



THE SYSTEM OF CONFORMITY ASSESSMENT

New Delhi, 30th June 2009

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European Commission
Enterprise and Industry



THE NEED FOR A SAFE ENVIRONMENT

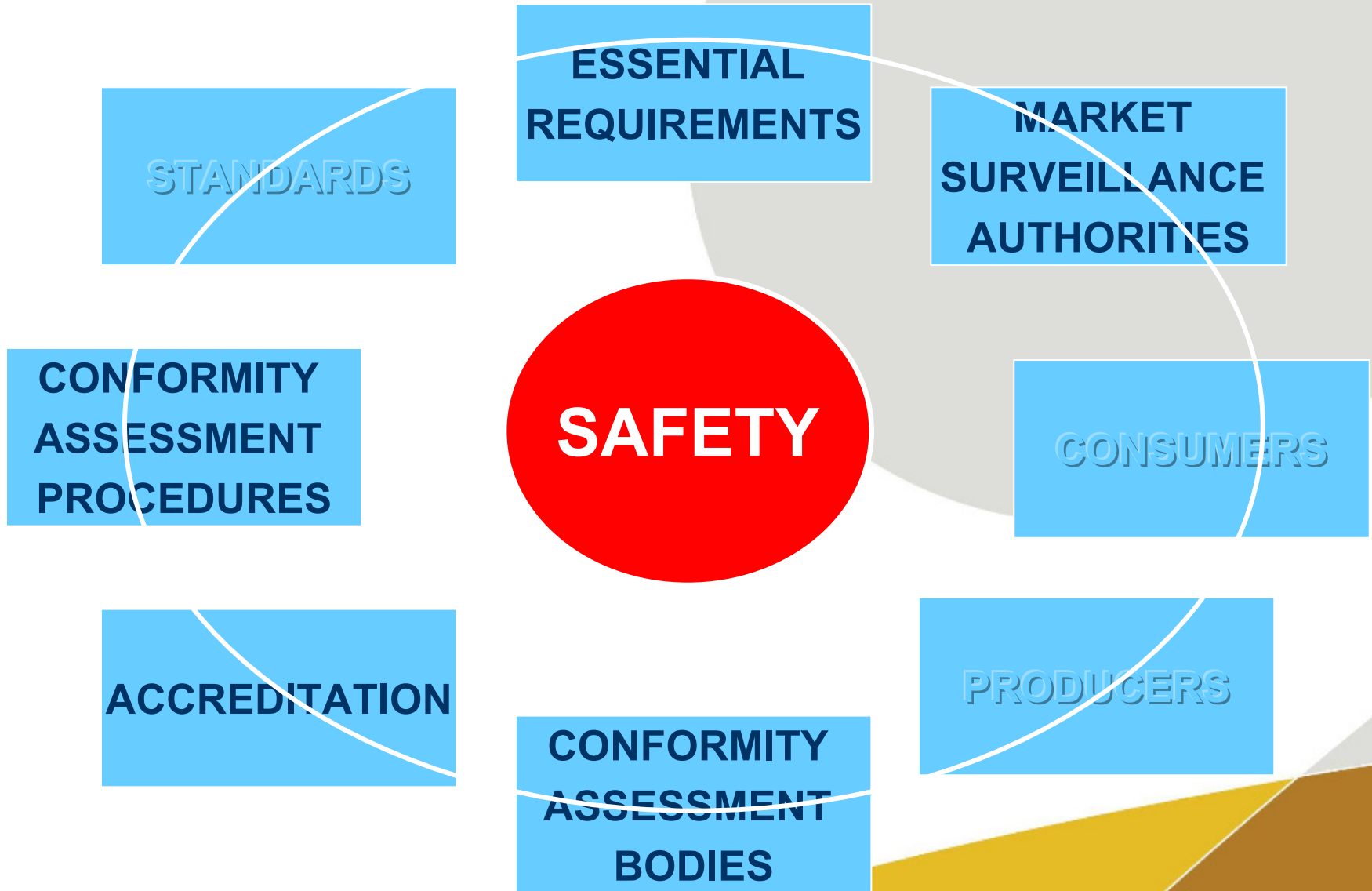
- Ensure safety
- Protect consumers
- Enhance trust
- Avoid distortion of competition
- Guarantee equal treatment

...but:

- No single solution
- Combination of several tools



AN INTERCONNECTED SYSTEM





EX-ANTE ASSESSMENT

ESSENTIAL REQUIREMENTS

- **Included in legislative acts**
- **Very general (i.e. ‘toys have to be safe’)**
- **Compulsory in all their parts**
- **Extensive geographical application**
- **Applicable to all items to be sold in the single market**



EX-ANTE ASSESSMENT

CONFORMITY ASSESSMENT PROCEDURES

- Chosen according to the risk involved
- Proportionate and effective
- Clear and certain (included in legislation)
- First party declaration as a priority (Supplier's Declaration of Conformity)
- Third party certification



EX-ANTE ASSESSMENT

CONFORMITY ASSESSMENT PROCEDURES

- **Procedures divided into 8 different modules**
- **Modules range from manufacturer's declaration to full quality assurance certification**
- **Range of options set in Directives**
- **All procedures give equivalent results: presumption of conformity**



EX-ANTE ASSESSMENT

CONFORMITY ASSESSMENT MODULES

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





EX-ANTE ASSESSMENT

STANDARDS

- **Developed by independent bodies**
- **Agreed among all stakeholders**
- **In line with international standards**
- **Voluntary**
- **Certain (but not included in legislation)**

Their use implies presumption of conformity with the essential requirements



EX-ANTE ASSESSMENT

ACCREDITATION

- **Single accreditation bodies**
- **Non-competition / public authority**
- **Requirements for accreditation bodies**
- **Peer evaluation**
- **Information obligation / transparency**
- **European Cooperation for Accreditation**



EX-ANTE ASSESSMENT

CONFORMITY ASSESSMENT BODIES

- **Responsible for conformity assessment**
- **Issue certification**
- **Independent / no conflict of interests**
- **Accredited in their Country**
- **Designated by a public authority**
- **Competition on the Single Market**
- **Free prices policy**



EX-POST CONTROLS

MARKET SURVEILLANCE

- **Responsibility of Members States**
- **Public authority**
- **Organisation / Surveillance measures**
- **Minimum requirements**
- **Communication and Co-ordination**



SHARED RESPONSIBILITIES

Manufacturers

PRE-MARKET ASSESSMENT

- **Products must fulfil Essential Requirements**
- **Products need to be tested**

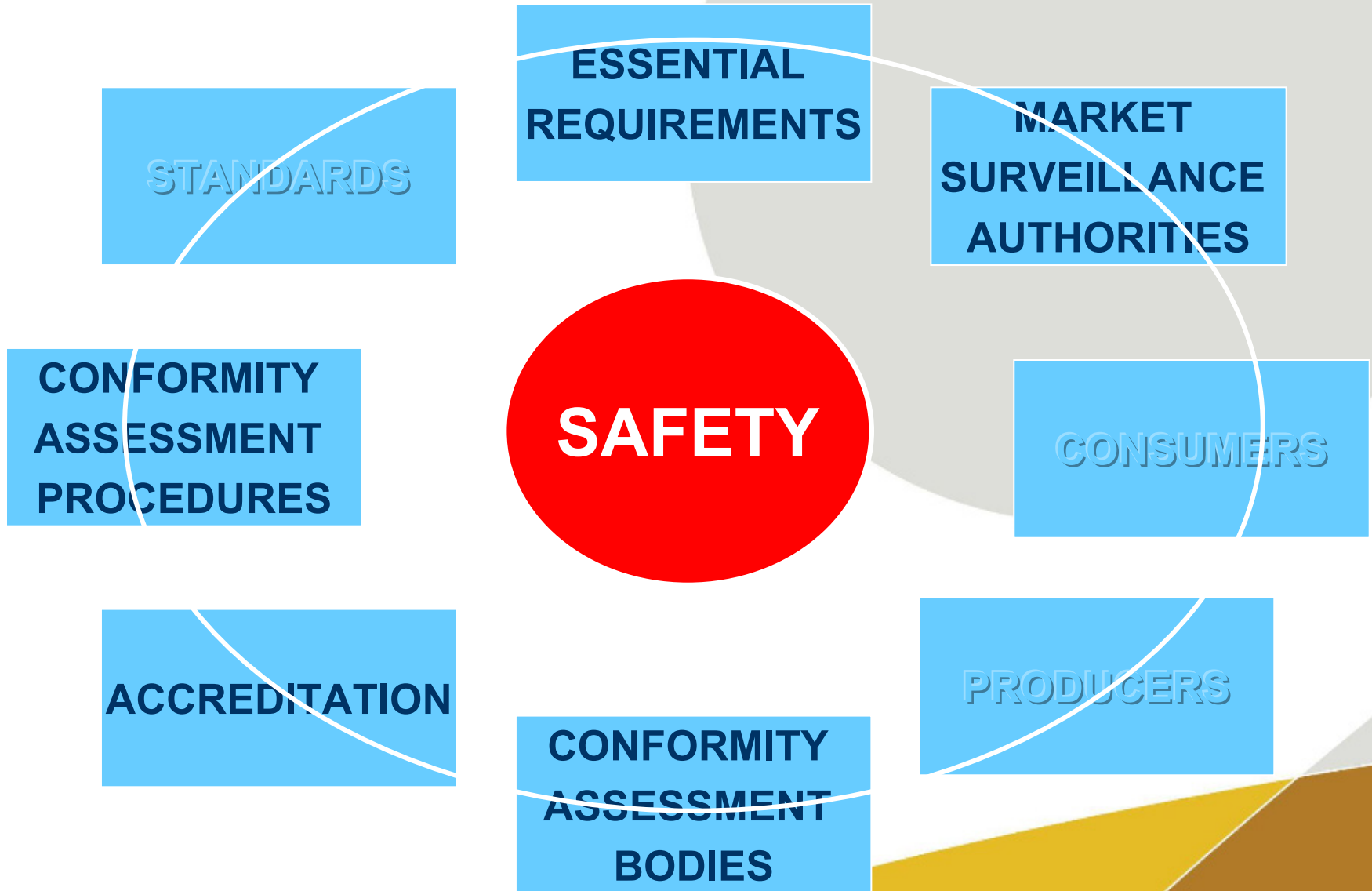
Member States

POST-MARKET CONTROL

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



AN INTERCONNECTED SYSTEM





LINKS

New Approach:

http://ec.europa.eu/enterprise/newapproach/index_en.htm

Market Surveillance:

http://ec.europa.eu/enterprise/newapproach/market_surveillance.htm

Questions:

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THANK YOU

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