



NLF : Decision 768/2008

Anneke van Spronssen



New Legal Framework

Purpose:

- ▶ To create a more coherent legislative framework for the marketing of products in the EU internal market.

How:

- ▶ Harmonisation of product directives:
Decision 768/2008
- ▶ Strengthening accreditation/market surveillance :
Regulation 765/2008

Concentrate on decision 768/2008



Decision 768/2008

Offers:

- ▶ common framework for future new approach directives/
harmonising existing new approach directives
- ▶ not immediately applicable: focus on European legislators
- ▶ intention: alignment (not revision)

Alignment means bringing an existing directive into line with provisions of Decision 765/2008

Basic principle: align unless there are important sector specific arguments to make an exception for that sector.



Reasons for Decision 768/2008

Non compliance of products

- ▶ to provide improved traceability with clearer requirements on manufacturer, importer and distributor and greater cooperation with enforcement authorities

Performance of notified bodies

- ▶ to provide greater accountability in designation and consistency of performance between notified bodies through reinforce designation process

Inconsistency between directives

- ▶ to provide an alignment of conformity procedures, commonly used definition and structure in the directives.



Measures to avoid non-compliance

Obligation of the Economic operators:

manufacturer:

(responsible for designing/manufacturing product and placing on the market under his own name/trademark)

Obligations extended/made more explicit

- ▶ design and manufacture to essential requirements, technical documentation, consistent production, legal markings, non conforming instruments, risk policy, cooperation with competent authority



Measures to avoid non-compliance

Obligation of the Economic operators:

Authorised representative

(established in EU and acts on behalf of the manufacturer)

Obligations extended/made more explicit

- ▶ Obligations can be the same as for the manufacturer
- ▶ Necessary: written mandate in which tasks are specified.

Following tasks can not be part of mandate:

- ▶ Drawing up the technical documentation (stays with manufacturer)
- ▶ Responsibility for conformity of products (stays with manufacturer)



Measures to avoid non-compliance

Obligation of the Economic operators:

Importer

(places products from a third country on the European market)

Explicit obligation for the first time

- ▶ place only compliant product on the market, ensure that manufacturer had fulfilled his obligations, check on correct conformity procedures and legal markings, cooperation with market surveillance authorities. Add name and address on product.



Measures to avoid non-compliance

Obligation of the Economic operators:

Distributor

(acquires products for further distribution from manufacturer, importer or other distributor.)

Explicit obligation for the first time

- ▶ check on legal markings, relevant documents, name and address of manufacturer and importer, cooperation with market surveillance authorities.



Performance of notified bodies

Role of notified bodies

- ▶ carry out specific tasks in conformity assessment procedures (service to manufacturer)
- ▶ must be competent, independent, impartial,
- ▶ ensure confidentiality of information obtained during conformity assessment
- ▶ information obligation to notifying authority, market surveillance authorities and other notified bodies



Performance of notified bodies

Reinforce designation process involving notifying authority

- ▶ Notifying authority responsible for performance notified body.
- ▶ Appointment notified body on basis of accreditation (preferred method)
- ▶ Appointment notified body on basis of alternative method
- ▶ Notification to the Commission and other member states
- ▶ Commission or other member state may object to designation.
- ▶ Appointment open to scrutiny:
 - a: 2 weeks where basis is accreditation
 - b: 2 months where alternative method is used.
- ▶ re-designation of existing notified bodies.



Measures against inconsistency in directives

- ▶ harmonised structure of directives.
- ▶ harmonised definitions,
- ▶ harmonised responsibilities for economic operators, notifying authorities, notified bodies,
- ▶ harmonised traceability requirements
- ▶ harmonised procedures for conformity assessment, notification
- ▶ harmonised safeguard mechanism.



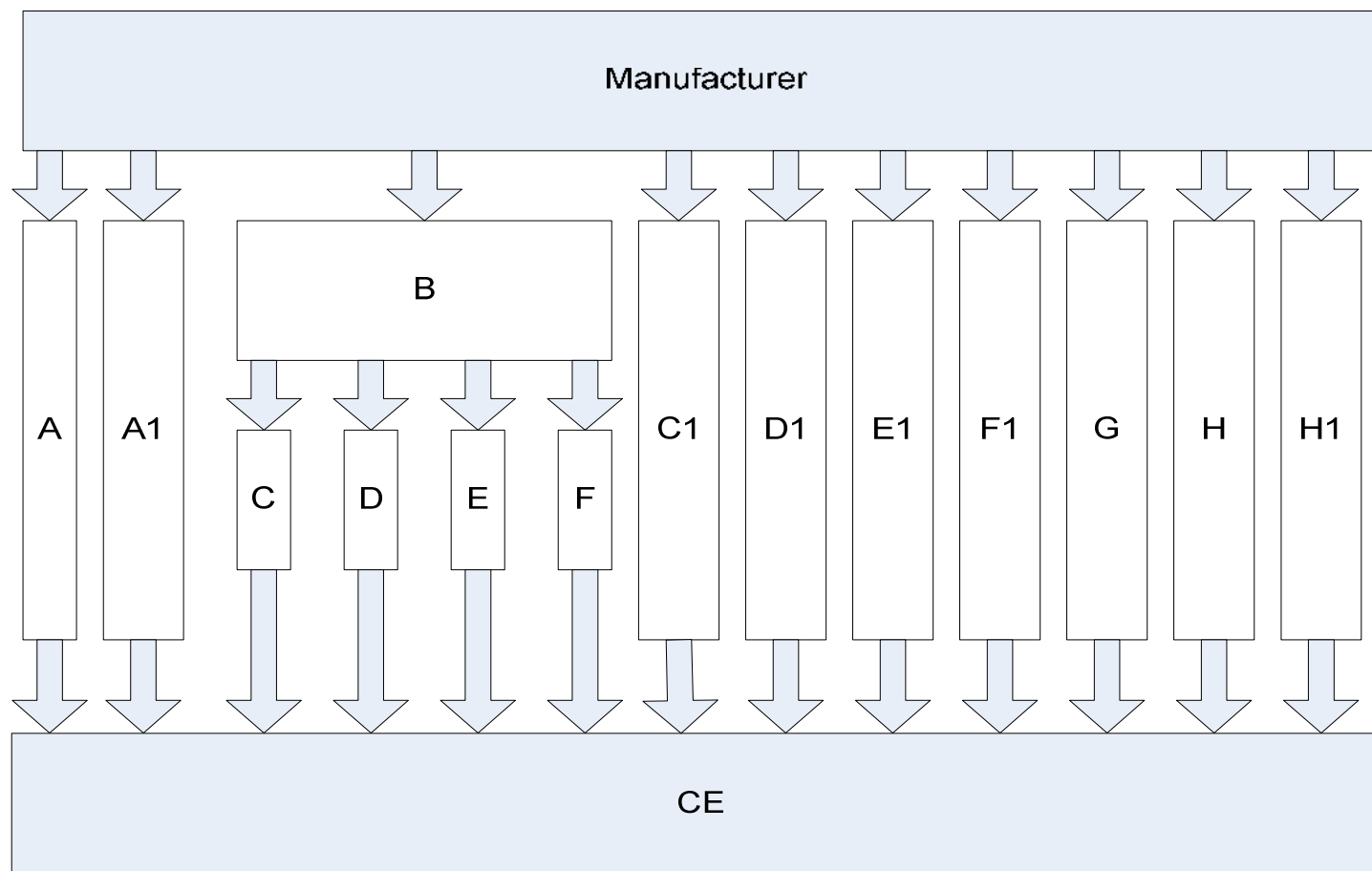
Measures against inconsistency in directives

General structure of directives.

- ▶ Chapter 1: General provisions: scope , definitions etc.
- ▶ Chapter 2: Obligations economic operators
- ▶ Chapter 3: Conformity of products
- ▶ Chapter 4: Notification of conformity assessment bodies.
- ▶ Chapter 5: Surveillance, products entering the Union and safeguard procedures
- ▶ Chapter 6: Committee and delegated acts
- ▶ Chapter 7: transitional and final provision,

Measures against inconsistency in directives

Conformity Assessment procedures



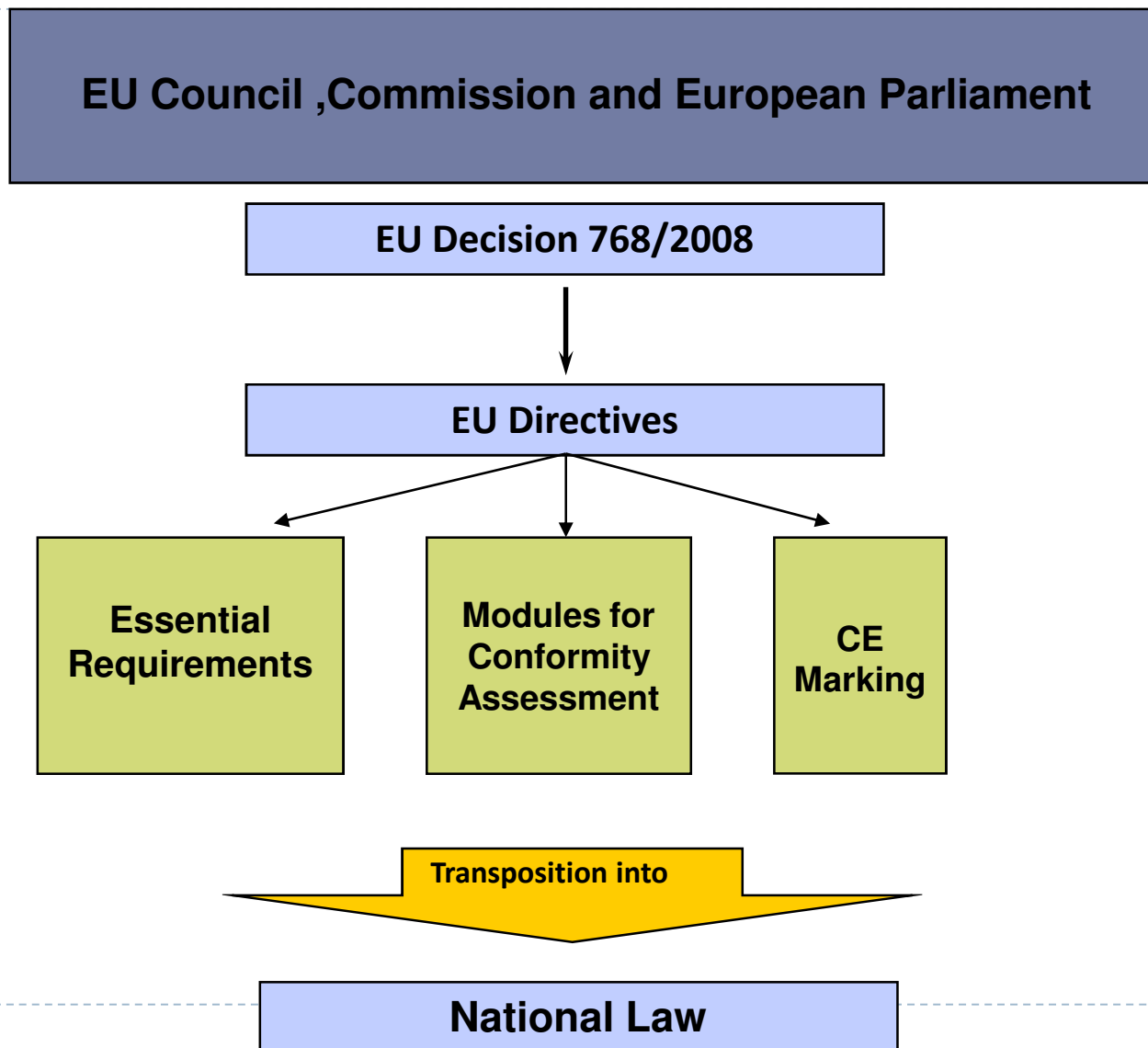


Measures against inconsistency in directives

Surveillance and safeguard procedures

- ▶ reminder to apply regulation 765/2008 by making it explicit
- ▶ requirement that economic operators resolve any non-compliance issues
- ▶ where non-compliance issues are outside national territories, Commission and other Member States are to be informed.
- ▶ Establish whether non-compliance is a failure to meet the requirements or a shortcoming in harmonised standards/normative documents
- ▶ Safeguard procedures available for products presenting a risk at national level

decision making procedure





Omnibus packet

1. Non-automatic weighing instruments: directive 2009/23/EEC
2. Measuring instruments: directive 2004/22/EC
3. Electromagnetic Compatibility: directive 2004/108/EC
4. Low voltage electric equipment: directive 2006/95/EC
5. ATEX: directive 94/9/EC (equipment etc for use in potentially Explosive Atmospheres)
6. Simple Pressure Vessels: directive 2009/105/EC
7. Civil Explosives: directive 93/15/EEC
8. Pyrotechnic Articles: directive 2007/23/EC
9. Lifts: 1995/16/EC

But also under discussion: directives for radio equipment, pressure equipment, marine equipment etc.



Responsibilities

Governments responsible for:

- ▶ implementation directives into national law
- ▶ notifying authority
- ▶ market surveillance

Trade and industry

- ▶ Harmonised standards (with CEN/CENELEC)
- ▶ Economic operators

Any

Questions ??