

Changes in legislation of the CR in the context of implementation of NLF



ÚŘAD PRO TECHNICKOU NORMALIZACI, METROLOGII A STÁTNÍ ZKUŠEBNICTVÍ

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Legislation before NLF (Decision 768/2008/EC) in the Czech republic:

ACT No 22/1997 COLL. ON TECHNICAL REQUIREMENTS FOR PRODUCTS AND ON AMENDMENTS TO SOME ACTS as amended by Act No 71/2000 Coll., Act No 102/2001 Coll., Act No 205/2002 Coll., Act No 226/2003 Coll., Act No 277/2003 Coll., Act No 186/2006 Coll., Act 229/2006 Coll., Act No 481/2008 Coll., Act No 281/2009 Coll., Act No 490/2009 Coll., Act. No 155/2010 Coll., Act No 34/2011 Coll., Act No 100/2013 Coll., and Act No. 64/2014 Coll.

+ Government Orders implementing Act No. 22/1997 Coll.,

- Government Order [No 426/2000 Coll.](#), that lays down technical requirements for **radio equipment and telecommunications terminal equipment**, (1999/5/EC)
- Government Order [No. 179/2001 Coll.](#), that lays down technical requirements for **refrigeration appliance** (96/57/EC)
- Government Order [No. 194/2001 Coll.](#), that lays down technical requirements for **aerosol dispensers**, (75/324/EEC)
- Government Order [No. 358/2001 Coll.](#), that lays down technical requirements relating to the placing on the market of **explosives for civil uses**, (93/15/EEC)
- Government Order [No. 9/2002 Coll.](#), that lays down technical requirements for products in relation to **noise emission**, (86/594/EEC, 2000/14/EC, 2005/88/EC)
- Government Order [No. 70/2002 Coll.](#), that lays down technical requirements for **equipments to carry persons** (2000/9/EC)
- Government Order [No. 190/2002 Coll.](#), that lays down technical requirements for **construction products bearing the CE marking**, (89/106/EEC)
- Government Order [No. 326/2002 Coll.](#), that lays down technical requirements for **non-automatic weighing instruments** (2009/23/EC; 90/384/EEC before 5.6.2009)
- Government Order [No. 17/2003 Coll.](#), that lays down technical requirements for low voltage **electrical equipment** (2006/95/EC; 73/23/EEC before 16.1.2007)
- Government Order [No. 20/2003 Coll.](#), that lays down technical requirements for **simple pressure vessels** (2009/105/EC; 87/404/EEC before 28.10.2009)
- Government Order [No. 21/2003 Coll.](#), that lays down technical requirements for **personal protective equipment** (89/686/EEC)
- Government Order [No. 22/2003 Coll.](#), that lays down technical requirements for **appliances burning gaseous fuels** (2009/142/EC; 90/396/EEC before 5.1.2010)
- Government Order [No. 23/2003 Coll.](#), that lays down technical requirements for equipment and protective systems intended for use in **potentially explosive atmospheres** (94/9/EEC)
- Government Order [No. 25/2003 Coll.](#), that lays down technical requirements for **efficiency requirements of new hot-water boilers** fired with liquid or gaseous fuels, (92/42/EEC)
- Government Order [No. 26/2003 Coll.](#), that lays down technical requirements for **pressure equipment**, (97/23/EC)
- Government Order [No. 27/2003 Coll.](#), that lays down technical requirements for **lifts**, (95/16/EC, 2006/42/EC)

- Government Order No. 55/2015 Coll., on the technical requirements for **active implantable medical devices** (90/385/EEC, as amended by 93/42/EEC and by 93/68/EEC)
- Government Order No. 54/2015 Coll., on the technical requirements for **medical devices** (93/42/EEC, 2003/32/EC)
- Government Order No. 56/2015 Coll., on the technical requirements for **"in vitro" diagnostic medical devices** (98/79/EC, as amended by 2011/100/EU)
- Government Order [No. 133/2005 Coll.](#), on technical requirements for **operational and technical interoperability of the trans-European rail system** (2008/57/EC)
- Government Order [No. 174/2005 Coll.](#), that lays down technical requirements for **recreational crafts** and partly completed boats and selected components, personal watercrafts and propulsion engines of recreational craft and personal watercrafts (94/25/EC, as amended by 2003/44/EC)
- Government Order [No. 365/2005 Coll.](#), on the **emission of pollutants** from exhaust gases of spark ignition engines to be installed in non-road mobile machinery (2002/88/EC)
- Government Order [No. 464/2005 Coll.](#), that lays down the technical requirements on **measuring instruments** (2004/22/EC)
- Government Order [No. 616/2006 Coll.](#), that lays down technical requirements for products relating to their **electromagnetic compatibility** (2004/108/EC)
- Government Order [No. 176/2008 Coll.](#), on technical requirements for **machinery** (2006/42/EC, 2009/127/ES, 2012/32/EU)
- Government Order [No. 266/2009 Coll.](#), that lays down the technical requirements for **marine equipment** (96/98/EC, 2010/68/EU)
- Government Order [No. 86/2011 Coll.](#), on technical requirements for **toys** (2010/35/EU)

- Government Order No. [481/2012 Sb.](#) /PDF 754 kB/ on the restriction of the use of certain hazardous substances in electrical and electronic equipment. (2011/65/EU)

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 - Government Order No. 339/2002 Coll. laying down procedures for the provision of information in the field of technical regulations, technical documents and standards, (98/34/EC, as amended by 98/38/EC)

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 - GOs - non harmonised national legislation – technical requirements on some products (construction products not covered by CPR...)

Changes in legislation of the CR in the context of implementation of NLF

Changes in the EU

- 2008 – New Legislative Framework (768/2008/EC)
- Set of 8 new/recasted directives in line with NLF principles:
 - Directive 2014/28/EU – explosives for civil use
 - Directive 2014/29/EU – simple pressure vessels
 - Directive 2014/30/EU – EMC
 - Directive 2014/31/EU – non automatic weighing instruments
 - Directive 2014/32/EU – measuring instruments
 - Directive 2014/33/EU – lifts
 - Directive 2014/34/EU – ATEX
 - Directive 2014/35/EU - LVD

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Decision in the Czech republic

- Act 22/1997 Coll. – to be kept for „classical“ New Approach directives + relevant GOs – it can be expected, that they will be later also changed according to NLF. GO related to this Act will be abolished when Directive´/s will be recasted
- New act for NLF was issued + GO orders for recasted Directives
- New notification of NBs was executed with validity according to date of validity of relevant Directive under NLF (mostly 20.4. 2016) – more simple procedure for notification

Changes in legislation of the CR in the context of implementation of NLF

New Act :

Act 90/2016 Coll. of 3 March 2016

on **conformity assessment of specified products** when made available on the market

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Set of relevant Government Orders published in Collection of Laws on March
18 2016

Changes in legislation of the CR in the context of implementation of NLF

Act 90/2016 Coll.

- Horizontal legislation which allows:
 - Transposition of directives allied with NLF (existing or expected = PPE, gas appliances, cable lifts)
 - Adaptation of directly applicable EU regulations (probably will be used more often in the EU in the future ...)
- ACT is divided to 4 basic parts/chapters:
 - Making products available on the market
 - Special provisions for certain products
 - Market surveillance
 - Administrative offences (sanctions)

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Making products available on the market

- Basic duties of economic operators
- Notified bodies – conditions for NBs according to NLF
- Notification of NBs – one level process (without authorisation) – for all new directives (GOs)
- Notification will be realised according to administrative procedure given by the Czech legislation

Special provisions for certain products

- Act contains adaptation measures for directly applicable EU legislation and specific arrangements of EU directives – f.e.:
 - Directive on recreational crafts – introduction of term „private importer“, definitions,...
 - PPE – national competent authority
 - Lifts – definitions, installer,
 - EMC - definitions
 - Marine equipment – definitions, EC declaration, marking of conformity, NBs inspection
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Market surveillance

- Act regulates the area of Market surveillance for placing on the market products covered by legislation under NLF
- Powers of Market surveillance authorities for directly applicable EU regulations (CPR)
- Law was prepared in cooperation with Czech Market inspectorate (ČOI)

Administrative offences (sanctions)

- Definitions
- Offences committed by natural persons
- Offences committed by legal persons

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Changes of existing legislation

- ACT 22/1997 – remains valid with few changes and will be used
 - For transposition of NA directives not covered by NLF
 - In future it will be used transposition of Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage (ATP) – for authorisation of bodies for conformity assessment of refrigerating units
 - For regulation of the area of standardisation
 - For regulation of accreditation
- GOs in the area covered by NLF were replaced by new GOs to Act 90/2016 (explosives for civil use, simple pressure vessels, EMC, non automatic weighing instruments, measuring instruments, lifts, ATEX, LVD)

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Texts of Acts (22/1997 and 90/2016) and list of GOs can be found (in English) at

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THANK YOU FOR YOUR ATTENTION

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