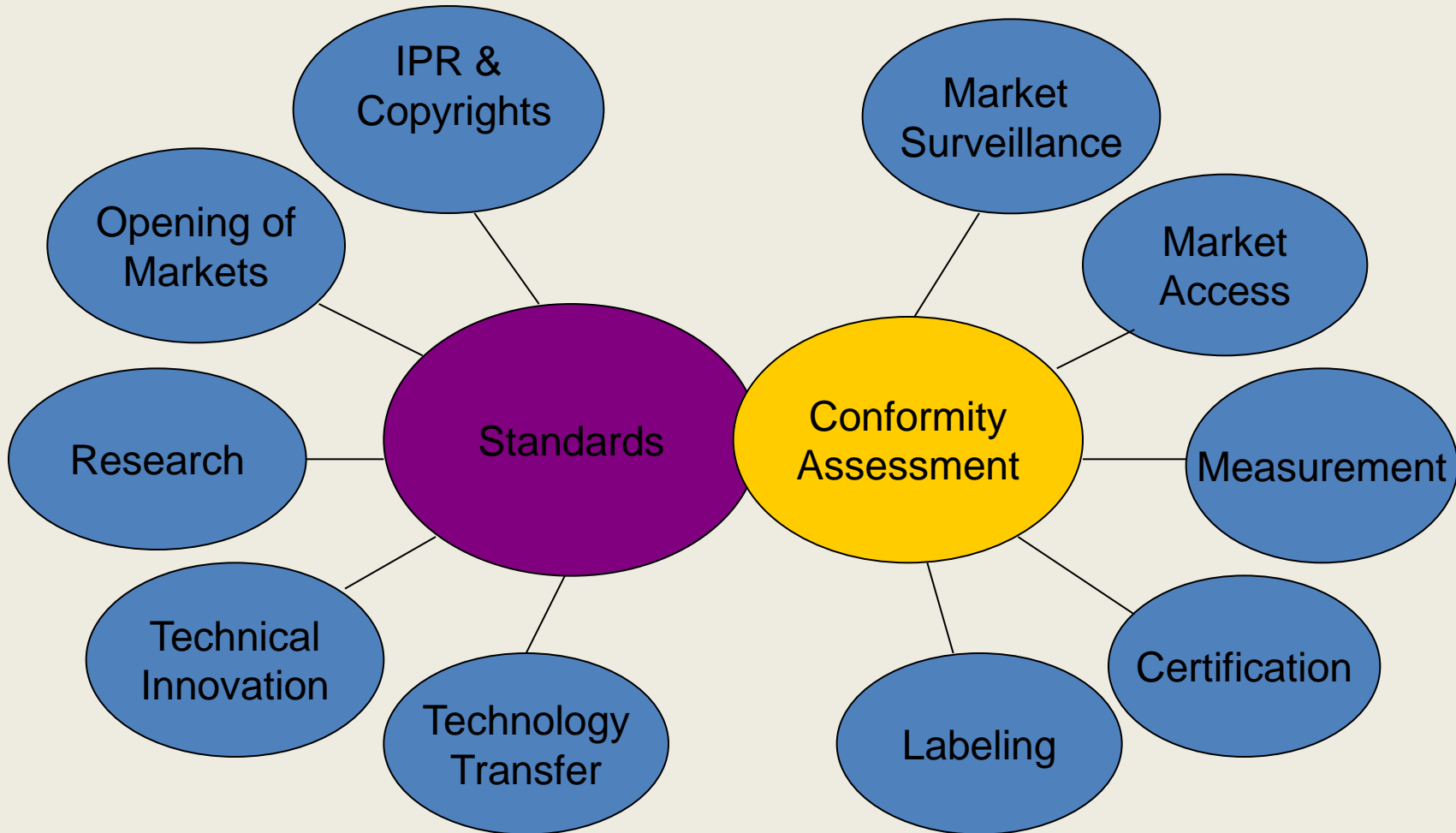
Manufacturer is responsible for conformity

- using defined procedures (“modules”)
- aided by Notified Bodies
- manufacturer free to choose Notified Body

AIM: Create the necessary level of confidence

- Integrative Approach established 8 different “modules” to cover different situations
 - Modules range from manufacturer’s declaration to full quality assurance certification
 - Choice of modules is laid down in each sectoral Directive, they cover both design and production phase
- **All procedures give equivalent results: presumption of conformity**

- A Internal production control
- B EC type examination
- C Conformity to type
- D Production quality assurance ISO 9001
- E Product quality assurance ISO 9001
- F Product verification
- G Unit verification
- H Full quality assurance ISO 9001



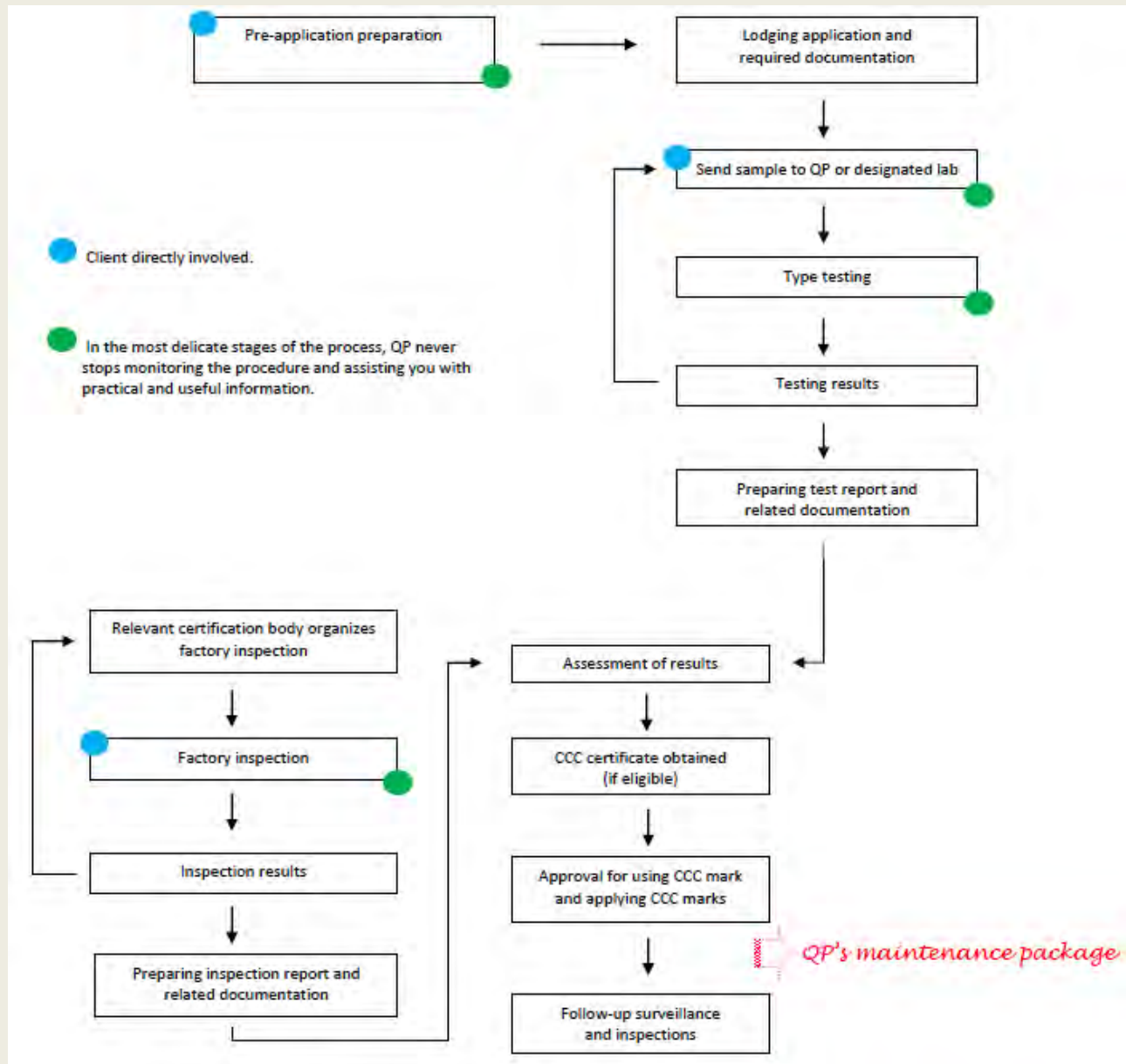
CCC at a glance:

- needed in China mainland only
- compulsory market-access license
- focus on product safety, environmental performance, consumer protection
- applies to 23 categories of products
- based on Chinese national standards (GB standards)

23 categories of products:

- ▶ Household appliances
- ▶ IT communication equipment
- ▶ Electric and electronics products
- ▶ Electrical Tools
- ▶ Toys and decorative articles
- ▶ Motor vehicle and safety parts
- ▶ Wires and cables, lamps
- ▶ Information security products
- ▶ Condoms
- ▶ Etc.

CCC was introduced in China on request of China's trading partners during the WTO accession negotiations. CCC is a unique Chinese system and cannot be compared with anything else (e.g. CE-Mark)

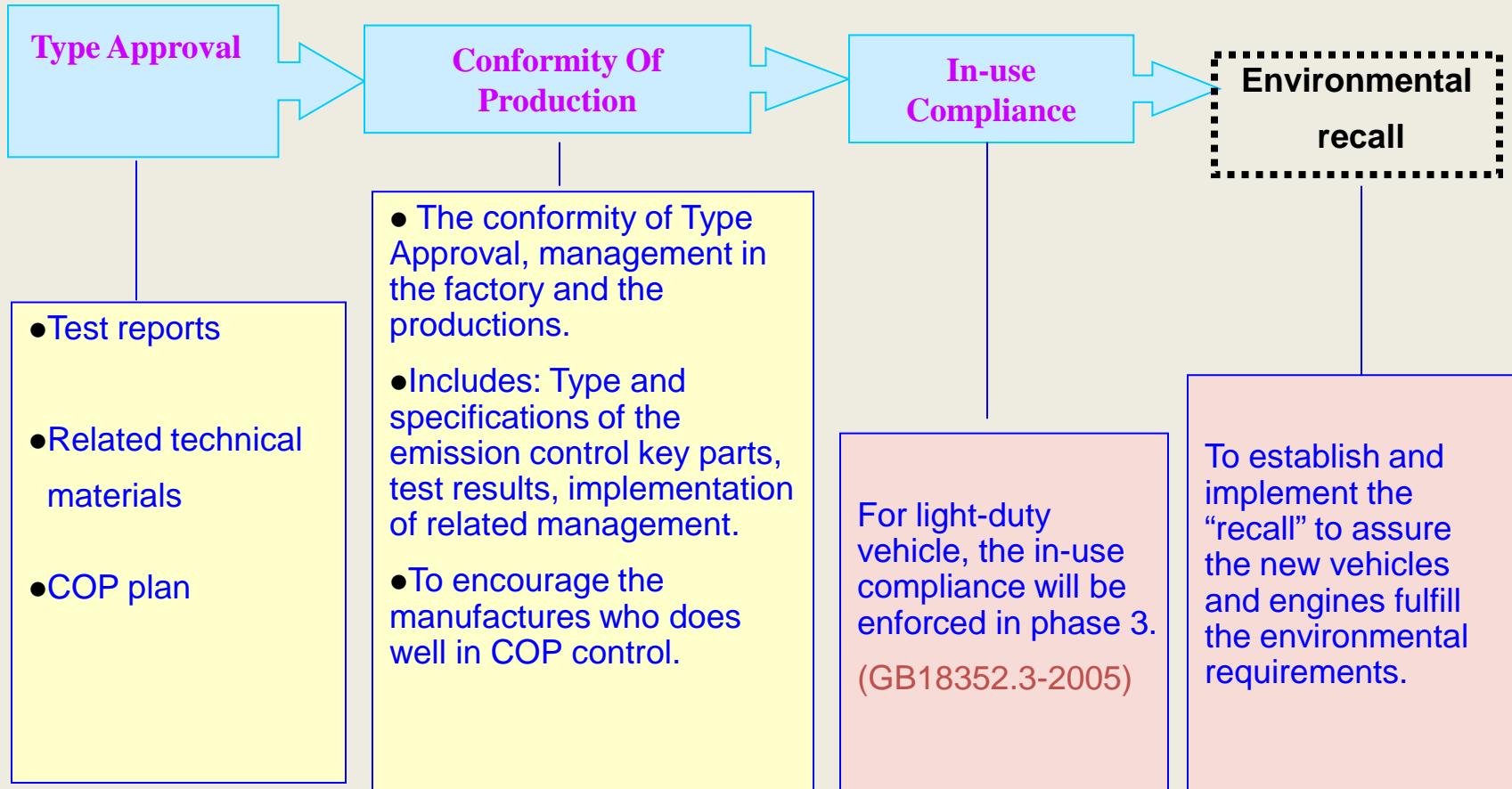


How to obtain CCC ?

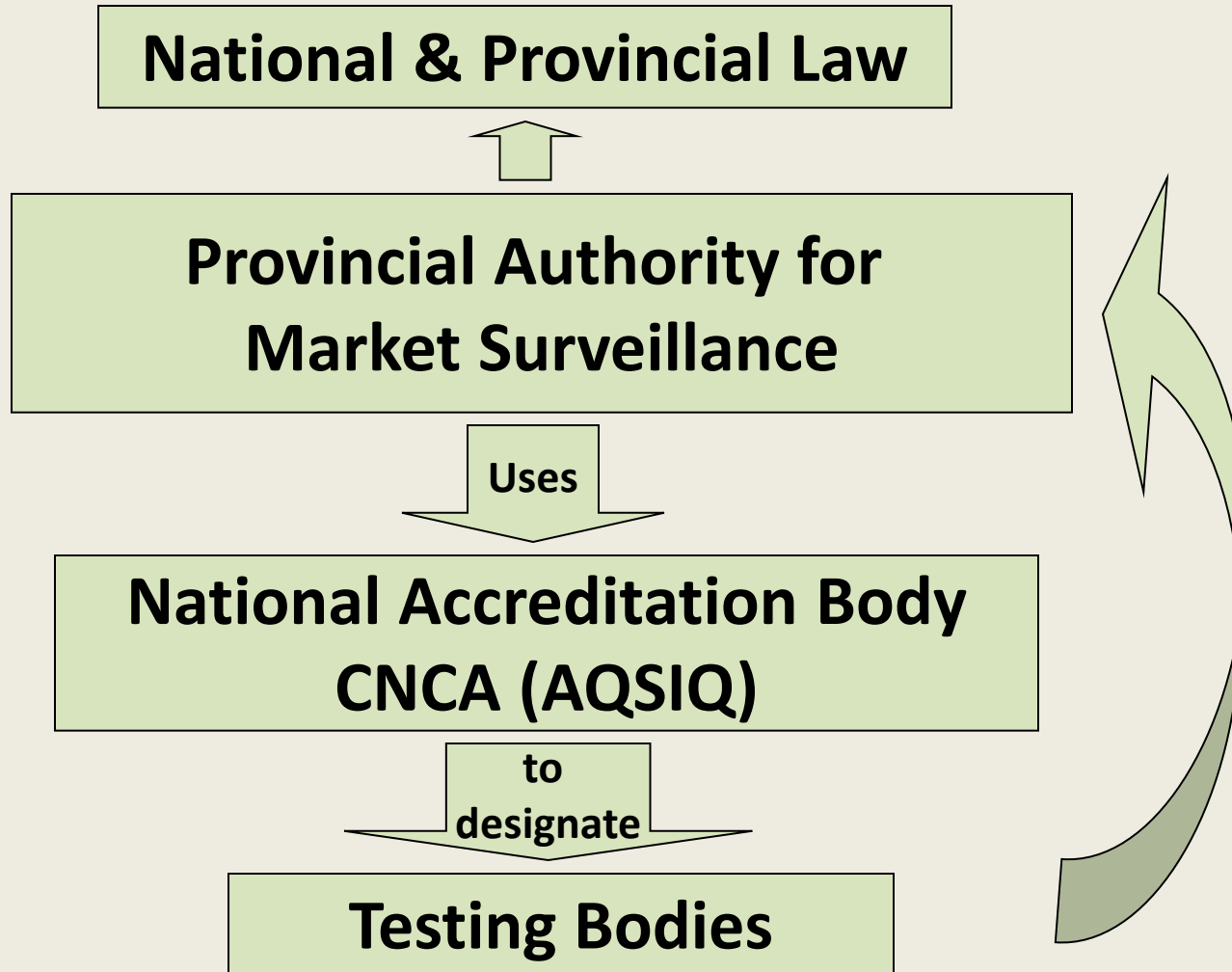
Besides CCC, there are **other mandatory schemes**, based on sector-specific rules and *Chinese standards* or *Chinese trade sector standards*:

- A **radio-transmission type approval**, which applies to equipment transmitting electromagnetic wave signals;
- A **network access license** for telecom equipment, including cellular phones;
- A **homologation process** for vehicles to be used on public roads;
- An **approval process for high risk equipment** ('Special Equipment') – particularly, pressure vessels, pipelines, elevators, cranes and lifts;
- A **licensing scheme for heavy polluting equipment**, such as vehicles exhausts;
- A **registration scheme for Health Care Equipment** ('HCE') with the respective health authorities;
- An **approbation for cosmetics and hygiene articles** with the respective health authorities.

Environmental Protection Requirements: Cars



- In principle: similar approach as Europe
 - Organizational / operational requirements
 - Cooperation between national and provincial authorities
 - Safeguard clause and information procedures
 - Obligations for economic operators
 - CCC certificate + licenses where applicable
- Two authorities share the task
 - AQSIQ on questions related to immediate health hazards, safety, and environmental protection
 - SAIC on all issues related to operation of factories
 - In addition: Multiple authorities have specialist inspectors on the ground (e.g.: fire protection, food safety, infosecurity, energy specialists, etc.)
- A special China feature: Export Controls
 - System similar to CCC system but without certificate
 - Catalogue of products published by CNCA



Cooperation Tools

In a Global World Without Barriers to Trade: Standards are the Tool for Market Access



- Regulatory Dialogue between EC (DG Enter) and AQSIQ: 12+ Working Groups, incl. Standardization and Conformity Assessment
- Dialogue between EC (DG Sanco) and SFDA: 3 Working Groups, plus cooperation on consumer protection issues and RAPEX (!), RASFF
- Dialogue mechanisms with NDRC and MIIT (incl. WG on SME)
- European Standardization Expert for China: Joint cooperation effort between European Standardization Organization, EC, EFTA
- EU-China Cooperation project facilities
- Joint China-EU Standards Internet Platform CESIP
- EU Member States initiatives
- Industry participation in Chinese Standardization Work

www.eu-china-standards.eu

www.eu-china-standards.cn

Mutual trade and investment flow

- The aim of the EU-China Standards Information Platform is to make standards and related technical regulations more accessible.

Europe-China cooperation

- The Platform is one of the main and more visible results of the cooperation of EC, EFTA and the ESOs with SAC

Access to industry standards

- The main complain of European industries is the lack of transparency and access to Chinese industry standards. This adds a unique feature to this Platform



Suggestions for active Participation of Industry



- Active participation in standards making process in China, especially also SMEs → source for invaluable market insights
- A proven tool: Expert Round Tables (exchange between standardization, testing, and inspection experts), if necessary with EU support
- Get to know your testing labs: Active participation in lab development can help solving major problems in future
- Give active support for Chinese contributions to ISO/IEC/ITU/UNECE standardization
- Participate in European and Chinese industry associations: The exchange between such organizations can be of great support
- Compulsory certification is often key to market access: You can actively contribute in the development of such schemes
- Seek professional advise: Quality Partnerships LLC

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Thank you