

13th MARS group meeting

**New Law of the Czech republic on Conformity
Assessment and Market Surveillance**

Igor Švarc

Legal department

Czech Office for Standards, Metrology and Testing

The „old“ law - Act no. 22/1997 Coll., on technical requirements for product

- Horizontal framework for establishing technical requirements and related provisions for specified products, both harmonized and non-harmonized.
- Specific provisions for each product group are listed in **government orders** (corresponding to Directives in harmonized area)

Act no. 22/1997 Coll., on technical requirements for product

- Drafted before CR's entry into EU, with the goal to align national conformity assessment procedures and related issues with those used in EU
- Ammended 13 times (mostly) in response to changes to those procedures

New legislative framework

- 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, and repealing Council Decision 93/465/EEC
- 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
- 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

New legislative framework

- Fundamental conceptual changes = act no. 22/1997 Coll. no longer a suitable tool for implementation
- Solution: The new **Act on conformity assessment of select products**
Legal framework tailored specifically for the implementation of EU legal instruments (directives, regulations) based on NLF principles
- Act no. 22 kept in force for non-harmonized, non-NLF and potentially non-EU (international agreements) sectors. Also contains auxiliary issues (standardisation)

The Act on conformity assessment of select products

First wave of implementation:

- 8 directives numbered 2014/28/EU to 2014/35/EU – „alignment package“ (formal changes only)
- Directives including technical changes:
 - 2013/53/EU - recreational craft and personal watercraft
 - 2014/53/EU - radio equipment
 - 2014/68/EU - pressure equipment
 - 2014/90/EU - marine equipment
- Regulation on personal protective equipment (draft)

The Act on conformity assessment of select products

Structure:

Part 1 – Placing products on the market

- General provisions – Scope, Definitions
- Economic operators
- Conformity assessment
- Notified bodies

Part 2 – Special provisions for certain products

Part 3 – Market surveillance

Part 4 – Offences

Part 5 – Final provisions

Market surveillance in the new law

ÚNMZ oversees the activities of notified bodies (including unauthorized practice of NB services)

Market surveillance in matters of

- Placing the products on the market/putting into service
- Duties of economic operators
- Affixing the CE mark or other conformity mark

is carried out by

- Czech trade inspection authority (by default)
- Another bureau if a special law says so (e.g. Czech mining authority in the field of explosives for civil use)

Market surveillance in the new law

During their investigation, market surveillance authority may (in addition to their usual procedures):

- Perform analyses to determine if the product complies with the requirements of the law
- Demand that the economic operator remedied any faults discovered
- Demand that the ec. o. informed the products users of any potential hazards
- Demand cooperation from notified body:
 - Info relating to conformity assesment of the product in question
 - Demand to reevaluate the certificate issued
 - Impose a withdrawal of the certificate

Market surveillance in the new law

Corrective measures

- Suspension – for a period necessary for investigation
- Ban / withdrawal – the product is found to be non-compliant, or ec. o. failed to remedy faults

Formal non-compliance (corr. measures follow after failure to remedy)

- No CE/other marking
- Marking affixed wrongfully
- Missing/faulty declaration of conformity or technical documentation

Market surveillance in the new law

Compliant products that still present a risk

- Demand for corrective measures, including withdrawal. This goes for all of their products on the Union market
- European Commission is informed for further proceedings

Ministry of industry and trade ensures communication with the Commission in all cases where the risk presented oversteps national borders.

Market surveillance in the new law

Offences and sanctions

Natural persons

- Abusing the CE/other marking
- Forgery/alteration of certificates and other such documents

Legal entities and enterprising natural persons (general)

- Abusing the CE/other marking
- Forgery/alteration of certificates and other such documents
- Unauthorized practice of NB services
- Failure to obey instructions and corrective measures of market surveillance authority

Market surveillance in the new law

Notified bodies

- Performance of services in breach of their authorization
- Violation of various NB duties

Economic operators

- Marketing a product without appropriate marking and/or document, or with faulty either
- Violation of various EO duties

Fines can reach as high as 50,000,000 CZK (potential serious consequences, including fatal, with certain products)