



NLF: Regulation 765/2008

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Regulation 765/2008

Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products:

- ▶ addresses mainly the duties and responsibilities of EU member states
- ▶ direct applicable with effect of 1 January 2010:
no implementation necessary
- ▶ Member states should withdraw any national legislation
- ▶ Member states should designate a single national accreditation body
- ▶ Market surveillance provisions considered alongside individual provisions.



Accreditation

General principles in 765/2008:

- ▶ One national accreditation body
- ▶ Non-profit basis
- ▶ Member of EA, European co-operation for Accreditation
- ▶ Principle of non-competition
- ▶ Subject to peer evaluation (4 year cycle by EA)



Accreditation

Cross border accreditation possible in following situations:

- ▶ No national accreditation body
- ▶ National accreditation body doesn't offer required accreditation service
- ▶ National accreditation body failed peer review for the required accreditation service.

Conformity assessment procedures

**D
E
S
I
G
N**

B Type examination

EN 17020
+ *EN 17025 taken into account for testing*
or
EN 17065
+ *EN 17025 taken into account for testing*

**P
R
O
D
U
C
T
I
O
N**

C
**Internal
production
control**

**No
interference
notified
body**

C1,C2
**Internal
production
control**

**EN 17025 +
EN 17020 +
EN 17065 +**

D
**Production
quality
assurance**

**EN 17021
+ product
related
knowledge**

E
**Production
quality
assurance**

**EN 17021
+ product
related
knowledge**

F
**Product
Verification**

**EN 17025 +
EN 17020 +
EN 17065 +**

Conformity assessment procedures

Modules referring to the design and production phase

- | | |
|--|----------------------------|
| ▶ A : Internal production control | Not applicable |
| ▶ A1 : Accredited in-house body
test on specific aspect | 17025+ or 17020+ or 17065+ |
| ▶ A2 : Products check at random intervals | 17025+ or 17020+ or 17065+ |
| ▶ D1 : Quality assurance production process | 17021+ |
| ▶ E1 : Quality assurance product inspection | 17021+ |
| ▶ F : Product verification | 17025+ or 17020+ or 17065+ |
| ▶ G : Unit verification | 17020+ or 17065+ |
| ▶ H : Full quality assurance | 17021+ |
| ▶ H : Full quality assurance +
design examination | 17021+17020 or 17021+17065 |

+ : to testing requirements, product knowledge or decision on conformity



Market surveillance

When: After product is placed on the market

Why : to prevent placing on the market/use of non-compliant products.
to secure level playing field for product

Powers market surveillance authorities:

- ▶ visit commercial, industrial and storage premises
- ▶ visit work places etc where products are put into service (petrol pump etc)
- ▶ organise random and spot checks
- ▶ take samples of product for testing
- ▶ require, upon reasoned request, all necessary information.
- ▶ all economic operators role and obligation in market surveillance



Market surveillance

Obligation of Member States

- ▶ organise effective surveillance of their market
- ▶ inform the public about the existence and responsibilities of national market surveillance authority.
- ▶ give market surveillance authorities the necessary power, recourses and knowledge for their task.
- ▶ install legal instruments for sanctions and determine the level of those sanctions.
- ▶ should draw up a national market surveillance program (NMPS)



Products from 3th countries

Important role for customs in supporting market surveillance:

- ▶ obligation of cooperation between customs and market surveillance authorities,
- ▶ to authorise the release of products for free circulation or not
- ▶ Customs suspend release of products by
 - ▶ serious risk
 - ▶ required documentation is missing
 - ▶ CE marking affix in false or misleading way

Market surveillance has 3 working days for first investigation.



Market surveillance

By a risk to public interests there are 4 market surveillance measures.

The economic operator is requested to:

- ▶ take corrective actions (bring product in line with requirements) and/or
- ▶ withdraw the product and/or
- ▶ recall the product and/or
- ▶ stop or restrict supplying the product.



Safeguard clause

Mechanism to keep all parties informed about restrictive measures.

Applicable under the following conditions:

- ▶ a systematic failure in the design of a whole series of products
- ▶ non-compliance not restricted to national territory
- ▶ risk is due to the product and not to its misuses
- ▶ restrictive measures to the free movement of products (f.i. prohibit or restrict placing on the market)
- ▶ economic operator doesn't take corrective actions within the allocated period



Safeguard clause

Notification to the Commission and other Member States

No objection: measure is justified and other Member States should take actions

Objection by other Member States or Commission:

- ▶ consultation member states and economic operators
- ▶ Commission decides if national measure is justified or not.
- ▶ When measure is justified all Member States should take actions to ensure non-compliant product is withdrawn.
- ▶ When measure is not justified the concerned Member State should withdrawn national measure.



Rapex

Community Rapid Information System

Information system for products presenting **a serious risk**.

- ▶ informs the Commission about product, the risk and the measures taken to prevent risk and accidents.
- ▶ Commission informs the National Contact Point of other Member States and publish weekly a overview.
- ▶ National Contact Point informs national market surveillance authority which takes appropriate actions to eliminate the risk.



Information and Communication for market surveillance (ICSMS)

Provides for a comprehensive communication platform between all market surveillance authorities.

- ▶ internal area (limited to market surveillance authorities)
- ▶ public area.

ICSMS offers the possibility to

- ▶ a quick and in time exchange of information on market surveillance measures/issues
- ▶ a effective coordination of activities/inspection on new products
- ▶ share recourses
- ▶ wide scale market interventions on dubious products
- ▶ avoid duplication of inspections
- ▶ share best practices

Are there any questions?