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ASSISTING MONTENEGRO IN DEVELOPING QUALITY INFRASTRUCTURE

**Obligations of economic operators and
powers of market surveillance authorities**

Podgorica, 23.04.2015

Dr. Matthias Honnacker



The aims of the Mission

- **two meetings/workshops** of respective WGs
- support of the preparation of rules for trade and free movement of goods in compliance with the **EU acquis communautaire** in the field of Chapter 1 - **Free movement of goods** and the WTO requirements.
- supporting and advising the Beneficiary and all stakeholders on implementation and enforcement of harmonisation rules on **personal protective equipment** and **safety of toys**
- **press/TV interview** to multiply information about the framework for the target that only safe and compliant products are made available on the market



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Content

- European legislation and legal framework
- Economic operators
- Market Surveillance
- RAPEX information system
- PPE and Toys





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Three general pillars of product legislation

official **product safety law** (e.g. GPSD, TD, PPED)
(Benchmark: 1:1-compliance with the written law)

producers' and product liability based on **civil right**
(Benchmark: Compliance with the state of science and technology)

product liability based on **criminal right**
(Benchmark: Compliance with the state of science and technology)



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Minimum



Product liability based on **criminal right**
(Benchmark: Compliance with the state of science and technology)



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Why is that important in the field of liability?

- Risk of trade ban
- Risk of been made look like fool for product liability issues
- Risk of criminal prosecution

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Structure of EU Product Safety Legislation

Art. 115 (old 95)



+



Art. 153 (old 137)

- Design, Manufacturing and Certification of Safe Products for the Free Movement of Goods
- Total Harmonisation: Removal of every additional national requirement

- Use of Equipment and Products at the Workplace (maintenance, testing frequency etc.)
- Minimum requirements may be supplemented by Member State regulations



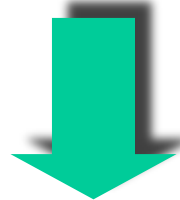
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Structure of the EU Product Safety Legislation

Art. 115



**Concept of the „New Legislative Framework“
formerly known as „New Approach“**



New Legislative Framework (NLF)

- **Regulation** (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national **technical rules to products lawfully marketed in another Member State** and repealing Decision No 3052/95/EC
- **Regulation** (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the **requirements for accreditation and market surveillance** relating to the **marketing of products** and repealing Regulation (EEC) No 339/93
- **Decision** No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a **common framework for the marketing of products**



Basic concept of NLF („new New Approach“)

- **Legislative harmonisation is limited to essential requirements** that products placed on the Community market must meet, if they are to benefit from free movement within the Community;
- **The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonised standards;**
- **Application of harmonised or other standards remains voluntary**, and the manufacturer may always apply other technical specifications to meet the requirements;
- **Products manufactured in compliance with harmonised standards benefit from a presumption of conformity** with the corresponding essential requirements.



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New Legislative Framework (New Approach)





The Role of European Standardisation

Essential safety requirements
(Directives)



Detailed by
Harmonised European Standards



Application of Harmonised Standards
is voluntary but leads to
presumption of conformity



The Role of EU Legislation

EU legislation

- has become a main source for product safety regulations during the last 30 years in order to remove technical barriers to trade for the internal market.

Member States

- transpose EU Directives into national legislation
- run institutions to guarantee a high level of safety in its national market
- participate in EU committees for change of directives and coordination of enforcement activities
- participate in European standardisation (CEN/CENELEC/ETSI) through the national standardisation body (Germany e.g. DIN)

EC - Directive



LVD

Toys

Simple Pressure Vessels

Gas Appliances

PPE

Machinery

Recreational Crafts

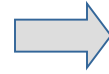
ATEX

Lifts

Aerosol Dispensers

Pressure Equipment

GPSD



ProdSG

+

+

+

+

+

+

+

+

+

+

+

1. GPSG-V

2. GPSG-V

6. GPSG-V

7. GPSG-V

8. GPSG-V

9. GPSG-V

10. GPSG-V

11. GPSG-V

12. GPSG-V

13. GPSG-V

14. GPSG-V

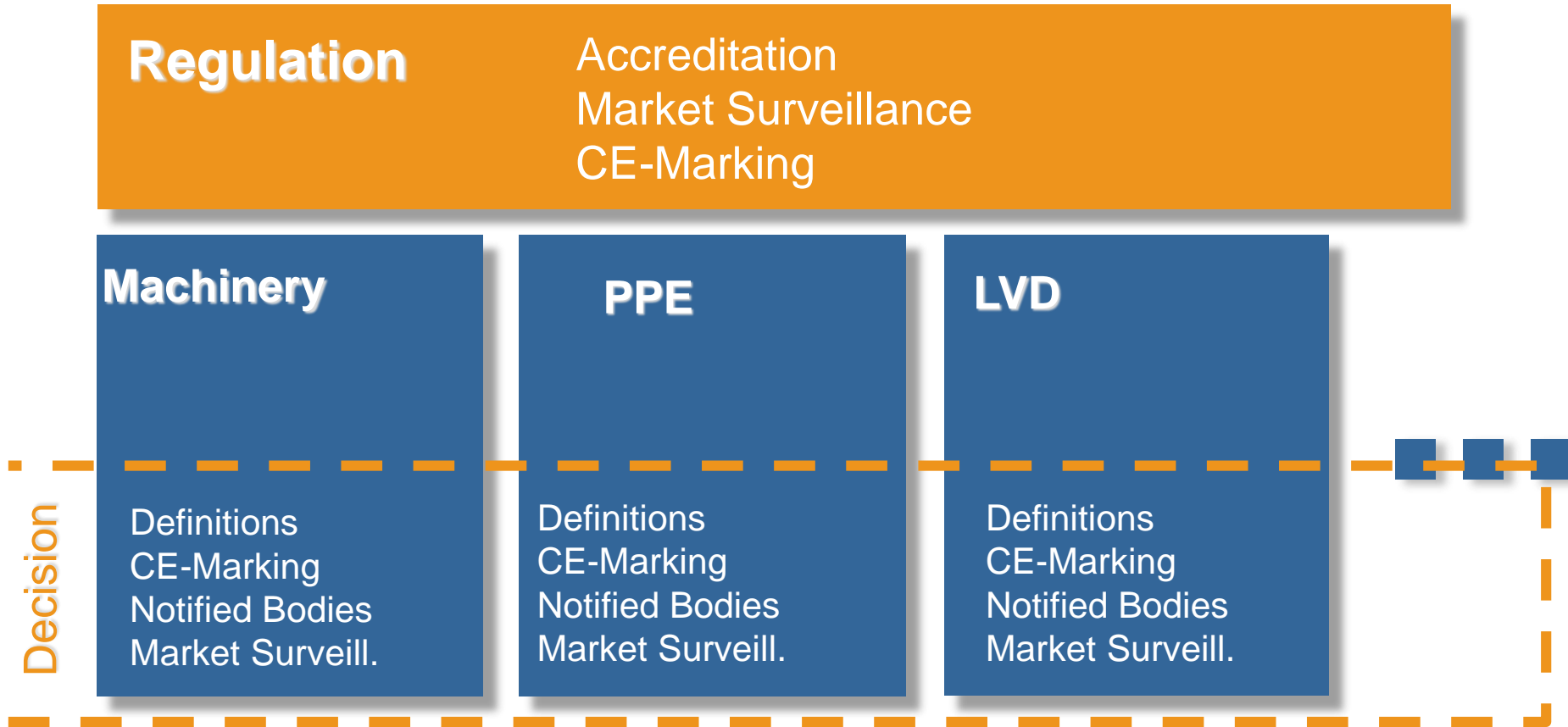


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Overall concept for the legal design of NLF





Reference provisions

- **Definitions** e.g.
 - making available on the market,
 - economic operators,
 - harmonised standard
- **Responsibilities** of the economic operators
- **Conformity** of the product (*e.g. presumption of conf., declaration of conf., CE-marking*)
- **Notification** of conformity assessment bodies
- **Safeguard** procedure

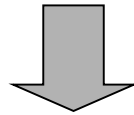


making available on the market

- making available on the market

vs.

placing on the market (= first making available)



all economic operators are addressed

- manufacturer
- authorized representative
- importer
- distributor



economic operators

Manufacturers, Authorized representatives, importers, distributors

Common responsibilities of the economic operators:

- To **withdraw** a product from the market, if it is not in conformity or to take the necessary corrective measures
- To provide all necessary **information**
- To **cooperate** with the market surveillance authorities



Manufacturers shall ...

- ensure, when placing their products on the market, that they have been designed and manufactured in accordance with the **relevant requirements**
- draw up the required technical **documentation**
- carry out or have carried out the applicable **conformity assessment** procedure
- draw up the **declaration of conformity**
- affix the **CE-marking**
- ensure that procedures are in place in order for series production to remain in conformity.



Authorized representatives shall

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...

- **keep the EC declaration** of conformity and the technical documentation at the disposal of national surveillance authorities for a period of time [to be specified proportionate to the lifecycle of the product and the level of risk]
- Due to the written mandate:
 - draw up the declaration of conformity
 - affix the CE-marking
 - ...



Importers shall ...

- ensure that the appropriate **conformity assessment** procedure has been carried out by the manufacturer and that the manufacturer has drawn up the technical documentation
- keep a copy of the **EC declaration of conformity**
- shall ensure that the product bears the **required conformity marking(s)**
- ensure that the technical **documentation** can be made available



Importers shall ...

- **indicate** their name, registered trade name or registered trade mark and the address at which they can be contacted on the product
- ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardize its **compliance** with the requirements



Distributors shall ...

- **verify** that the product bears the required conformity marking(s) and is accompanied by the required documents and by instructions and safety information
- **verify** that the manufacturer and the importer have respected the traceability-requirements
- **ensure** that, while a product is under his responsibility, storage or transport conditions do not jeopardize its compliance
- **shall not make** a product available on the market, if he has reason to believe that the product is not in conformity

Notified Bodies – Roles and Responsibility

- offer their conformity assessment services, **within their scope** of notification
- must **provide relevant information** to their notifying authority, the market surveillance authorities and other notified bodies.
- **operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner.**
- employ the **necessary personnel**, which has sufficient and relevant knowledge and experience
- make adequate arrangements to ensure **confidentiality** of the information obtained
- must be adequately **insured**.
- may demonstrate their **competence** through accreditation, which is the preferred way to assess their technical competence.



Traceability

- Economic operators shall be able, on request, to identify the following to the market surveillance authorities:
 - **any economic operator** who has supplied them with a product;
 - any economic operator to whom they have supplied a product.
- **Type-, batch- or serial number and name and address** of the manufacturer on the product (or, where the size or nature of the product does not allow it, on the packaging or in a document accompanying the product.)
- **name and address of the importer** on the product, or, if this is not possible, on the packaging or in a document accompanying the product.



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Conformity Assessment

- Conformity assessment is subdivided into **modules**, which comprise a limited number of different procedures applicable to the widest range of products.
- The modules relate to the design phase of products, their production phase or both.
- The **basic modules** and their **possible variants** can be combined with each other in a variety of ways in order to establish complete conformity assessment procedures.

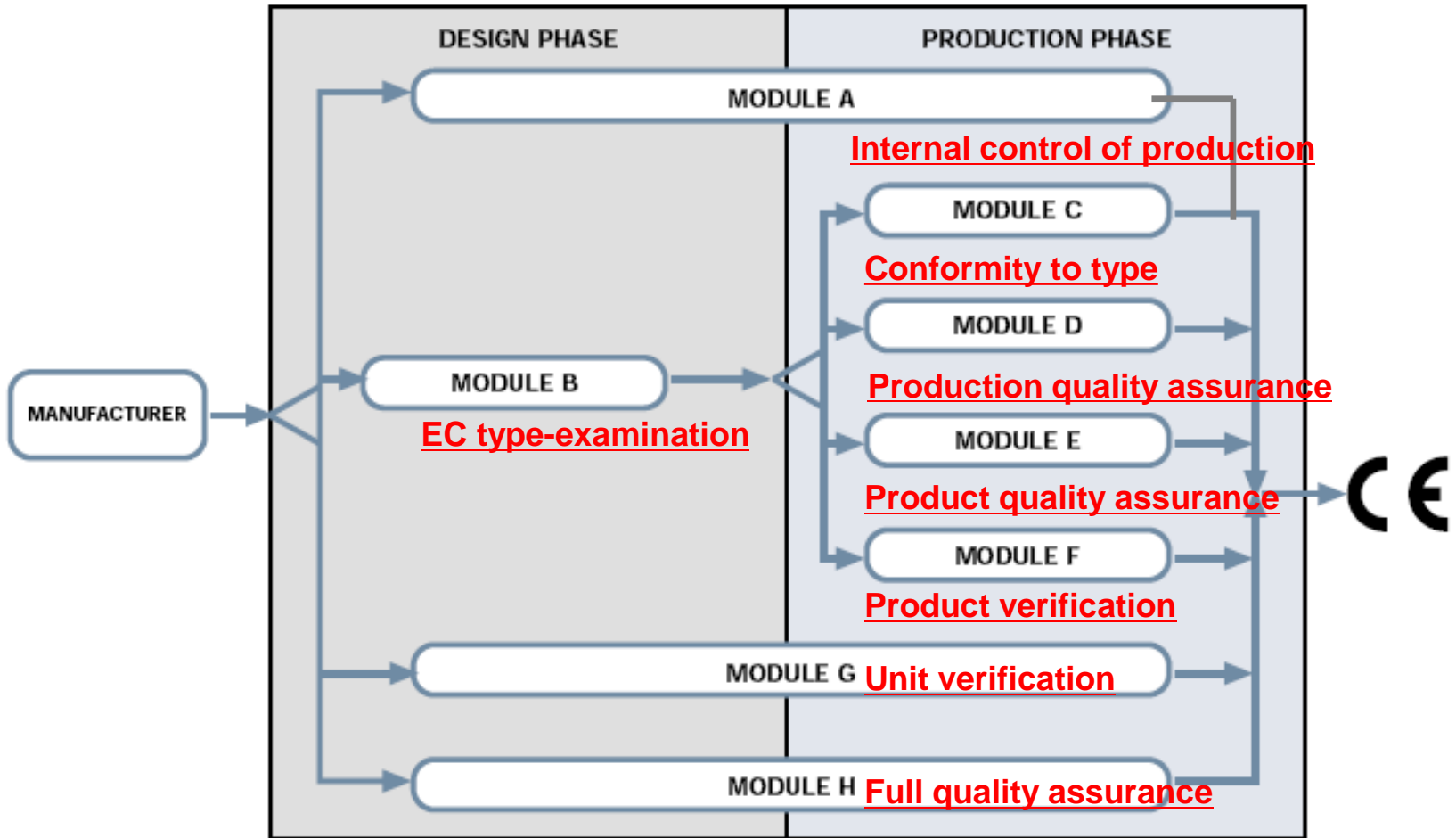


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Conformity Assessment Modules



One product, several legal acts

- Products have to fulfil the requirements of all legal acts which are applicable to the product.
- e.g. a toy might have to fulfill
 - **TSD**
 - EMC
 - RTTE
 - RoHS
 - LVD
 - MD
- Market Surveillance only needs to identify on failure to stop the product, the economic operator has cover all requirements.



Market Surveillance

- the competent authorities **under state law** shall be responsible
- **effective surveillance** regarding major deficiencies and goods flows
- **spot-checking** and with the scope of testing required
- regular checking and evaluation of the **efficacy** of the approach

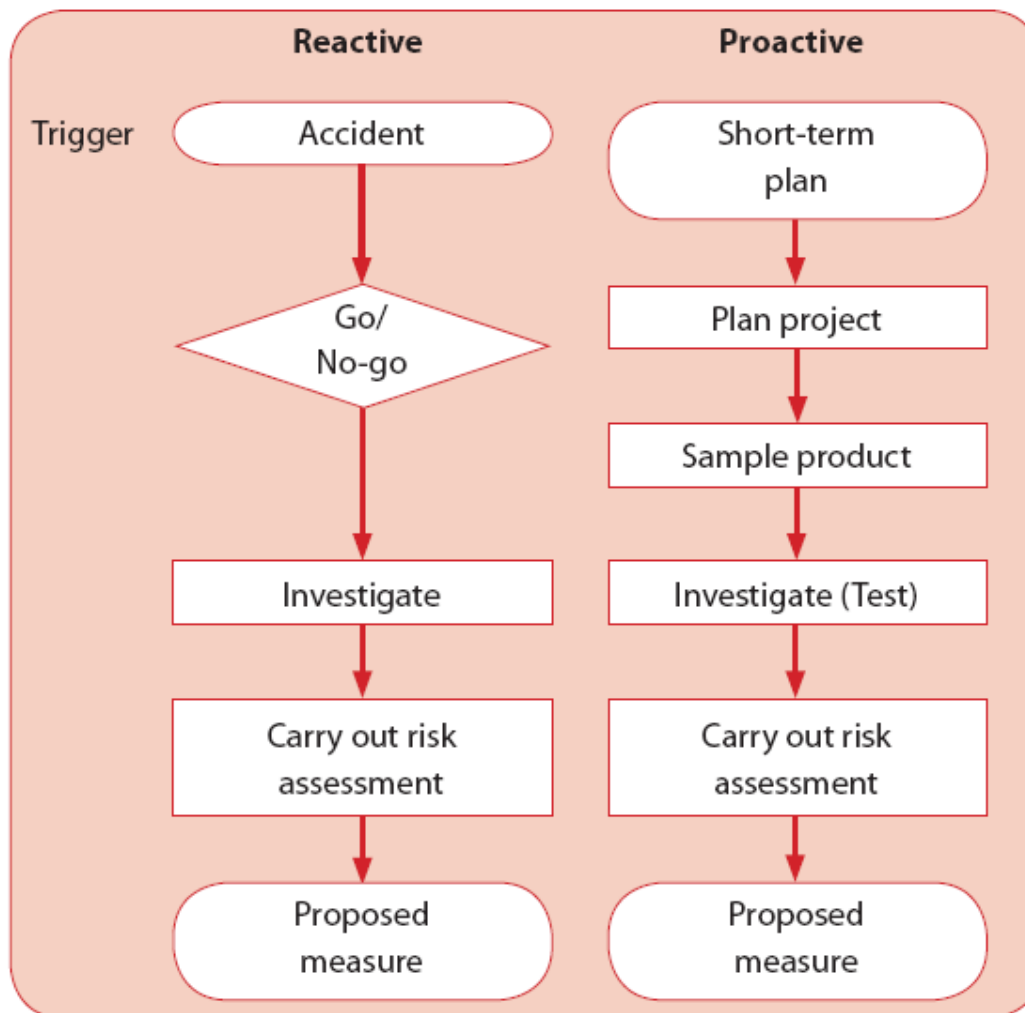


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Market Surveillance: Reactive - proactive





Market Surveillance

The authority shall take the necessary measures, in particular:

- to **prohibit displaying** of a product
- to **order measures** which ensure that a product is only brought into circulation if it satisfies the requirements
- to **order** that a product is **inspected**
- to **order warning signs**
- to **prohibit temporarily or finally** the bringing into circulation
- to **order** that a product is **taken back or recalled**
- to **seize product** and if necessary to **arrange for its safe disposal**
- to **order information** of those who may be exposed to a danger in good time in a suitable form, especially **by the manufacturer**

Market Surveillance - Customs

Where in a Member State more than one authority is responsible for **market surveillance or external border controls**, those authorities shall

- **cooperate** with each other,
- by **sharing information** relevant to their functions and
- **otherwise** as appropriate.

The authorities in charge of external border controls shall immediately **notify the market surveillance authorities** of any such suspension.

Market Surveillance - Customs

The authorities in charge of external border controls shall **suspend release of a product for free circulation** on the Community market when

- the product displays characteristics which give cause to believe that the product presents a **serious risk** to health, safety, the environment or any other public interest;
- the product is not accompanied by the written or electronic **documentation required** by the relevant Community harmonisation legislation or is not marked in accordance with that legislation;
- the **CE marking** has been affixed to the product in a false or misleading manner.



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Market Surveillance - Disclosure of information

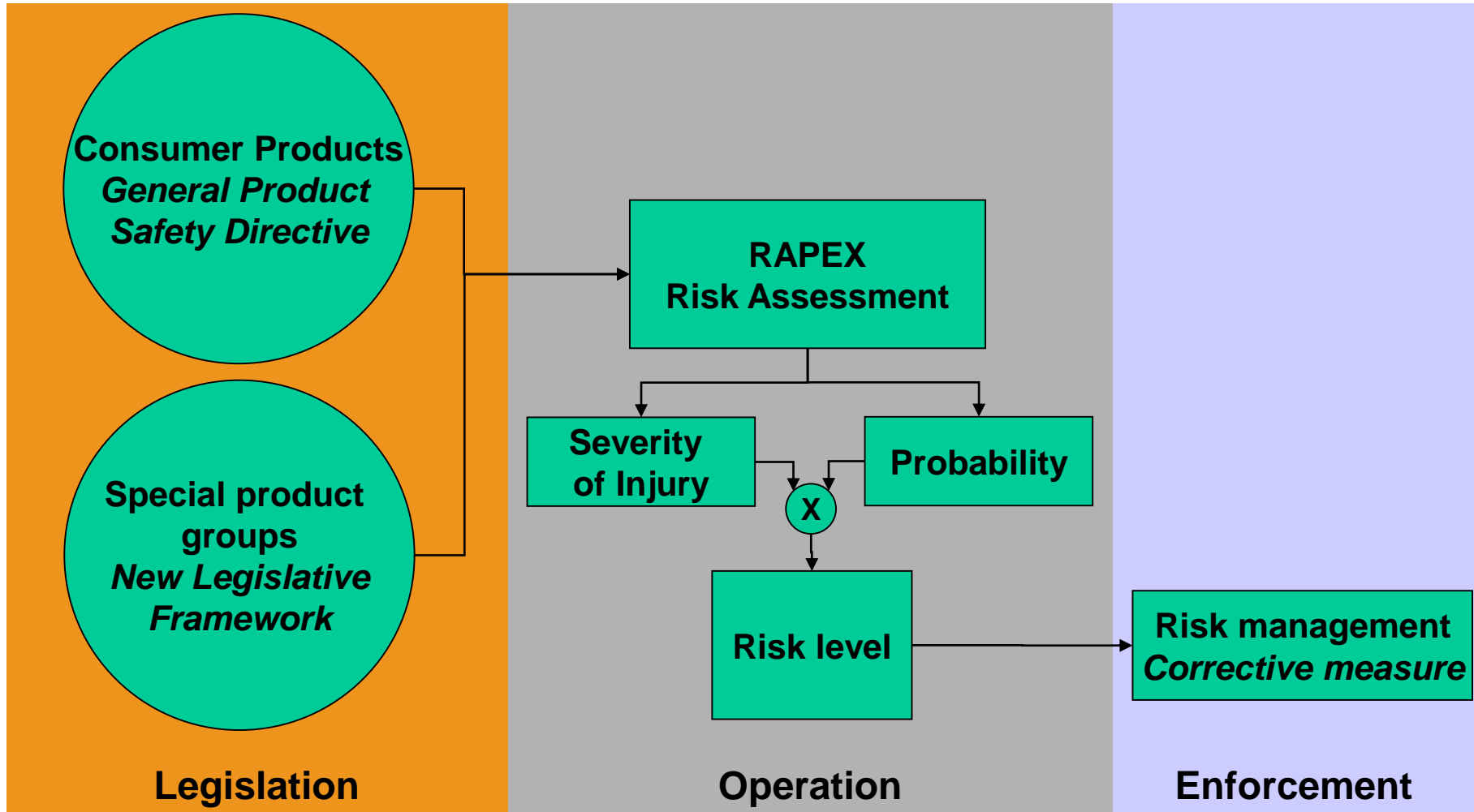
Market surveillance authorities have a general duty
to open **information about dangerous consumer
products**

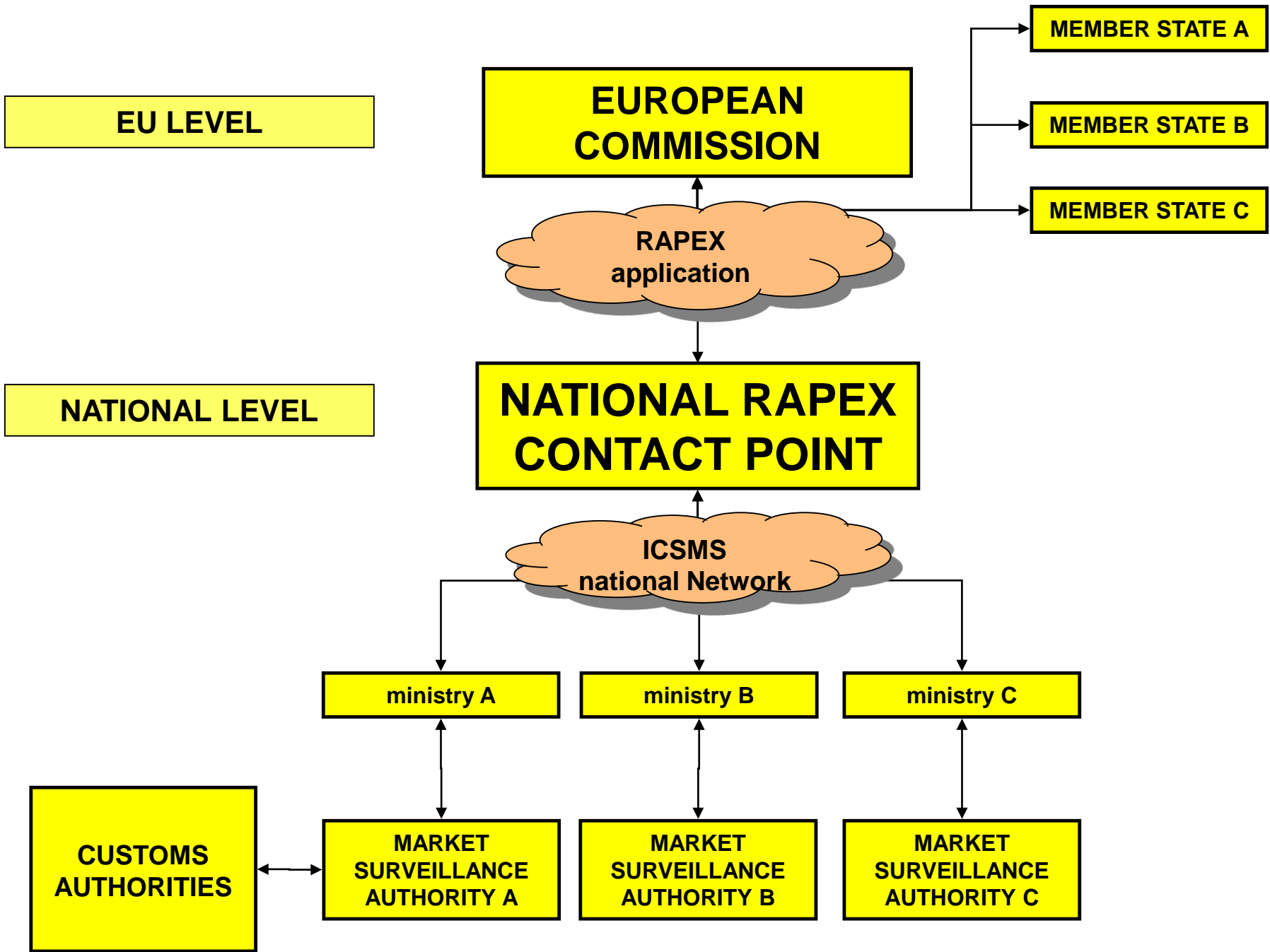
- Orders which have become indisputable
- Orders whose immediate enforcement has been ordered
- To the general public
- Hazards for user safety and health
- In electronical way



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European Approach







RAPEX Information

- **RAPEX (Rapid Information Exchange System)**
 - is a **European warning system** for dangerous consumer products.
 - ensures that information concerning dangerous goods, discovered by national authorities, are **forwarded rapidly** towards other national authorities and the European Commission,
 - to **prevent or limit sales** of these products.



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Swimming aids – PPE or Toy?

- Floating ring with child appealing designs – TSD
- swimming aid, often in orange warning color – PPE





PPE Legal Framework

- Council Directive **89/686/EEC** of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment
- Harmonised Standards
- PPE Guidelines – (updated continuously)
- Expert Group meetings since 2002 (updated continuously)
- Proposal for a Regulation of the European Parliament and of the Council on personal protective equipment COM/2014/0186 final - 2014/0108 (COD)



4/27/2015

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Personal Protective Equipment Directive 89/686/EEC

- The PPE Directive 89/686/EEC covers the manufacture and marketing of personal protective equipment.
- It defines legal obligations to ensure that PPE on the European market provides the highest level of protection against hazards.
- The CE marking affixed to PPE provides evidence of this protection.



PPE

- Personal protective equipment (PPE) are products that the user can wear or hold, in order to be protected against hazards either **at home**, **at work** or whilst engaging **in leisure activities**.
- Statistics on fatal and major work accidents underline the importance of protection and prevention, for which personal protective equipment plays an important role.



PPE definition

- Personal Protective Equipment (device or appliance) shall:
 - reduce the risk for safety and health of a person (a „**shield**“ **between hazard and person**) and
 - be worn or held by an individual for protection.
- PPE shall also mean:
 - a unit constituted by several devices or appliances (e.g. helmet with combined hearing protection)
 - a protective device or appliance combined, separably or inseparably, with personal non-protective equipment (e.g. protectors in motorcycle jackets)
 - interchangeable PPE components which are essential to its satisfactory functioning (e.g. filter respirators)
 - its connection to another external, additional device (e.g. air hose to a compressor for respiratory protective equipment)





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Exclusions = not PPE

- PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets, shields, etc.).
- PPE for self-defence (aerosol canisters, personal deterrent weapons, etc.).
- PPE designed and manufactured for private use against:
 - adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.),
 - damp and water (dish-washing gloves, etc.),
 - heat (gloves etc.).





Toy Safety Directive 2009/48/EC

- This Directive shall apply to products designed or intended, whether or not exclusively, for **use in play by children under 14 years of age**
- This Directive shall not apply to the following toys:
 - **playground equipment** intended for public use;
 - **automatic playing machines**, whether coin operated or not, intended for public use;
 - toy vehicles equipped with **combustion engines**;
 - toy **steam engines**; and
 - **slings and catapults**.



Exclusions

The products listed in **Annex I shall not be considered as toys within the meaning of this Directive,**

1. Decorative objects for festivities and celebrations
2. Products for collectors,
3. Sports equipment,
4. Bicycles with a maximum saddle height of more than 435 mm,
5. Scooters and other means of transport designed for sport,
6. Electrically driven vehicles which are intended to be used for travel on public roads,
7. Aquatic equipment intended to be used in deep water, swimming learning devices for children,
8. Puzzles with more than 500 pieces
9. Guns and pistols using compressed gas,
10. Fireworks, including percussion caps which are not specifically designed for toys
11. Products and games using sharp-pointed missiles, such as sets of darts with metallic points
12. Functional educational products,
13. Products intended for use for educational purposes in schools and other pedagogical contexts
14. Electronic equipment, such as personal computers and game consoles,
15. Interactive software,
16. Babies' soothers
17. Child-appealing luminaires
18. Electrical transformers for toys
19. Fashion accessories for children which are not for use in play





Essential safety requirements

- Toys may not be placed on the market unless they comply with the **essential and particular safety requirements**.
- Toys, including the chemicals they contain, shall not jeopardise safety or health when they are **used as intended or in a foreseeable way**, bearing in mind the behaviour of children.





Essential safety requirements

- The **ability of the users** and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups.
- Toys placed on the market shall comply with the essential safety requirements during their **foreseeable and normal period of use**.





Particular safety requirements

Annex II

- i. Physical and mechanical properties
- ii. Flammability
- iii. Chemical properties
- iv. Electrical properties
- v. Hygiene
- vi. Radioactivity





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Time for your questions!

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