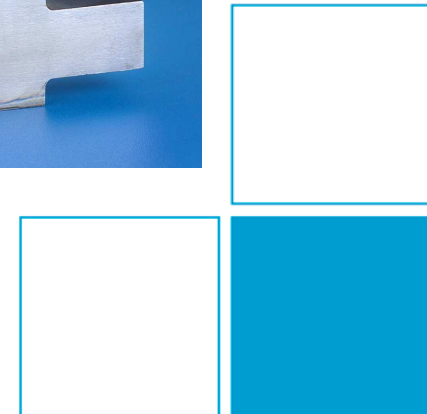


Legal Metrology in Europe

Oliver Mack



Workshop "Initial Verification Of NAWI"
Beijing, China, 18 – 21 July 2016



fair trade



official
measurements



environmental
protection



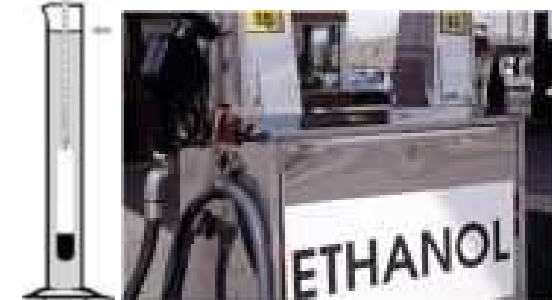
safety at work



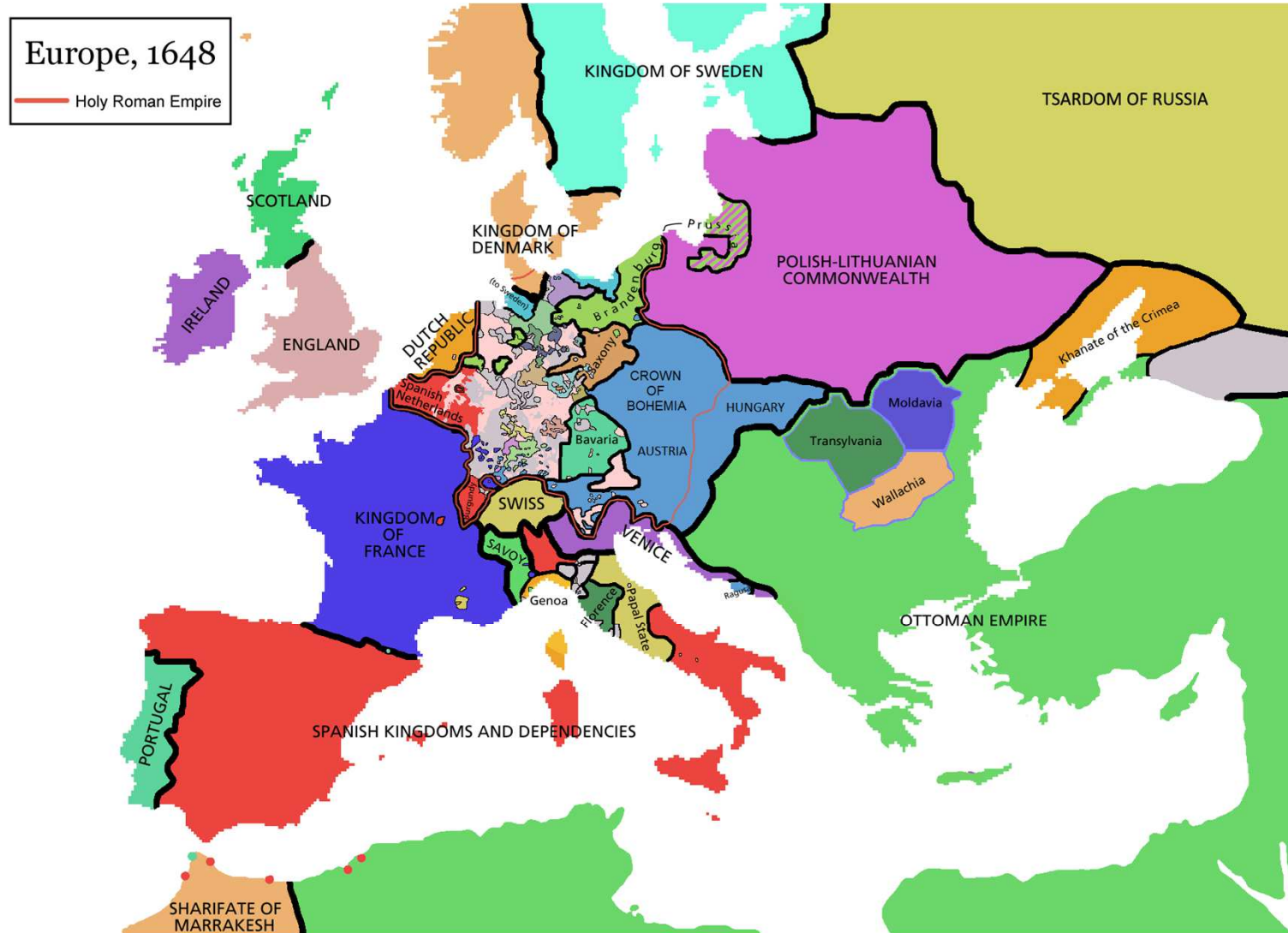
health protection

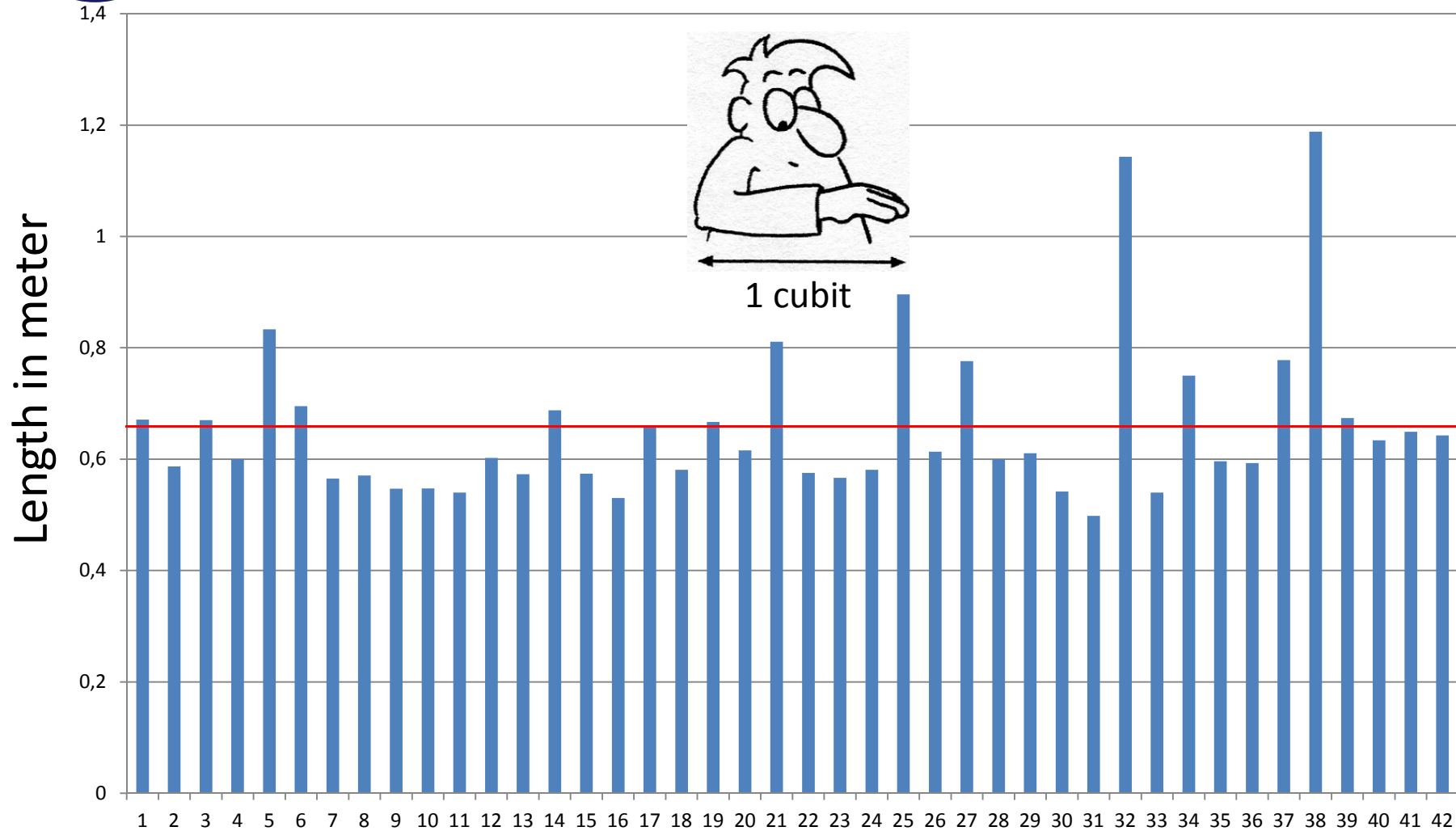


fiscal fairness



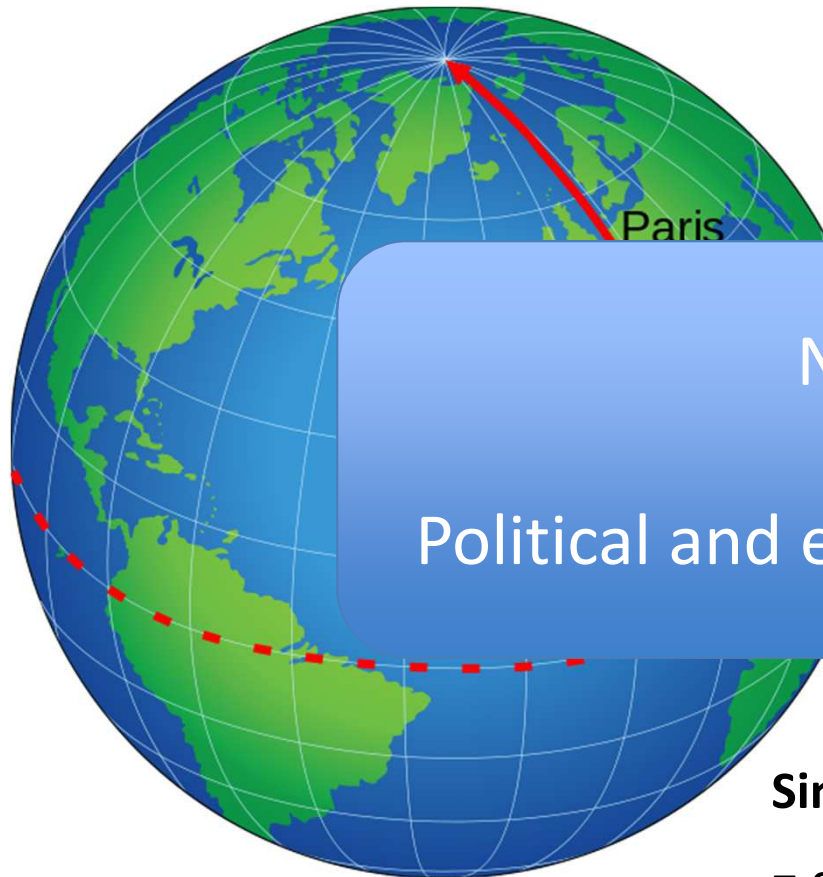






Originally introduced in 1799:

= 1 part of 10.000.000 parts of the distance between north pole and equator (= 10000 km)



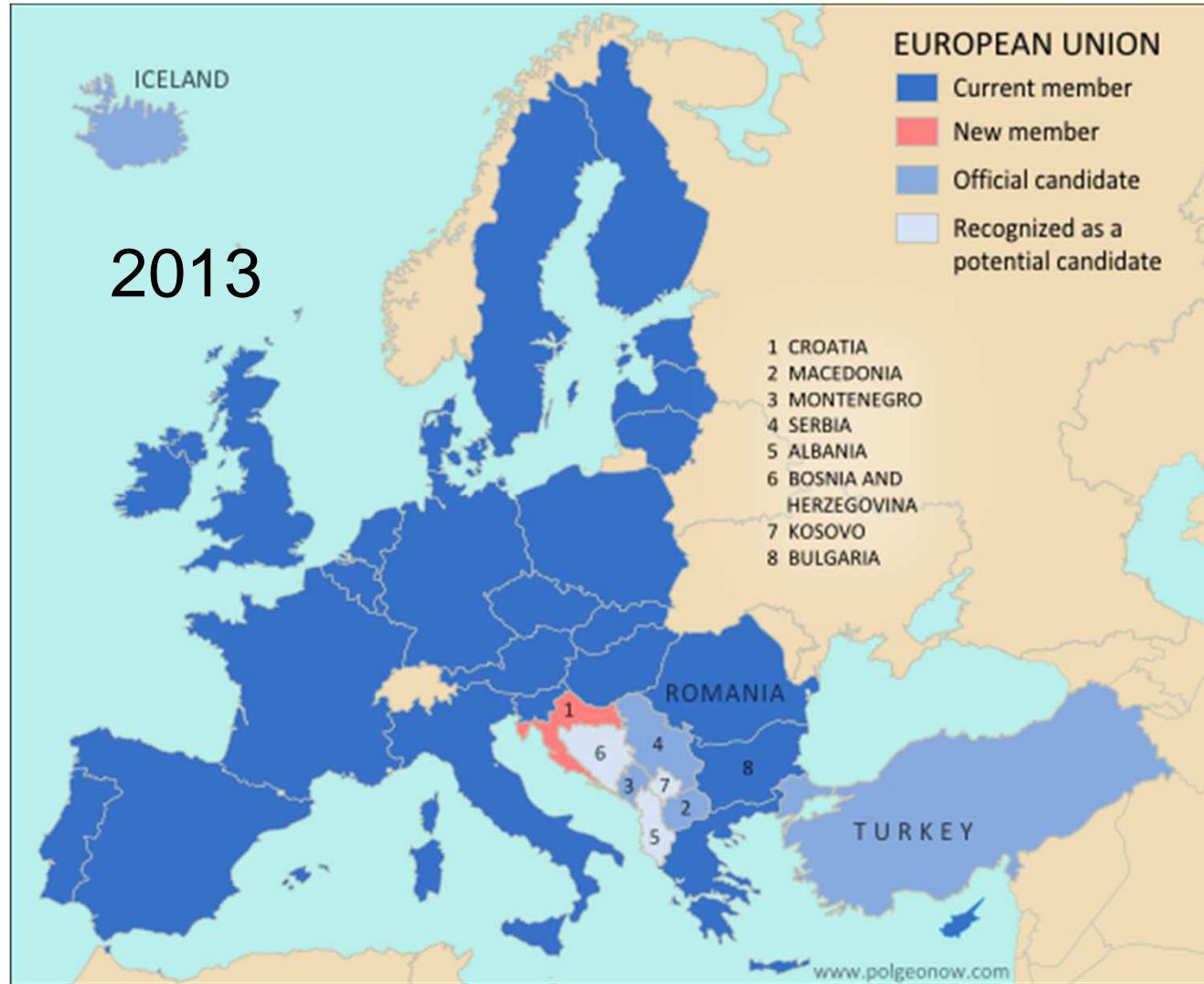
Next step:

Political and economical unification

Since 1983:

= definition by the speed of light in vacuum







1996 MAGELLAN Geographix/SMART Santa Barbara, CA 805 683-3100

before 1971:

- only national pattern approvals
- takes cost and time
- sometimes different requirements
- time to market relatively long

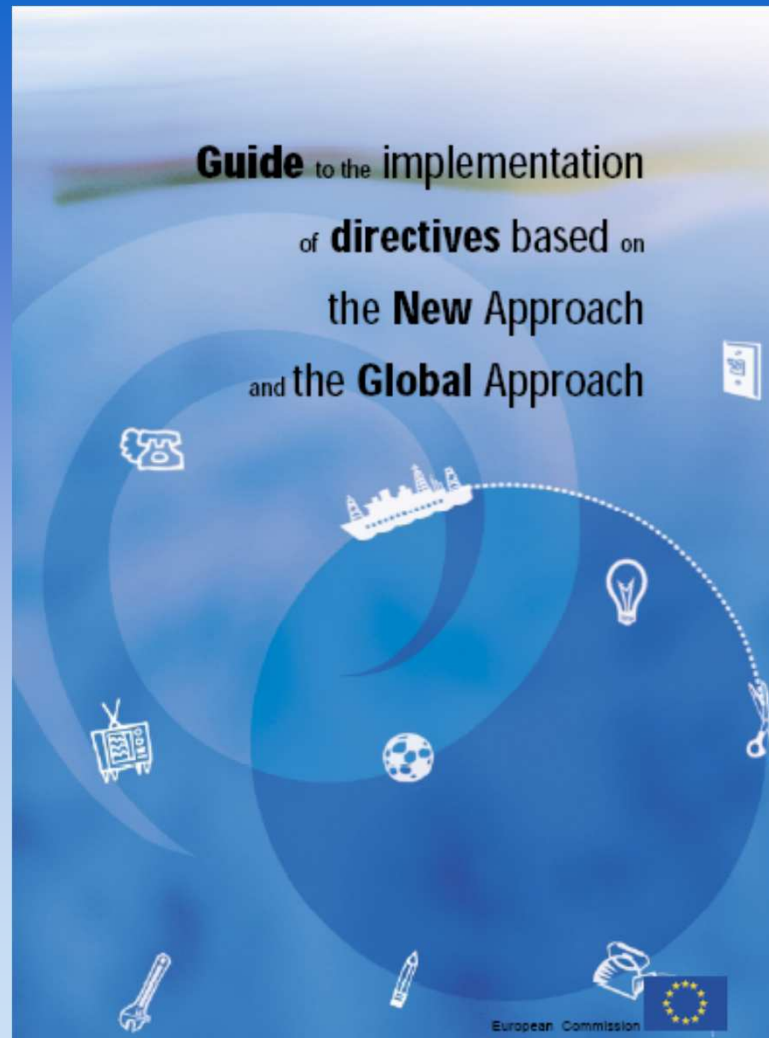


1996 MAGELLAN Geographix/SMSanta Barbara, CA 805 685-3100

European type approval

- since 1971 (71/316/EEC) for 8 instruments
- one certificate for whole Europe
- saves cost and time
- harmonized requirements





„blue guide“ (1999):

- how to place goods in the EC-market and how to put them into use
- responsibilities (manufacturer, user ...)
- EC declaration of conformity (CE marking)
- notified bodies
- market surveillance



1996 MAGELLAN GeographixSMSanta Barbara, CA 805 683-3100

Measuring Instruments Directive (MID)

- since 2004 (2004/22/EC) for 10 instruments
- based on „New Approach“
- Conformity Assessment modules





New Approach principles:

- Based on New Approach directives (NAd).
- The provisions of NAd supersede all corresponding national provisions.
- Member States have an obligation to transpose and implement NAd into their national legislation as appropriate.
- National laws, regulations or administrative provisions, which are adopted in order to transpose a directive, must be communicated to the Commission.





Basic Principle:

Regulation for legally controlled instruments on the European level are limited until “placing on the market” and/or “putting into use”

- Member states remain responsible for their legal metrological control (choice of regulated instruments, market surveillance), but
- National metrological control shall not lead to barriers for free movement of measuring instruments and
- Directives have to be implemented into national legislation.



MID

= Measuring Instruments Directive

(Directive EC/2014/32)

80 pages + 800 pages
(WELMEC guides)

NAWID

= Non-Automatic Weighing Instruments Directive

(Directive EC/2014/31)

20 pages + 200 pages
(WELMEC guides)



Overview about the MID



- MI-001 Water Meters
- MI-002 Gas Meters and Volume Conversion Devices
- MI-003 Active Electrical Energy Meters
- MI-004 Heat Meters
(MI-001 to MI-004: for utility measuring purposes)
- MI-005 Measuring Systems for the Measurement of
Quantities of Liquids other than Water
- MI-006 Automatic Weighing Instruments
- MI-007 Taximeters
- MI-008 Material Measures (length, capacity measure)
- MI-009 Dimensional Measuring Instruments (e.g. area)
- MI-010 Exhaust Gas Analysers



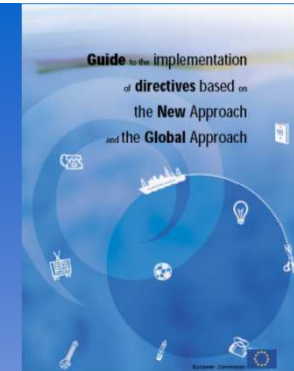
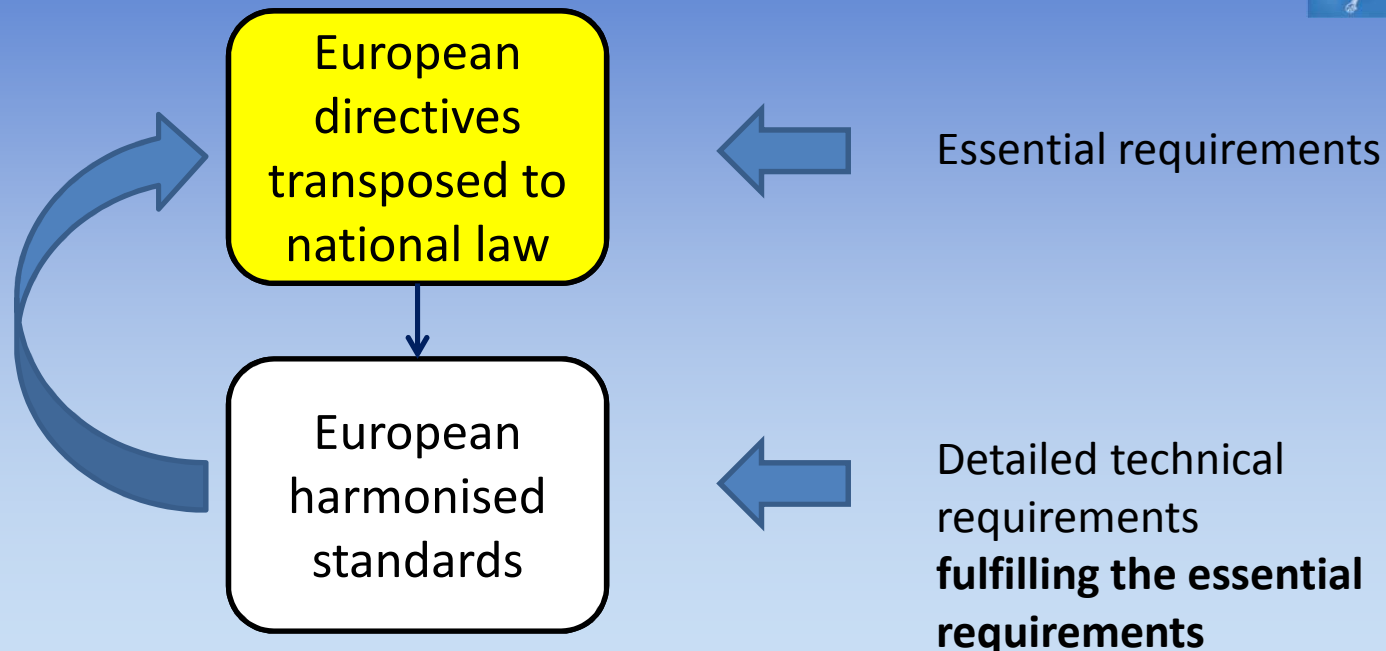
New Approach principles:

- Legislation is limited to essential requirements.
- Only products fulfilling the essential requirements may be placed on the market and put into use.
- Harmonised standards, which have been published in the Official EU-Journal and which have been transposed into national standards, are presumed to be conform to the corresponding essential requirements.



New Approach principles:

- Clear division of requirements:





MID

= Measuring Instruments Directive

(Directive EC/2014/32)

OIML recommendations as normative documents
in combination with cross reference tables

(e.g. OIML R50, R51, R61, R106 and R107 for automatic weighing instruments)

NAWID

= Non-Automatic Weighing Instruments Directive

(Directive EC/2014/31)

Harmonized Standard EN 45501 (widely identical with OIML R76)



Publication in the official Journal of the European Commission



Example: Cross Reference Table

Essential requirements in MID	OIML R 21 Edition 2007	Comment
ANNEX 1		
1.1	2.4.5.4; 2.5.5	Covered
1.2	A.5.4.5	Covered
1.3	3.5.2	Covered
1.3.1	3.5.1; 5.1.2	Covered

(¹) OJ L 135, 30.4.2004, p. 1.



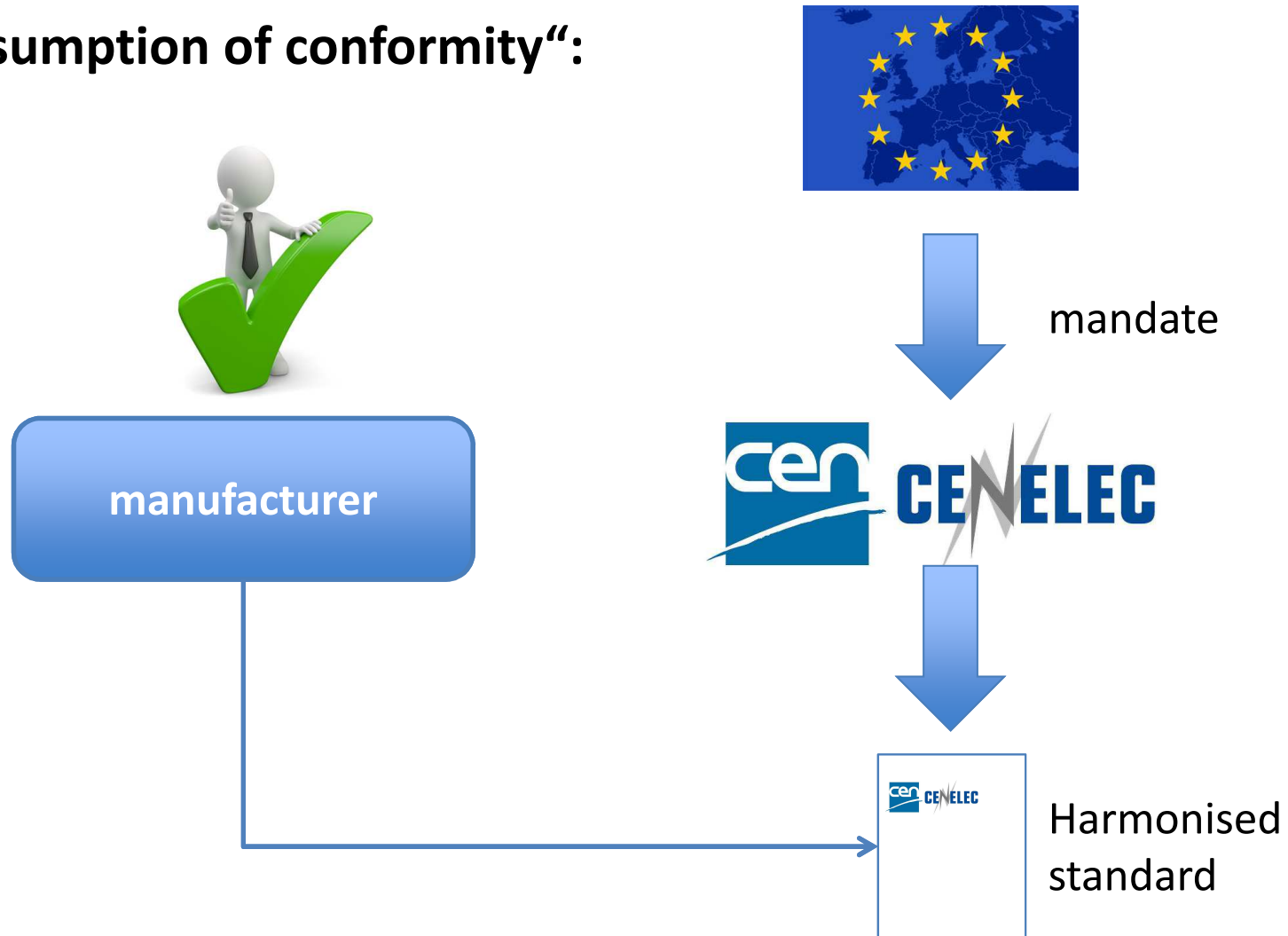
Publication in the officinal Journal of the European Commission



Example: Harmonized Standard EN 45501 for the NAWID

11.9.2015	EN	Official Journal of the European Union	C 300/3	
<p>Commission communication in the framework of the implementation of Directive 2009/23/EC of the European Parliament and of the Council on non-automatic weighing instruments (Codified version)</p> <p><i>(Publication of titles and references of harmonised standards under Union harmonisation legislation)</i></p> <p>(Text with EEA relevance)</p> <p><i>(2015/C 300/02)</i></p>				
ESO ⁽¹⁾	Reference and title of the standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
(1)	(2)	(3)	(4)	(5)
Cenelec	EN 45501:2015 Metrological aspects of non-automatic weighing instruments	This is the first publication	EN 45501:1992 Note 2.1	19.4.2016

„Presumption of conformity“:



New Approach principles:

- Application of harmonized standards or other technical specifications remains voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements.
- Manufacturers may choose between different conformity assessment procedures provided for in the corresponding directive („Global Approach“).

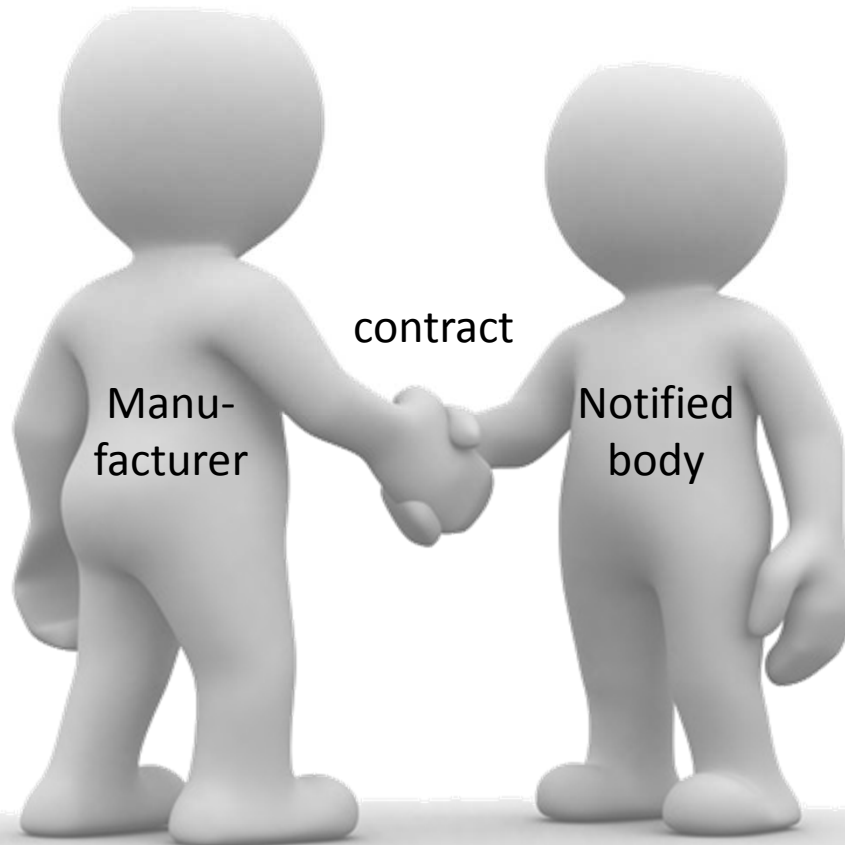




Presumption of conformity



European harmonised standards



Conformity assessment:

Type examination

Product verification

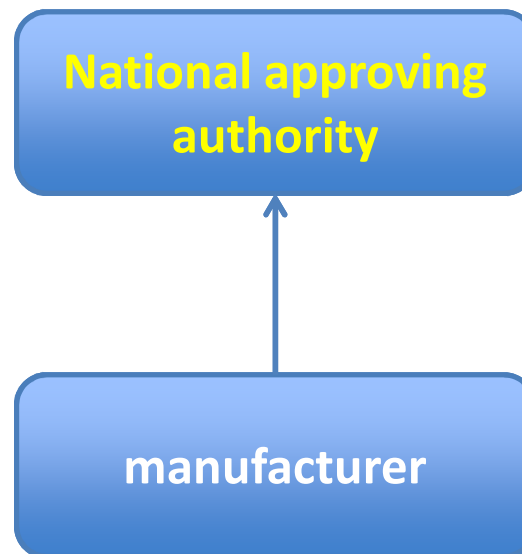
Quality assurance of production Process

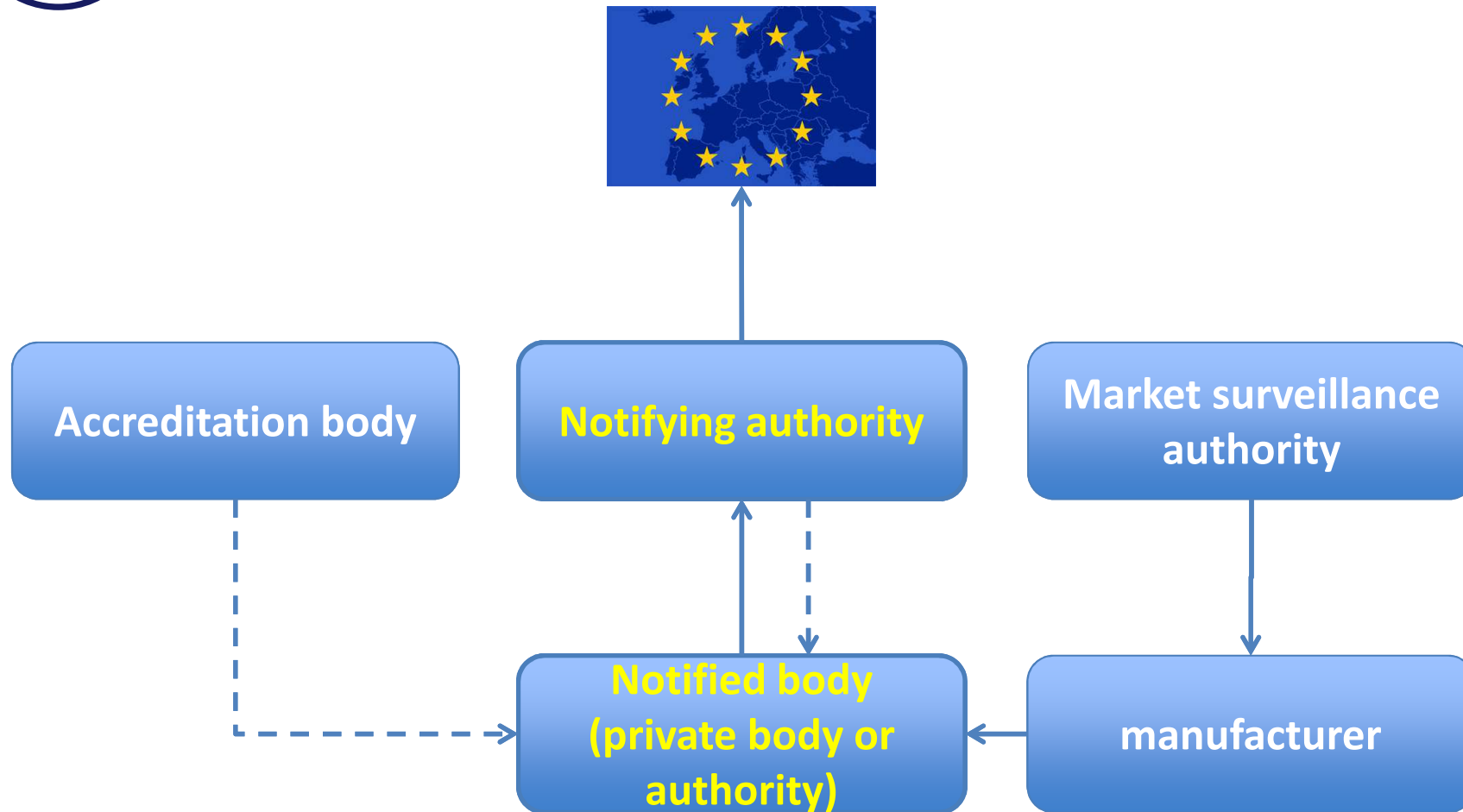
...

A notified body helps the manufacturer to declare the conformity.



From old approach ...







Notifying authority

How to set up a notifying authority?

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary **procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies.**
2. Member States may decide that the assessment and monitoring shall be **carried out by a national accreditation body** within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring to a body **which is not a governmental entity, that body shall be a legal entity and shall comply with some necessary changes with the requirements.** In addition it shall have arrangements to cover liabilities arising out of its activities.

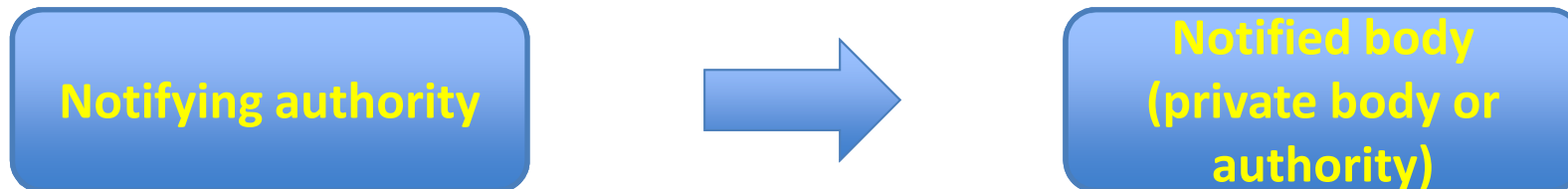


The system of Notified Bodies



Requirements relating to a **notifying authority**:

No conflict of interest!



- = impartial and objective
- = 4-eye-principle for assessment and decision
- = no conformity assessment activities
- = confidential
- = sufficient number of competent staff members

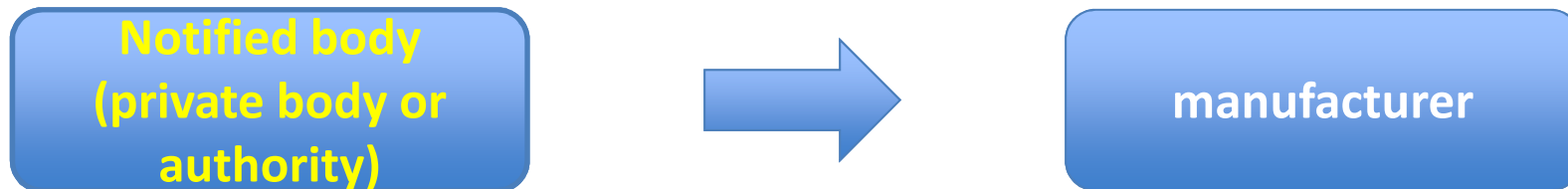


The system of Notified Bodies



Requirements relating to a **notified body**:

Shall not engage in any activity!

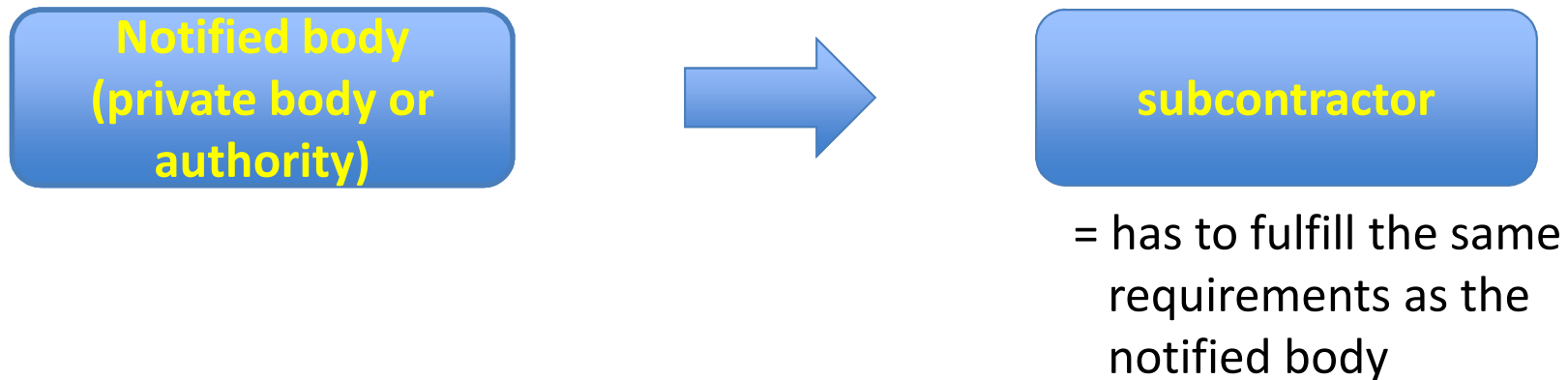


- = has legal personality
- = third-party body
- = could be business association body
- = free from all pressures
- = competent
- = capable of carrying out all tasks of conf. assessment
- = liability insurance or liability by the state
- = confidential
- = active participation in standardisation and coordination group

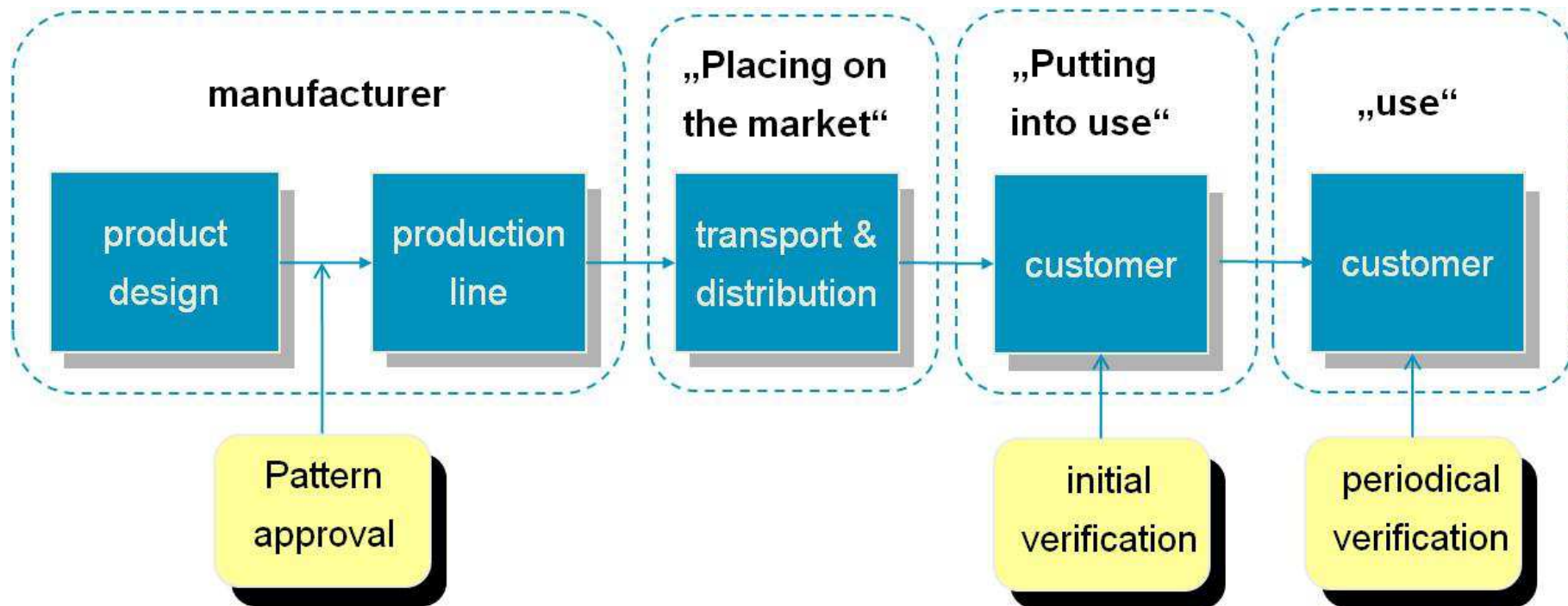


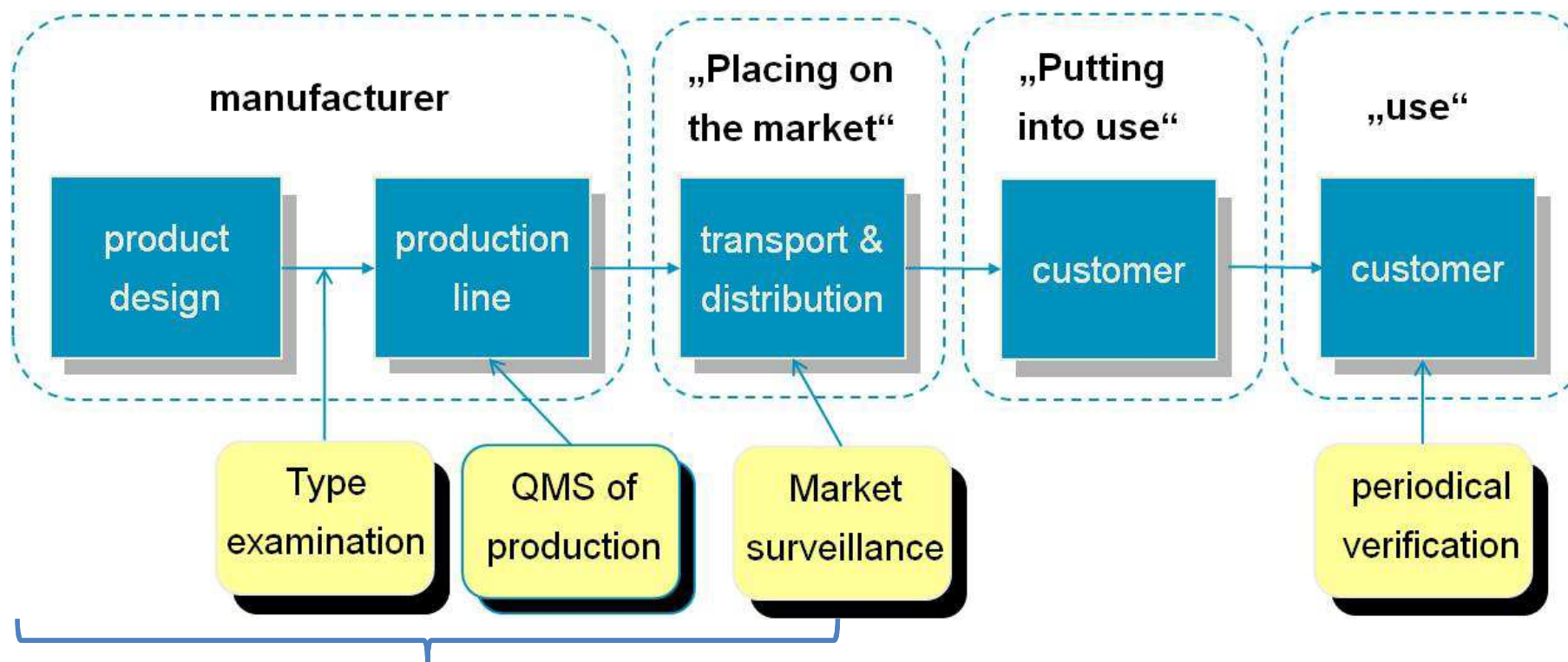
Requirements concerning **subcontracting**:

Subcontracting is possible!

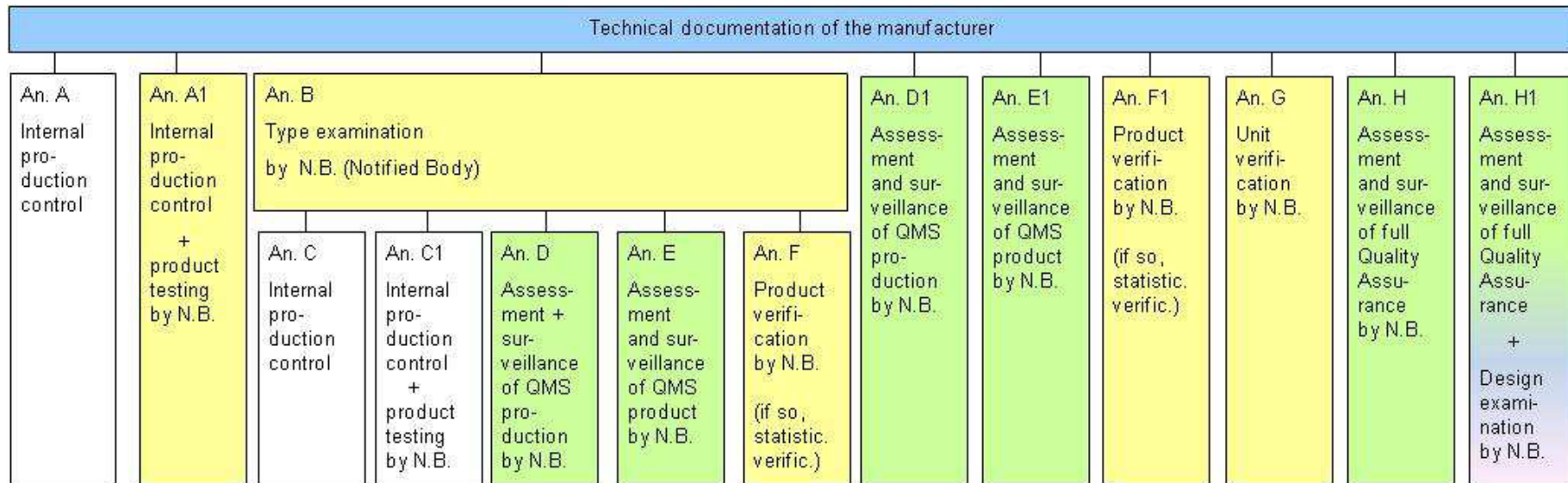


The „Old Approach“ (example measuring instruments)





14 different **conformity assessment**
procedures



Possible conformity assessment modules for each instrument are given by the corresponding EU directive (e. g. B+D, B+F, G, H1)

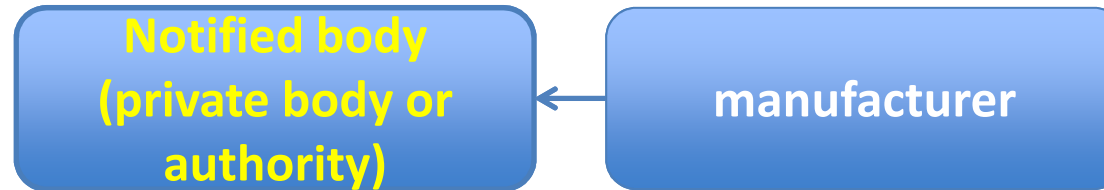
➔ **manufacturer chooses** from that the module (or module combination) he likes



ANNEX B

TYPE EXAMINATION

1. 'Type examination' is the part of a conformity assessment procedure whereby **a notified body examines the technical design** of a measuring instrument and **ensures and declares** that the technical design meets the appropriate requirements of a Directive.



- **technical documentation** about the product
(if the product has got software: description of the software)
- **checklist** demonstrating how the product fulfills all the relevant European harmonised standards
(e. g. measuring instruments directive, electromagnetic compatibility directive, machinery directive etc.)
- **a sample („pattern“)** of your product => usually the prototype
(if it is required by the conformity assessment module)
- etc.



ANNEX F

DECLARATION OF CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

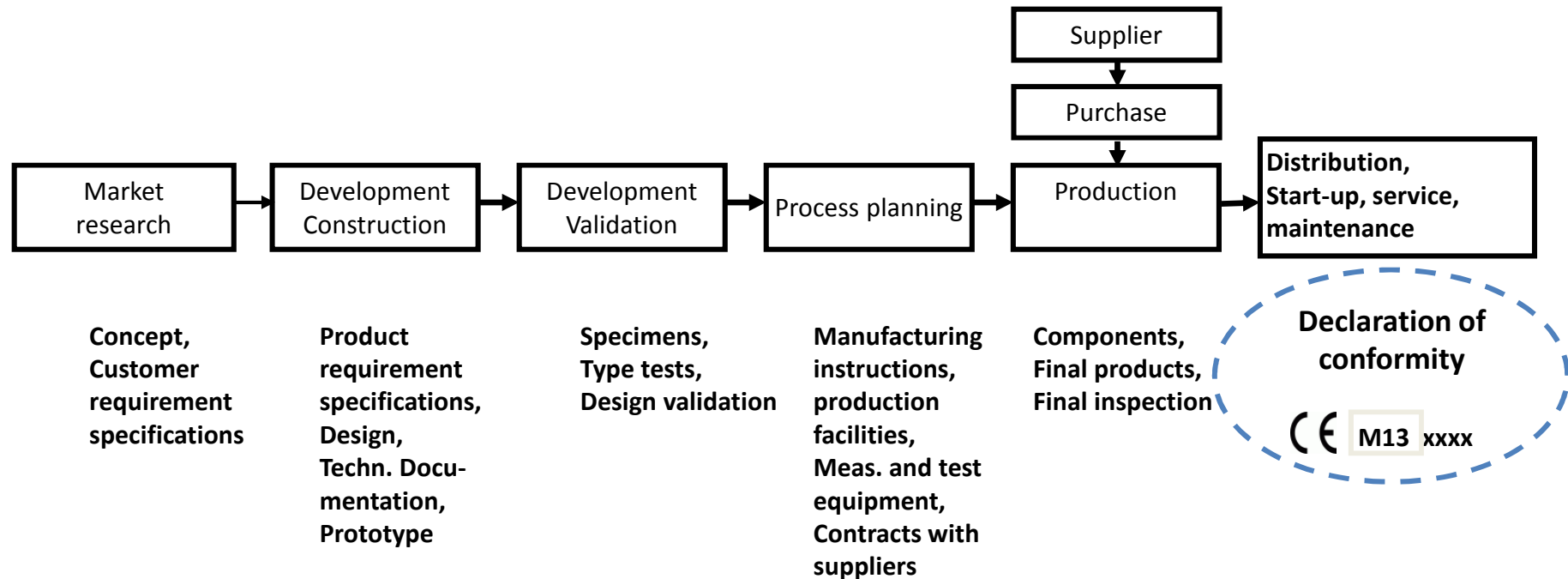
1. 'Declaration of conformity to type based on product verification' is the part of a conformity assessment procedure whereby **the manufacturer fulfils the obligations** laid down in this Annex and **ensures and declares** that the measuring instruments that have been are **in conformity with the type as described in the EC-type examination certificate** and satisfy the appropriate requirements of a Directive.



MODULE D:

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on **quality assurance of the production process** is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations and ensures and declares on his sole responsibility **that the measuring instruments concerned are in conformity with the type** described in the EU-type examination certificate and satisfy the requirements of the Directive that apply to them.



Module A: Conformity Declaration on base of internal production control of manufacturer (without notified body)



Module B = „type examination“

The notified body examines one pattern, the documentation and the software.

➔ in principle the same as „type approval“

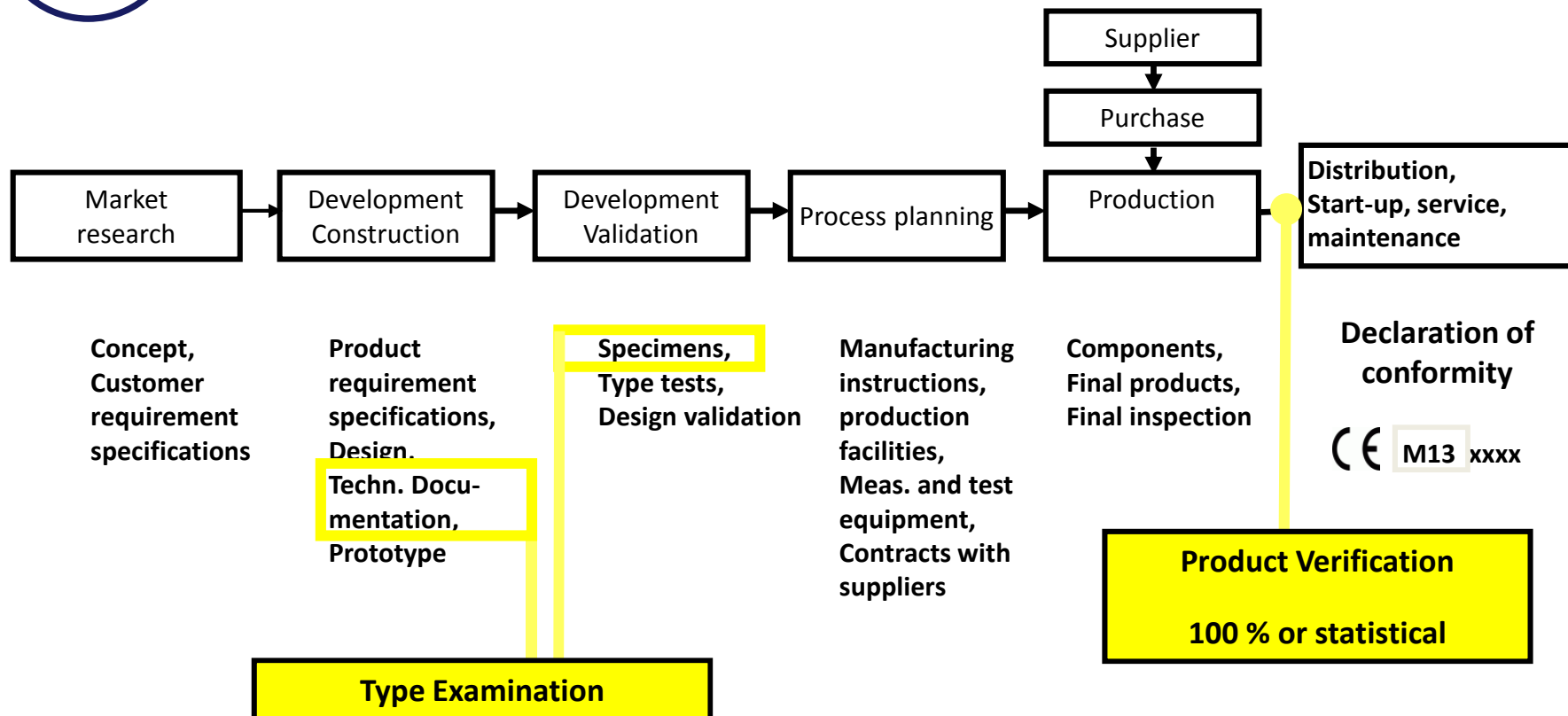
Module F = „conformity to type of every single instrument“

The notified body examines every pattern (or uses statistical examination of a lot of the instruments)

➔ in principle the same as „initial verification“



Conformity assessment modules for non-automatic weighing instruments



Modules B+F: Type Examination (B) and Product Verification (F)
 Applicable for small batch production of instruments MI-001 bis MI-007, MI-009, MI-010, NAWID
 (corresponds to former type approval and initial verification)

Philosophy of module B and D:

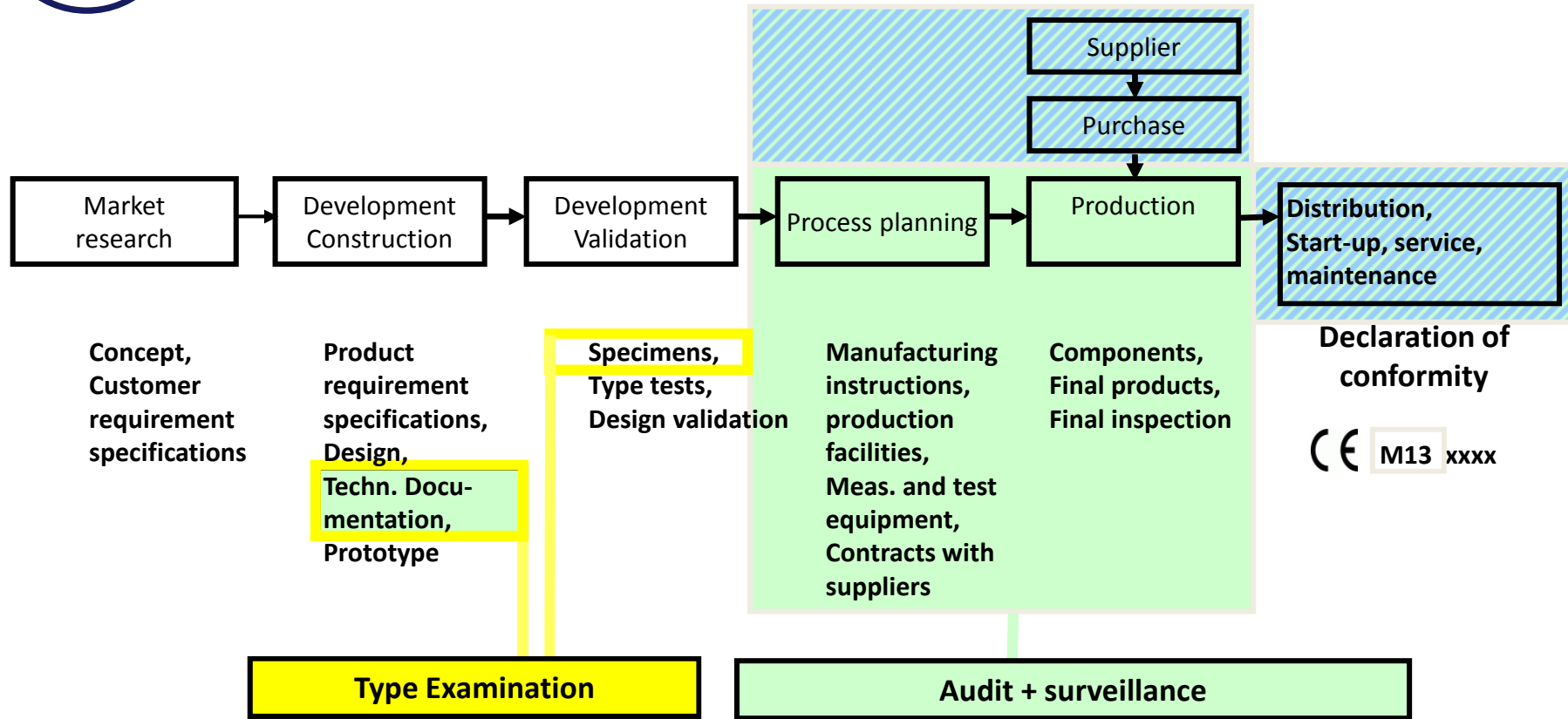
- every single instrument, which leaves production, was tested several times during production with suitable test equipment
- the whole process is described in the quality management handbook



**Every single product
leaving the production
fulfills the directive!**



Conformity assessment modules for non-automatic weighing instruments



Modules B+D: Type examination (B) and approval of quality system for production (D) MI-001...MI-010 and NAWID

Philosophy of module G:

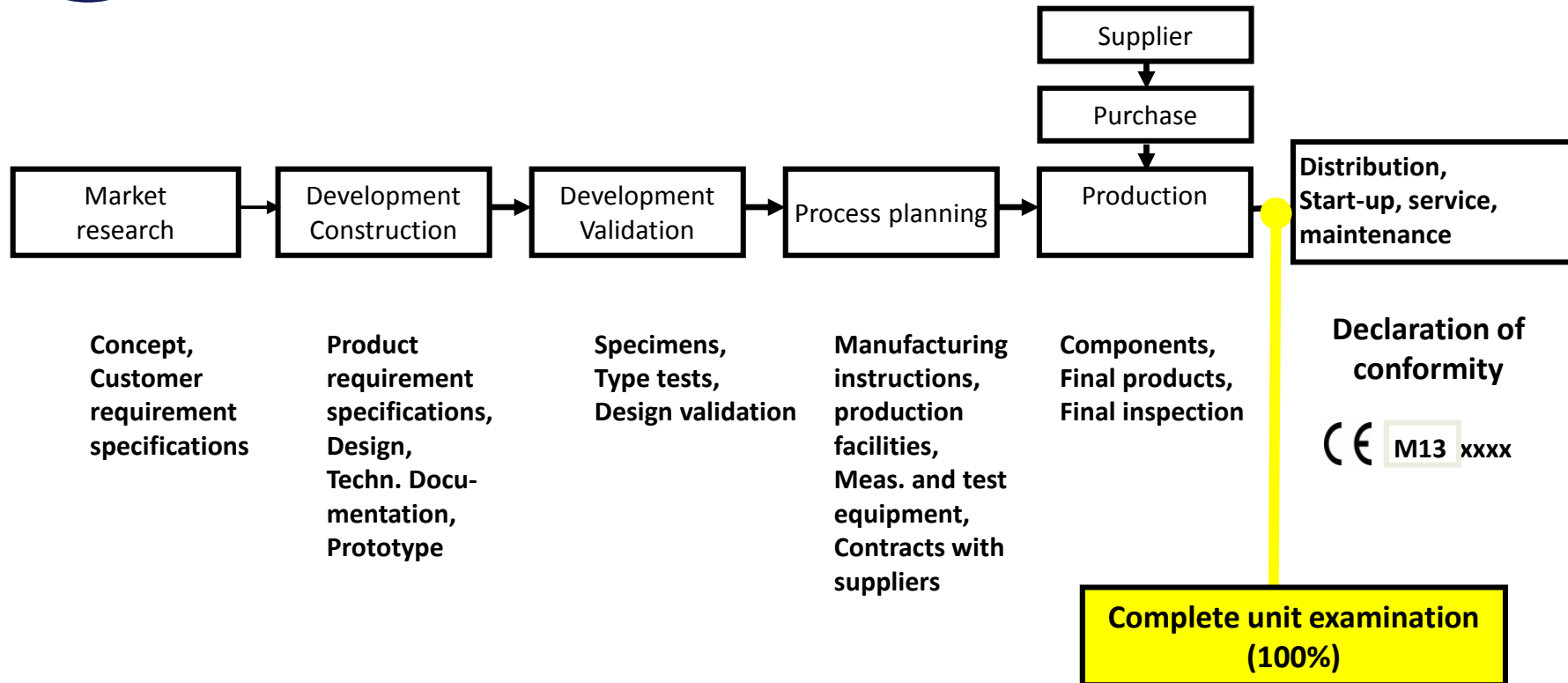
- a single instrument is examined
- the examination represents more or less a mixture of type examination and initial verification



**Notified body performs
tests of the type
examination procedure and
a verification**



Conformity assessment modules for non-automatic weighing instruments

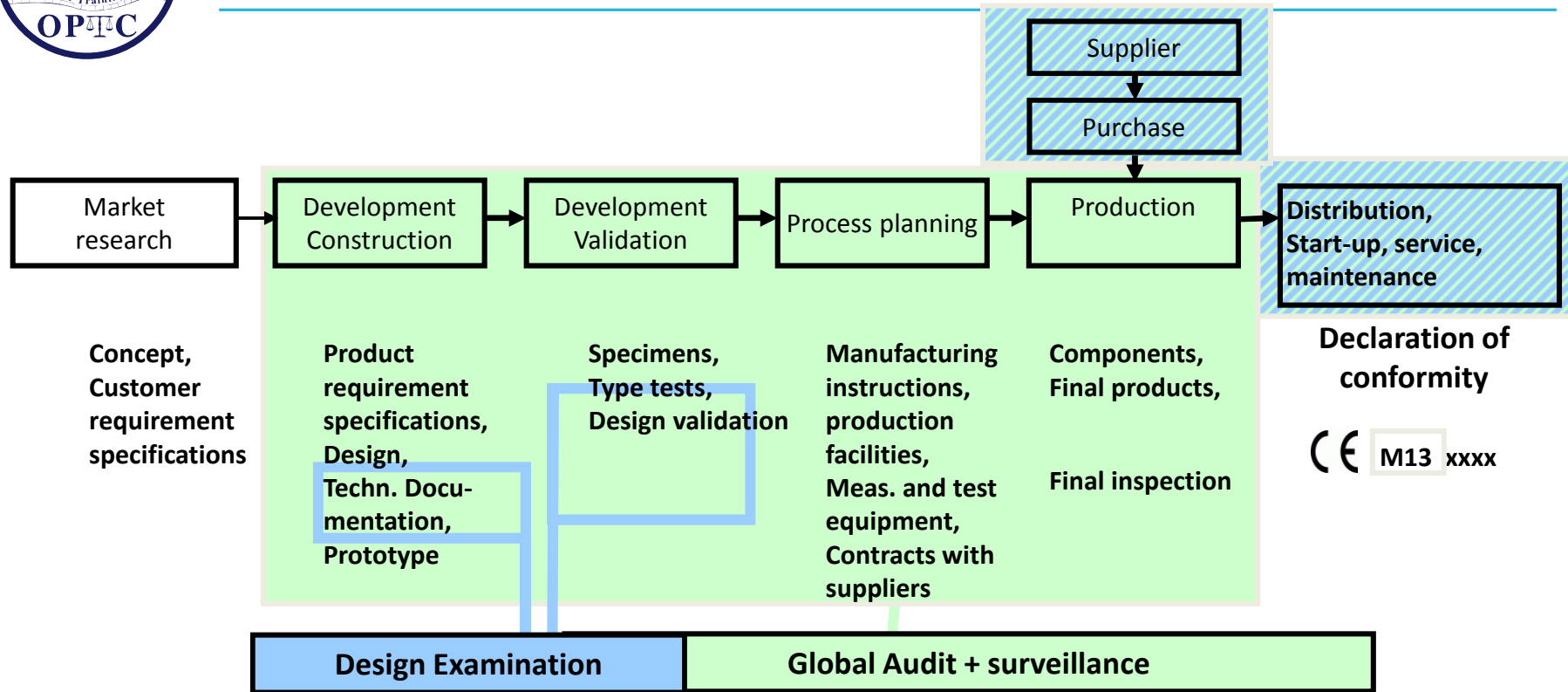


Module G: Unit verification of each single instrument

Applicable for non-mass-produced single instruments MI-005, MI-006, MI-008, MI-009 and NAWID



Conformity assessment modules

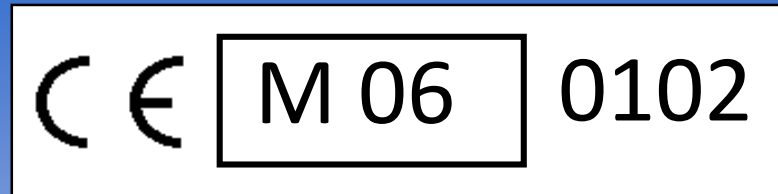


Module H1: Approval of quality management system for development and production + Design examination

MI-001...MI-007, MI-009, MI-010

Applicable for manufacturers with own type test equipment and ISO 9001-certificate

Ticket for the EC-Market since 30th October 2006:



C E = Conformity to applicable technical harmonisation Directives

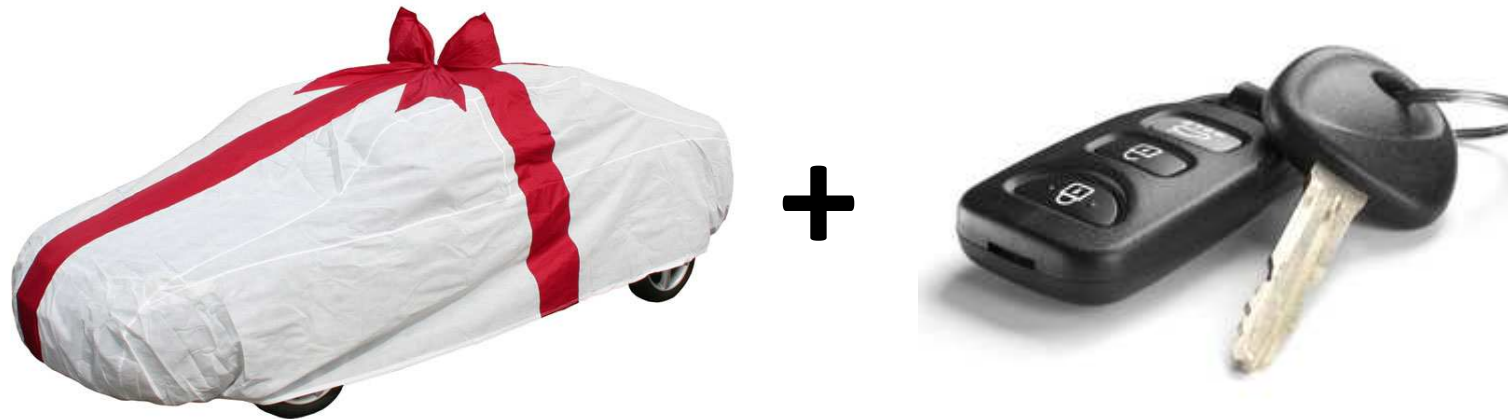
M = Conformity to the legal metrology Directive 2004/22/EC

06 = Year of affixing the CE- and the metrology marking

0102 = Identification no. of the notified body, responsible for the conformity assessment procedure for 'placing on the market' and/or 'putting into use'

Comparison:

Buying a new car and driving after obtaining it,
without any additional testing on national level.



The manufacturer takes over the responsibility,
that the car is conform with European regulation.

**A notified body helps the manufacturer to declare
the conformity.**



Market surveillance



The new approach gives freedom to the manufacturer to place his instrument on the market after finishing successfully the conformity assessment procedures,

⇒ **without any additional national examination!**

But who knows, whether everything is o.k. with the instrument?

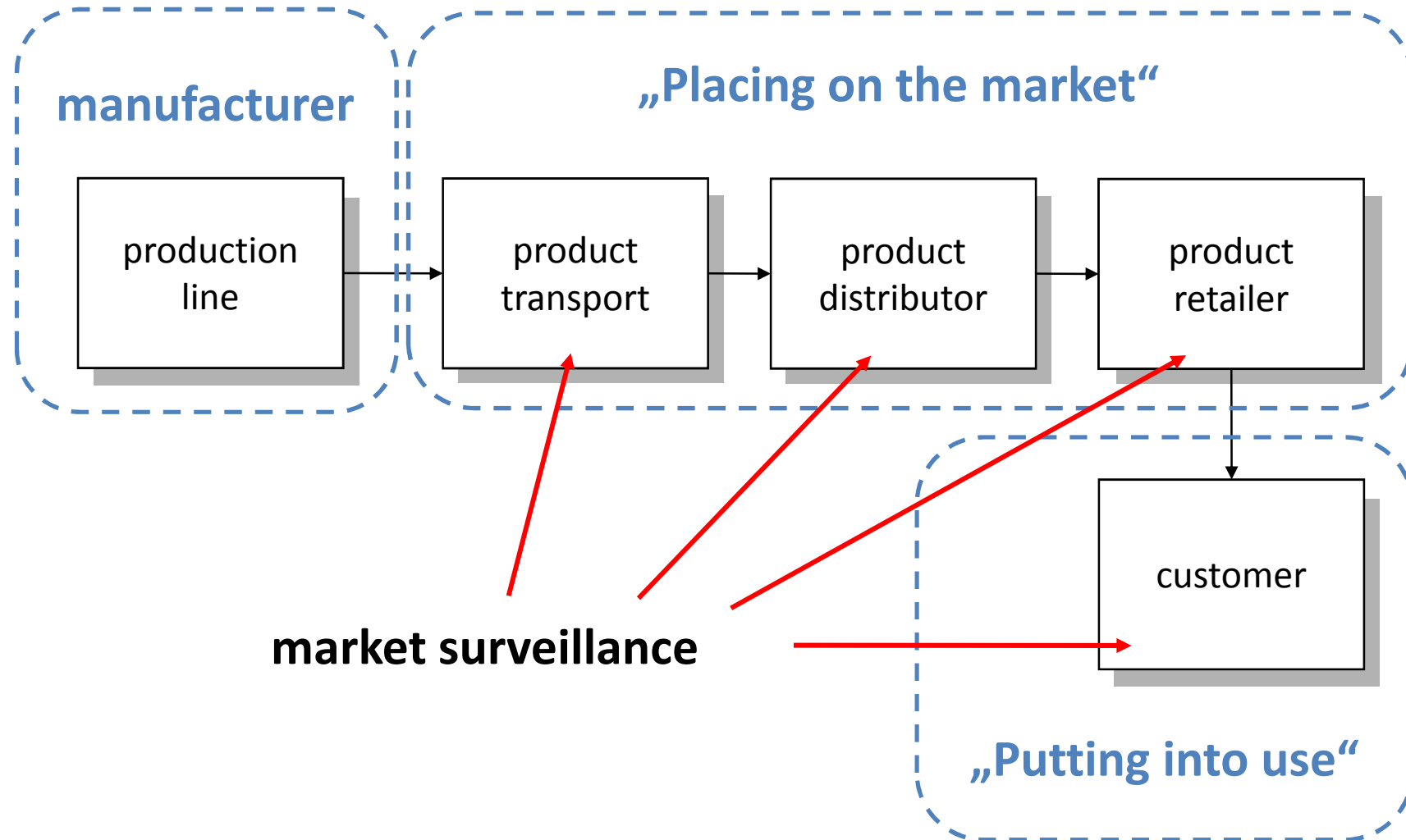
⇒ **The member states have to carry out market surveillance activities!**





Definitions given by Decision EC 768/2008:

1. 'making available on the market' shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;
2. 'placing on the market' shall mean the first making available of a product on the Community market;





section 1:

General provisions



General requirements:

1. Member states shall **organise and carry out** market surveillance.
2. Member states have to provide national **annual market surveillance programs** and have to inform the European commission about them.



3. Products covered by Community harmonisation legislation which

- when used in accordance with their intended purpose or
- under conditions which can be reasonably foreseen and
- when properly installed and maintained,

are liable to **compromise the health or safety of users, or which otherwise do not conform to applicable requirements** set out in Community harmonisation legislation

- are **withdrawn** or
- their being made available on the market is **prohibited or restricted** and that
- the public, the Commission and the other Member States are informed accordingly.



section 2:

Community market surveillance framework



Market surveillance measures

Market surveillance authorities shall perform **appropriate checks** on the characteristics of products on an adequate scale, by means of **documentary checks** and, where appropriate, **physical and laboratory checks** on the basis of adequate samples.

When doing so they shall take account of established principles of **risk assessment, complaints** and other information.



Market surveillance authorities may require economic operators

- to make such **documentation and information available** as appear to them to be necessary for the purpose of carrying out their activities, and,
- where it is necessary and justified, **enter the premises** of economic operators and **take the necessary samples** of products.

They may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary.



Market surveillance **authorities shall cooperate** with economic operators regarding actions which could prevent or reduce risks caused by products made available by those operators.

Where the market surveillance authorities of one Member State decide to withdraw a product manufactured in another Member State, they shall **inform** the economic operator concerned **at the address indicated on the product** in question or in the documentation accompanying that product.



Frequent question:

How to interpret the requirements of the MID and NAWID in the right way???

Example:

“The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. Components that may not be dismantled or adjusted by the user shall be secured against such actions.”



Problem:

Different notified bodies could interpret the Directive differently!



WELMEC (Western European Legal Metrology Cooperation)

Founded on 8 June 1990
by 13 authorities
to harmonise legal metrology
in western Europe



Today:
„European Legal Metrology Cooperation“



Role of WELMEC



31 Members:

28 EU + 3 EFTA

6 Associate Members:

Albania, Bosnia and Herzegovina, FYRM, Montenegro, Serbia, Turkey





WELMEC Working Groups



Working Group 2:
Weighing Instruments

Working Group 5:
Metrol. Supervision

Working Group 6:
Pre-Packages

Working Group 7:
Software

Working Group 8:
Meas. Instr. Directive

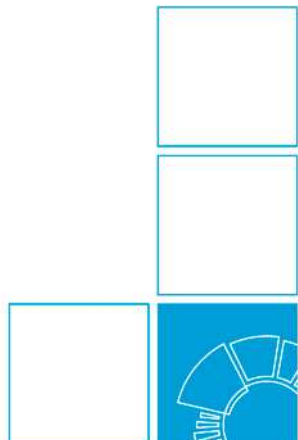
Working Group 10:
Measuring Liquids

Working Group 11:
Utility Meters



What is necessary for a manufacturer to place an instrument on the European market?

- to fulfill the essential and the instrument specific requirements
- to fulfill harmonised standards (i. e. OIML recommendations) or to choose equivalent solutions
- it is recommended to fulfill the corresponding WELMEC guides to fulfill all the requirements
- to choose the conformity assessment modules
- to find a notified body for the conformity assessment (=> NANDO)



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Braunschweig und Berlin**

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