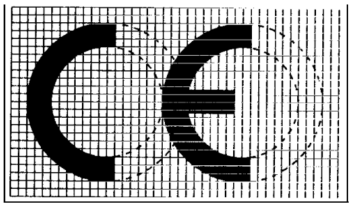
ASSOCIATION OF ACCREDITED AND AUTHORIZED ORGANIZATIONS, z.s. ®
Secretariat: Prosecká 412/74, 190 00 Praha 9 - Prosek
tel. +420 286 019 420
e-mail: aaao@aaao.cz
http://www.aaao.cz



Placing of products on the Internal Market of the European Economic Area

Procedures of economic operators

Services of testing, inspection and certification bodies of the Czech Republic – an EU Member State

Version 2021

This document is addressed primarily to manufacturers (established everywhere incl. in the Czech Republic) placing their products on the market of the European Economic Area (EEA). It may be used also by importers of products to the EEA, distributors as well as authorised representatives established within the EEA, especially those established in the Czech Republic.
It can be useful also for staff members of authorized/notified bodies and recognised third-party organisations, fulfilment service providers, and end users of products. It can be used also by associations of economic operators, training and educational organizations and institutions, national authorities, and other expert public.

Contents:

Foreword

The optimum way how to use this publication is to copy it to a PC with internet access and use the hypertext links to external information sources.
All active links used in the publication (and many other) are listed in ***Annex A****. In the relevant part of the text, the non-active link is represented by a number in square brackets – e.g. [A1.1]. The same number is used for the activated link in Annex A. The link can be opened by combination Ctrl+click or in any other way used by the concrete PC (creating a separate working file with Annex A will make the use of links prompter).*

For easier understanding of the text, it is recommended first to pay attention to ***Chapter 0*** *of this publication which contains basic* ***terms and abbreviations*** *(definitions) used in the text.*

Introduction

Supported by the Czech Office for Standards, Metrology and Testing – **ÚNMZ** – [A3.1] under the Standardisation Plan – Program for Development of Testing [A6.8] – the Association of accredited and authorised organisations **AAAO** [A3.2] issued in 2013, 2016, 2018, and 2020 publications for manufacturers (and other economic operators) from third countries concerning rules for placing of products on the internal market in the EU/EEA (hereinafter the **internal market**) [A1.11]. In 2015, 2017, and 2019, publications with the same subject matter and updated text were issued for economic operators in the Czech Republic.

In this "Version 2021", the text is consolidated foe economic operators in the Czech Republic (EU) and for economic operators from third countries.

The rules described in the following text apply generally to products posing a higher degree of danger to justified concern. They can be placed on the market provided (a.o.) their conformity with the essential requirements of the relevant legislation acts has been assessed.

This applies only to products, for which conditions for their entry on the internal market in the EEA [A1.11] are regulated by **EU harmonisation legislative acts of the "New Approach"** [A1.12]. These are currently being completed and replaced by **EU harmonisation legislative acts** (directives, regulations) of the "**New Legislative Framework"** [A1.13] for which these rules are also valid. Recently also legislative acts of the "**Goods Package: Reinforcing trust in the single market"** [A1.14] apply.

In the Czech Republic, these rules apply in principle also to products placed on the market in accordance to the national Czech legislative acts not harmonised with the EU legislation.

In the Czech Republic, the rules described in the following text apply to products called in this publication **"specified products"**, see definition 026 in Chapter 0.

Information and recommendations in this publication are concerning specifically the placing of products on the market **in the Czech Republic**, which means also their placing on the internal market.

This publication describes only the **basic principles** which the manufacturer (established anywhere in the world) should not ignore when placing his products on the market in the EEA in accordance with the legislative acts. Further details can be found in the information sources mentioned in the publication (repeatedly, if appropriate). As these sources including

information contained are subject to development and changes, their **up-to-date version** should always be used.

This publication therefore applies to various types of products described further as "sectors" [A5.1], [A5.6]. In different sectors, some rules are similar or even identical (rules being continuously consolidated), some differ for various reasons. This publication tries to grasp the main rules common to all sectors.

***Note:** Only the **sector of construction products** is currently cut out of this publication. This specific area is described in Appendix 2.*

0 Selected basic terms and abbreviations

01 ČR – Czech Republic, Member of the EU;

02 European Economic Area (EEA) [A1.1] – consists of the EU Member States, Liechtenstein, Norway, and Iceland.

***Note 1:** Countries outside this list are **third countries**.*

***Note 2**: On 1 February 2020, the United Kingdom of Great Britain and Northern Ireland (hereafter the United Kingdom) withdrew from the European Union. The Withdrawal Agreement provides for a transition period ending on 31 December 2020. Since 1 January 2021, the United Kingdom is regarded as "a third country" with all consequences (for example, the Notified Bodies established in the United Kingdom lost their NB status and their outputs are longer usable for placing products on the internal market). The economic operators concerned should therefore consider very carefully the impact of this change of legal situation. For more information concerning the product sectors, see the European Commission website on Brexit [A1.17].*

***Note 3:** in EU documents and quotation from them, "Union" is also used instead of "EU";*

03 Internal market [A1.11] – the market of the EU/EEA states to which a.o. free movement of products applies (see also 1.4 below); in the frame of the Custom Union Agreement the rules for free movement of products also enclose Turkey;

***Note:** If "market" is mentioned in further text, this means the "internal market".*

04 Regulated area – the public life area in which requirements and rules are laid down by special legislative acts;

***Note 1**: in this publication – for "specified products" (see definition 026) – concerns rather individual qualities than products, services etc. in the whole;*

***Note 2**: the regulated area is much larger than the "specified products" area (see definition 026) and also much larger than the area in which a notified body (definition 020) is taking part in conformity assessment (definition 018);*

05 Harmonised area – the part of the regulated area where the legislative acts containing rules and requirements are **harmonised within the EU** and replace individual national legislative acts with common regulation:

- either **directly applicable** (regulations), or
- **transposed** in all Member States (from EU directives into national legislation);

06 Non-harmonised area – the part of the regulated area where harmonisation within the EU has not been accomplished yet. In this area national requirements and procedures apply which for entry and movement of products on the internal market under the requirements laid down by legal legislative acts (e.g. in the Czech Republic Section 13b of Act 22 [4.1]) can be regarded as **equivalent**; eventual problems were solved in accordance with Regulation 764 [A2.2]; since its withdrawal on 19 April 2020 (see also definition 011) problems have been solved in accordance with **Regulation 515** [A2.6] – see definition 011.1;

07 EU harmonisation legislative acts:
- generally – legislative acts of the EU harmonising rules within the EU in areas where the Member States have agreed to harmonised texts;
- for this publication – all pieces of the EU legislation harmonising conditions for placing of products (specified – see definition 026) on the internal market;

08 New Approach (NA) [A1.12] – the set of EU activities and documents applied in the EU since ca 1985. It is based on laying down binding "essential requirements" in legislative acts with detailed specification in non-binding harmonised standards or other harmonised specifications;

08.1 "The Guide to the implementation of directives based on the New Approach and the Global Approach" (the Blue Guide) – published by the European Commission in 2000 containing rules (more detailed than this publication) for placing most of "specified products" (definition 026) on the market in accordance with the **New Approach** [A1.12]. In praxis and in this publication – the **"Blue Guide 2000"** [A6.1];

08.2 "The Blue Guide on the implementation of EU products rules 2016" – published by the European Commission in 2016 as update of the Blue Guide 2000 (see 08.1 above) containing rules (more detailed than this publication) for placing most of "specified products" (definition 026) on the market in accordance with the **New Approach** [A1.12]. In praxis and in this publication – the **"Blue Guide 2016"** [A6.1.1];

08.3 Blue Guide updated – prepared by the European Commission as an update of the Blue Guide 2016 (see 08.2 above) with rules (more detailed than this publication) for placing most of "specified products" (definition 026) on the market in accordance with the **New Legislative Framework** [A1.13] – see [A6.1.2]. *It will be available on the website of the European Commission [A1.2] and the ÚNMZ [A3.1] after publication of the official text by the Commission.*

09 Presumption of conformity – the basic principle of the New Approach [A1.12] – fulfilling of the relevant requirements of a harmonised specification (standard or other relevant document) is considered to be fulfilling of corresponding (essential) requirements of the legislative act;

010 New Legislative Framework (NLF) [A1.13] – the result of so called "revision of the New Approach [A1.12]" in the years 2005-2008 consisting of the following legislative acts:
- Regulation 515 [A2.6] – in force since 19 April 2020, replaces Regulation 764 [A2.2] (see definition 011.1);
- Regulation 765 [A2.3] (on 16 July 2021 amended by Regulation 1020 [A2.8]);
- Decision 768 [A2.4].

011 Regulation 764 (repealed from 19 April 2020 – see definition 011.1) – 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 [A2.2];
*(This was one of **directly applicable** EU legislative acts in the Czech Republic and other Member States.)*

011.1 Regulation 515 – Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 [A2.6];
*(this is one of **directly applicable** EU legislative acts in the Czech Republic and other Member States);*
(new legislative act – in force since 19 April 2020);

012 Regulation 765 – 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. This regulation is directly applicable to all Member States [A2.3];
*(this is one of **directly applicable** EU legislative acts in the Czech Republic and other Member States);*
Amendments (incl. title) by Regulation 1020 [A2.8], Article 39 entered into force on 16 July 2021, the new title being "Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93". See also definition 012.1.

012.1 Regulation 1020 – Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 [A2.8];
*(this is one of **directly applicable** EU legislative acts in the Czech Republic and other Member States);*
(new legislative act – in force since 16 July 2021, some articles since 1 January 2021);

***Note 1**: New draft of Czech market surveillance act [A4.8] is being prepared implementing this directly applicable regulation – see Appendix 1, Items 4 and 10.*

013 Decision 768 – 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 [A2.4];

014 CPR – Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC [A8.2];
*(this is one of **directly applicable** EU legislative acts in the Czech Republic and other Member States);*
Amendments of Article 56 by Regulation 1020 [A2.8], Article 40 entered into force on 16 July 2021. See also definition 012.1 above.

015 Act 22 – in the Czech Republic only – Act No. 22/1997 Coll., on Technical Requirements for Products and on Amendments to Some Acts, as amended [A4.1]. It implements the New Approach [A1.12] principles into the Czech legislation and the relevant government orders implement the EU harmonisation legislative acts issued **before implementation** of the New

Legislative Framework [A1.13] (except for the Toys' safety Directive which is harmonised with its principles). Some government orders which do not transpose European harmonisation legislative acts have been issued for implementation of Act 22. In such cases no bodies are notified;

016 Act 90 – in the Czech Republic only – Act No. 90/2016 Coll., on Conformity Assessment of Specified Products when Made Available on the Market, as amended [A4.2] – it implements principles of the New Legislative Framework [A1.13] (especially using Decision 768 [A2.4]) into the Czech legislation and the relevant government orders implement the EU harmonisation legislative acts issued **in compliance with** the New Legislative Framework [A1.13];

017 Government orders – in the Czech Republic – in this form of Czech legislative act, the EU harmonisation legislative act (EU directive) is usually transposed into the Czech legislation. In this publication, only government orders issued for implementation of **Act 22** [A4.1], **Act 90** [A4.2] and **Act 206** [A4.3] are mentioned;

018 Conformity assessment

- according to Decision 768/Act 90 [A2.4/A4.2] – the process of demonstrating whether specified technical/essential requirements relating to a product, process, service, system, person or body have been fulfilled;
- according to the Blue Guide 2016 [A6.1.1] – the process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled. A product is subjected to conformity assessment during both the design and the production phase;
- practical definition (for the Czech Republic and for this publication) – the set of activities by which fulfilling of relevant requirements of legislative acts valid in the Czech Republic (directly applicable, or harmonised with the EU, or national ones for the Czech Republic only) on performance of the product and activities of the manufacturer is ascertained, confirmed and documented for the specified products (see definition 026); fulfilling of the requirements is the condition for legal placing of the product on the market in the Czech Republic and thus on the internal market;

019 Conformity assessment body

- in the Czech Republic – according to Section 3 paragraph h) of Act 90 [A4.2] – a person or an organisational unit of the state performing conformity assessment activities including calibration, testing, certification and inspection;
- according to the Blue Guide 2016 [A6.1.1] – a body performing activities concerning conformity assessment procedures laid down in valid technical harmonisation legislative acts, if involvement of a third party is required;

020 Notified body – a legal entity notified according to the relevant piece of EU New Approach legislation and listed in the **NANDO** database [A6.6]. It is notified by an EU/EEA Member State (also by the Czech Republic) for conformity assessment activities (testing, inspection, certification) at which its involvement is required or enabled by the relevant EU New Approach harmonisation legislation.
When listed in NANDO, the notified body is entitled to act in the whole EU/EEA.

Note 1: *the* ***term "notified body"*** *used in this publication covers* ***in the Czech Republic also subjects with different names*** *corresponding with the Czech legislative acts issued in the past: authorized body, recognized third-party organization;*

***Note 2**: the scope of notification is always specified for:*
- *a product (product group);*
- *a legislative act or its part;*
- *and a module/assessment procedure with possible further specification;*

***Note 3**: the scope of notification of different bodies is different, scopes of their activities overlap;*

***Note 4**: if the scope of notification of*
different notified bodies in one Member State does not cover all needs/obligations of manufacturers from the said Member State, services of notified bodies from other Member States have to be used;

021 hEN – harmonised European standard;

022 hČSN – in the Czech Republic only – harmonised Czech standard;

023 uČSN – in the Czech Republic only – specified Czech standard;

024 ÚNMZ – in the Czech Republic only – Czech Office for Standards, Metrology and Testing (an organisational unit of the state) [A3.1];

025 ČAS – in the Czech Republic only – Czech Standardization Agency [A3.4] (a state contributory organization established by the ÚNMZ) [A3.1];

026 Specified product – only in the Czech Republic and for this publication – a product (sort of products) representing higher degree of endangering of public interest. Therefore, conformity of such products with legislative acts has to be ensured and assessed before their placing on the market. These products are (in the Czech Republic) **covered by**:
a) **directly applicable** EU legislative acts concerning placing products on the market (the Czech legislation is adapted to these EU acts by means of Act 22 [A4.1] or Act 90 [A4.2], or other Czech legislative acts);
b) Czech **Government Orders** issued for implementation of Act 22 [A4.1] or other laws. This concerns also products covered by Czech national government orders for selected products [A4.6] and selected construction products [A8.6] as well as products covered by the Atomic Act 263 [A4.5] and its implementing regulations [A4.5.1];
c) Czech **Government Orders** issued for implementation of Act 90 [A4.2];
d) **Act No 206/2015 Coll.** on pyrotechnics (hereinafter Act 206) [A4.3];

027 Making available on the market – any supply of a product for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge (according to Decision 768 [A2.4] and since 16 July 2021 similarly according to Regulation 1020 [A2.8]);

028 Placing on the market – the first making available of a product on the market (according to Decision 768 [A2.4] and since 16 July 2021 similarly according to Regulation 1020 [A2.8]);

***Note**: the meaning may be made more precise in some sectors – for example for lifts Act 90 [A4.2] in Section 28, paragraph d) defines placing on the market as the supply of a lift for use on the market of the European Union...;*

029 Economic operators

- according to Decision 768 [A2.4] – the manufacturer, the importer, the distributor, and the authorised representative;
- according to Regulation 1020 [A2.8] (see definition 012.1 above) – ditto plus the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant EU harmonisation legislation;

***Note**: one legal subject may – for different products or even for the same product – be concurrently in the position of different economic operators;*

030 Manufacturer – established anywhere in the world:

- according to Decision 768 [A2.4] – any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;
- according to Act 90 [A4.2] – only in the Czech Republic – any person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark or uses it, if so stipulated by the Government in its Order, for his own use;
- according to Act 22 [A4.1] – only in the Czech Republic – any person who manufactures or just has designed a product, and where stipulated so by the Government in its Order, also a person who assembles, packs, processes or marks a product for which he is responsible under this Act and which he intends to place on the market under his name or trademark; where stipulated so by the Government for a product or for a group of products in its Order, as a manufacturer shall be deemed also a person who modifies a product already placed on the market in such a way that its compliance with the applicable technical requirements may be affected;
- since 16 July 2021 according to Regulation 1020 [A2.8] – any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark;

***Note**: The term **manufacturer** covers in this publication in accordance with some EU harmonisation/Czech legislative acts also subjects responsible for the final product at products which are finalised (and thus placed on the market) at the place of use, often from components – products – from various manufacturers (e.g. lifts, some machinery, pressure equipment etc.). Namely, for lifts, the responsibility for a final product placed on the market (i.e. completed on the spot and put into use) lies with the **installer**, whereas the components for assembling the lift are supplied to him by their **manufacturers**.*

031 Authorised representative – established within the EU

- according to Decision 768 [A2.4] – any natural or legal person who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- since 16 July 2021 according to Regulation 1020 [A2.8] – any natural or legal person who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the relevant EU harmonisation legislation or under the requirements of Regulation 1020;

032 Importer – established within the EU – any natural or legal person who places a product from a **third country** (outside the EU) (according to Decision 768 [A2.4] and since 16 July 2021 similarly according to Regulation 1020 [A2.8]);

033 Distributor – established anywhere – any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the internal market (according to Decision 768 [A2.4] and since 16 July 2021 similarly according to Regulation 1020 [A2.8]);

034 Fulfilment service provider – since 16 July 2021 (according to Regulation 1020 [A2.8]) – any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding any postal services or freight transport services;

035 End user – since 16 July 2021 (according to Regulation 1020 [A2.8]) – any natural or legal person residing or established in the EU, to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities;

036 CE marking – a marking by which the manufacturer on his responsibility indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing (according to Decision 768 [A2.4]);

037 Recall – any measure aimed at achieving the return of a product that has already been made available to the end user, to the person who has delivered the product to the end user (according to Decision 768 [A2.4]);

038 Withdrawal – any measure aimed at preventing a product in the supply chain from being made available on the market (according to the Decision 768 [A2.4]);

039 Non-compliance – since 16 July 2021 (according to Regulation 1020 [A2.8]) – any failure to comply with any requirement under the Union harmonisation legislation or under Regulation 1020;

040 Risk – since 16 July 2021 (according to Regulation 1020 [A2.8]) – the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;

041 Online interface – since 16 July 2021 (according to Regulation 1020 [A2.8]) – any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end users access to the economic operator's products;

1 Basic rules for entry of a product on the market

1.1 A **product** can be **placed** on the market only if:

a) it is **safe** – a product is safe if, under normal conditions – presumable, foreseeable – during its declared or normal usability does not present any risk or its use presents only minimum risk from the point of view of safety and health or protection of property and the environment which can be considered to be acceptable when using the product;
and if:
b) it fulfils **essential requirements** of the legislative acts concerning health and safety or the environment provided the product is used in accordance with the manufacturer's

instructions or within the "foreseeable use";
and if:

c) it fulfils requirements of the legislative acts for **marking** of the product and for the **accompanying documentation** for use (especially instructions for use and safety information);
and if:

d) its **conformity has been successfully assessed** by the procedure laid down by the relevant legislative act and the **EU Declaration** of Conformity (EC Declaration of Conformity according to the older legislation) or another document required by the relevant act has been issued.

1.2 The **manufacturer** of a product (irrespective of the country where he is established) **is responsible** for placing on the internal market only products meeting these requirements. The product (an identifiable piece, assembly, delivery and the like) must fulfil legal requirements in force **in the moment of its placing on the market**.

***Note 1**: The term **manufacturer** covers (in general and **everywhere** in this publication) also the subject responsible for a product assembled **on the place of use** (e.g. some machinery and pressure equipment).*
Instead of the term manufacturer, the term installer is used only in legal acts concerning lifts where this term is properly defined. In the Czech legislation, the installer of a lift is defined in Section 28, subsection 2 of Act 90 [A4.2] as the person who is responsible for the design, manufacture, installation and placing of the lift on the market. Therefore, the installer of the lift is the person which takes over obligations attributed in other harmonisation legislative acts usually to the manufacturer.
The concept of manufacturer according to the EU harmonisation legislation based on the New Legislative Framework [A1.13] is different from the concept of manufacturer in Directive 85/374/EEC concerning liability of consumer products [A2.7].

***Note 2**: Some EU harmonisation legislation contain also terms "putting into service" (e.g. lifts [A5.6.13]) or "own use" (e.g. machinery [A5.6.27] to be used by the manufacturer himself) which are equivalent to "placing on the market".*

1.3 The EU harmonisation legislation and the corresponding Member States' national legislative acts lay down requirements for placing of products on the market:

- **for manufacturers**; and
- for other **economic operators** – authorised representatives, importers, distributors, and according to Regulation 1020 [A2.8] (see definition 012.1 above) for fulfilment service providers.

1.4 The basic types of EU legislation from the point of view of their application in the Member States are:

a) **directly applicable** EU acts – regulations (EU) of the European Parliament and of the Council or implementing regulations of the European Commission, or decisions of the European Parliament and of the Council;
b) EU acts **intended for transposition** into the Member States' legislation – EU directives (currently the mostly used form, but in future directly applicable acts should be more frequent);
c) **delegated acts** adopted by the European Commission according to relevant provisions and duly notified to the European Parliament and the Council;

The European Commission publishes also **interpretative** documents – not binding guidelines supporting proper use of the legislative acts mentioned. Even though these guidelines are not legally binding, they are based on the consensus of all interested parties (legislators, representatives of economic operators, state and market surveillance authorities etc.) and contain guides, instructions and explanations for application of concrete articles in concrete situations. As these materials are widely respected, their knowledge and use is highly recommended.

1.5 According to Article 4 of Regulation 1020 [A2.8], since 16 July 2021 a product may, in specified cases, be placed on the market only if there is an economic operator established in the EU who is responsible for the tasks set out in this article in respect of that product.

1.6 In the Czech Republic, basic legislative acts for the **harmonised area** of specified products are **Act 22** [A4.1] based on principles of the New Approach, and **Act 90** [A4.2] based on the principles of the New Legislative Framework, and **Act 206** [A4.3].
These principles cover sectors (areas) listed in **Annex A**, Part No. 5 of this publication, the current state can be followed in the **ÚNMZ Information Portal** [A6.2] in the following sections:

a) product areas (sectors) to **Act 22** [A5.2];
b) product areas (sectors) to **Act 90** [A5.3].

In addition to products from the above mentioned sectors (areas), in the Czech Republic products from the **non-harmonised area** (general [A5.6.34] and construction [A8.6] are also covered by **Act 22**, see also 2.8.

1.7 Legal placing of a product on the market in any EU/EEA Member State (including the Czech Republic) means placing of the product on the internal market. If the product has been placed on the market in compliance with legislation of the state of placing on the market, such a product can be further distributed freely into other Member States without technical barriers on the Member States' borders.
Specific requirements such as requirements related to language of accompanying documentation for use of the product are laid down by relevant legislative acts of the Member State in which the products is distributed.
Problems with application of technical and administrative requirements of other Member State (which in the past were solved by Regulation 764 [A2.2]) have since 19 April 2020 been solved by Regulation 515 [A2.6].

1.8 A Czech manufacturer (similarly a third-country manufacturer) can, prior to placing his product on the market, fulfil the requirements of legislative acts by two ways:

a) if he places his product on the market in the Czech Republic, he applies the relevant Czech legislative acts transposing the EU harmonisation legislative acts including directly applicable acts – EU regulations (if they exist);
b) if he places his product on the market in another Member State, he applies the directly applicable EU harmonisation legislative acts and/or the legislative acts of this other Member State into which the EU harmonisation legislative acts are implemented.

1.9 The Czech Republic is an EU Member State. For manufacturers from the Czech Republic and for manufacturers and importers from third countries, it represents one of **possible entry states** for placing their products on the market in the Czech Republic and thus on the internal market.

1.10 The infrastructure of testing, inspection and certification bodies in the Czech Republic is both technically and legally competent. These bodies are able to provide all expert services with their mandatory assistance in the process of conformity assessment required by the legislative acts as well as voluntary services.

2 Technical requirements for products

2.1 The basic EU legislative act containing requirements for safety of consumer products is Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 "on **General Product Safety"** (the General Product Safety Directive or the GPSD [A2.1]). The GPSD is transposed into the Czech legislation by Act No. 102/2001 Coll., on General Product Safety and on the amendment to certain Acts (Act on **General Product Safety**), as amended **[**A4.4]. This Act relates to the requirements for performance and placing on the internal market of products for which specific requirements of this type are not laid down by a specific EU legislative act or a Member State's (e.g. Czech Republic's) law.

Note 1: *If requirements for products performance are imposed by EU directives or directly applicable EU regulations, the* ***relevant part of the GPSD shall not apply****.*
But one has to be ***careful*** *– this should be seen from the point of view of* ***individual requirements (safety aspects)****, not of the complete product. There can be a situation when essential requirements from both a directive or an EU directly applicable regulation and GPSD requirements apply – the latter covering requirements/procedures not imposed by the directive or the EU directly applicable regulation.*

Note 2: *Directive 2001/95/EC [A2.1] is currently under revision, the first draft of a new regulation [A2.1.1] having been published on 5 August 2021.*

2.2 The EU **harmonisation legislative** acts with specific requirements for products and conditions for their placing on the internal market are predominantly the directives. For useful information concerning the directives, see "The Guide to the implementation of directives based on the New Approach and the Global Approach (the Blue Guide 2000)" [A6.1].

2.3 The EU harmonisation legislative acts based on the New Approach [A1.12] use the principle of laying down only the **essential requirements** which are substantial for ensuring of safety of products and protection of health, property and the environment. The essential requirements represent the goal which has to be achieved (as far as the product safety is concerned), usually without specifying the way how to achieve it.
Detailed technical specifications of these requirements and technical ways how to fulfil them are included in **harmonised technical specifications**, mainly in **harmonised European standards**.

2.4 In the formerly issued EU New Approach harmonisation legislative acts, conditions for placing of products on the market often vary in detail. As a result of practical use, the rules for the area of free movement of products on the internal market had to be made more precise and unified. Therefore the New Approach was revised and documents representing the "**New Legislative Framework**" (NLF) [A1.13] prepared. The NLF creates conditions for unification of substantial part of these rules. It consists of the following three documents – see also definitions in **Chapter 0**:

- Regulation (EU) 2019/515 of the European Parliament and of the Council (hereinafter **Regulation 515** [A2.6], since 19 April 2020 replacing Regulation (EC) No 764/2008 (**Regulation 764**) [A2.2];

- Regulation (EC) No 765/2008 of the European Parliament and of the Council (hereinafter **Regulation 765**) [A2.3] – in 2021 the title has been changed and some parts replaced by Regulation 1020 [A2.8];
- Decision No 768/2008/EC of the European Parliament and of the Council (hereinafter **Decision 768**) [A2.4].

2.5 Following principles of the New Legislative Framework, the process of adaptation of individual directives formerly issued in accordance with the New Approach is in progress. Some of the EC/EU directives have been or will be transformed into the form of directly applicable regulations (currently for example the Cableways Regulation, the Personal Protective Equipment Regulation, the Gas Appliances Regulation, the Regulation on emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, European railway system, refrigerating appliances, three regulations in the sector of medical devices).

The base for all these changes is Decision 768 [A2.4]. Hitherto different texts in some parts of the directives are being substituted with reference provisions of Decision 768. The recast does not concern essential requirements; their eventual change would be subject of planned full revision of the relevant directive.

***Note 1**: Decision 768 [A2.4] as such is not intended for practical use. It represents only the binding guide for EU legislators. Nevertheless, it is very useful to familiarise oneself with its text, especially with the preambles explaining the principles.*

***Note 2**: Detailed and extensive preambles of harmonisation EU legislative acts contain useful explanations and justifications of binding parts of the texts. Therefore, it is most important to acquaint oneself with these parts in English version or in official (e.g. Czech) translations (see for example Annex A, part 5.6).*

2.6 All EC/EU directives based on principles of the New Approach have been in the Czech Republic transposed into the government orders implementing **Act 22** [A4.1]. Some of them have been recast and newly issued following principles of the New Legislative Framework and are being transposed into new government orders implementing **Act 90** [A4.2].

2.7 For the monthly updated complex information about legislative acts and harmonised standards (with possibility of opening full texts), see the **ÚNMZ Information Portal** [A6.2]:
- the product areas (sectors) under **Act 22** [A5.2];
- the product areas (sectors) under **Act 90** [A5.3].

2.8 Apart from the government orders which represent transposition of EU harmonisation legislative acts into the Czech legislation, the Czech national legislative acts are in force in the Czech Republic:
a) Act No. 263/2016 Coll., the **Atomic Act** [A4.5] and its implementing regulations (Decrees No. 358, 359, 360, 361, 362/2016 Coll.) [A4.5.1];
b) Government Order No. 173/1997 Coll., that specifies selected products for the conformity assessment, as amended [A4.6];
c) Government Order No. 163/2002 Coll., that lays down technical requirements for selected construction products, as amended [A8.6].

For placing on the internal market of these products as well as for their distribution, **Regulation 764** also applied [A2.5] – on 19 April 2020, this regulation was repealed and replaced with **Regulation 515** [A2.6];

2.9 Some NLF directives may be transposed into the Czech government orders implementing other laws than **Act 22** [A4.1] or **Act 90** [A4.2] (for example **Directive 2013/29/EU** of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles [A2.5]).

Note: *The way of implementation of the EU harmonisation legislative acts into the national legislation may differ in various Member States.*

2.10 Many other product sectors (for example food products, cars, tractors, chemicals, medicinal products) **are not specified products** and are regulated in the EU by so called "**Old Approach**" directives or other legislative acts. These legislative acts apply to concrete product categories, are very detailed (and therefore very extensive), contain a.o. technical requirements, methods of their determination including conformity assessment, declaration and marking of conformity etc.
They are harmonised legislative acts in the EU; however they can be also non-harmonised legislative acts of the Member States.
Conditions for entry of such products on the internal market are derived from those legislative acts and often differ from the rules described in this publication for products called **"specified"** in the Czech Republic. Requirements and procedures from those legislative acts are **outside the scope of this publication**.
Products from those sectors, once legally placed on the market in an EU/EEA Member State enjoy the guarantee of **free movement** within the internal market on conditions laid down by those legislative acts and **Regulation 515** [A2.6] (since 19 April 2020 replacing repealed **Regulation 764** [A2.2]).
Regulation 1020 [A2.8] (effective since 16 July 2021, some articles since 1 January 2021) introduces new provisions for placing of such products on the market common/unified with those for specified products.

2.11 For products not posing danger to justified concern **neither** harmonised "New Approach" documents **nor** "Old Approach" legislative acts **have been issued**. Nevertheless, even they have to fulfil the relevant **general safety** requirements (see 2.1). Even products from this **non-harmonised sphere** once legally placed on the market in an EU/EEA Member State enjoy the guarantee of **free movement** within the internal market.

Note*: Possible problems with free movement of such products within the internal market were solved in* ***Regulation 764*** *[A2.2] which was repealed on 19 April 2020 and replaced with* ***Regulation 515*** *[A2.6].*
In doubt, the service of the ***Product Contact Points*** *[A1.15] can be contacted. The contact points provide, free of charge, in each EU Member State a.o. information from the area of free movement of products in the non-harmonised sphere to entrepreneurs and authorities from other Member States. More precise information on Product Contact Points can be found in Regulation 515 [A2.6].*
In the Czech Republic, the ***Product Contact Point (ProCoP)*** *is currently established under the umbrella of Ministry of Industry and Trade [A1.16].*

3 Obligations of and procedures recommended to economic operators

3.1 Common principles

3.1.1 Generally, each economic operator (manufacturer, authorised representative, importer, distributor, fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant EU harmonisation legislation – see definition 029 above) is obliged to ensure in the frame of his role in the supply chain that the basic rules for placing of his product on the market (and putting into use – e.g. lifts) and its distribution are fulfilled – see 1.1.
Especially the obligations of importers and distributors of specified products widely **exceed usual commercial practices**.

3.1.2 Obligations of economic operators are specified in the reference articles of **Decision 768** [A2.4]:
- obligations of manufacturers (R2);
- obligations of authorised representations (R3);
- obligations of importers (R4);
- obligations of distributors (R5).

3.1.3 If individual sectoral legislative acts differ from the general principles of Decision 768 [A2.4], then such specific provisions take precedence over the general principles. Direct application of Decision 768 [A2.4] without backup in the sectoral legislative act **is not allowed**.

3.1.4 Without prejudice to any obligations of economic operators laid down in the relevant EU legislative acts, Regulation 1020 [A2.8] (effective since 16 July 2021, some articles since 1 January 2021) summarizes and complements obligations of economic operators concerning placing of products on the market, especially in relation to efficient market surveillance. See also Article 4 of Regulation 1020 [A2.8].

3.2 Outline of obligations of economic operators (some possibly established also in the third countries)

3.2.1 Obligations of **manufacturers** apply also to subjects established outside the EU and are practically identical with those of manufacturers established within the EU. Topics:
- design and production in accordance with requirements of up-to-date legal legislative acts (even when the product or the legislative acts have been changed);
- drawing up of the technical documentation covering the product and its production;
- application of the required conformity assessment procedure in the pre-production and production stages;
- drawing up of the EC/EU declaration of conformity;
- affixing of the conformity marking (the CE marking or/and another marking if so required by legislation);
- keeping of the technical documentation (covering the product, its production and conformity assessment) and concerning the EC/EU declaration of conformity;
- identification of the product and the manufacturer on/at the product (to ensure the product's traceability);
- instructions and safety information for users in the relevant language;

- copy of the EC/EU declaration of conformity with each product (only if required by the relevant legislation) and/or its archiving for the specified period of time (a.o. for market surveillance authorities);
- tests of products prior to their placing on the market or putting into service (especially at mass or repeated production);
- corrective measures for non-conformed products, recall, withdrawal;
- evidence of complaints and of recalled products;
- informing of distributors;
- informing of market surveillance authorities;
- cooperation with market surveillance authorities;
- right to appoint an authorised representative.

3.2.2 Obligations of **authorised representatives** concern the subjects in the EU representing in the EU the manufacturer. Topics:
- establishing of the authorised representative within the EU (for example in the Czech Republic);
- performing of tasks specified in the written mandate from the manufacturer;
- keeping the EC/EU declaration of conformity;
- keeping of the technical documentation;
- providing the surveillance authorities with information and documentation;
- cooperation with surveillance authorities in order to eliminate the risks posed by the product.

Depending on the conformity assessment procedure and the relevant EU legal act, the authorised representative may also be empowered to affix the CE marking (or other relevant markings) and draw up and sign the EC/EU declaration of conformity.

3.2.3 Obligations of **importers** concern subjects established within the EU.

3.2.4 Obligations of **distributors** concern subjects marketing the specified products in the EU/EEA countries.

3.2.5 Since 16 July 2021, without prejudice to the above mentioned general obligations of economic operators and their detailed obligations laid down in the relevant EU harmonisation legislative acts concerning placing of products on the market etc., economic operators have to fulfil a.o. obligations laid down in Chapter II of Regulation 1020 [A2.8].

3.2.6 Since 16 July 2021, without prejudice to the above mentioned general obligations of economic operators and their detailed obligations laid down in the relevant EU harmonisation legislative acts in relation to market surveillance authorities etc., economic operators a.o. have to cooperate with market surveillance authorities, realize the appropriate corrective actions imposed by market surveillance authorities to bring an instance of non-compliance to an end or to eliminate the risk and prevent damages, recover the costs of market surveillance authorities etc. as laid down in Chapter V of Regulation 1020 [A2.8].

3.3 The New Legislative Framework [A1.13] and in the Czech Republic **Act 90** [A4.2] also lay down in detail the requirements on **traceability of products** which enables the market surveillance authorities to find the history of movements of the product. The traceability requirements are in particular:
- marking of the product;
- identification of economic operators in the distribution chain;
- keeping of technical documentation.

Economic operators are obliged a.o., for the specified period, to **identify** to market surveillance authorities all economic operators

a) they bought the product from (their suppliers), and
b) whom they supplied the product to (their customers).

3.4 Optimum procedures of the manufacturer

3.4.1 A manufacturer from the Czech Republic or from a third country can place his product on the internal market or put it into use in the Czech Republic or any EU/EEA Member State. This publication describes in the following text primarily situations when the entry state is the Czech Republic.

A manufacturer is obliged to supply the product **in conformity** with all requirements of the relevant EU harmonisation legislative acts and, if applicable, with requirements of relevant national legislative acts of EU Member States not covered by the harmonisation legislation.

3.4.2 To fulfil these requirements, the following basic steps have to be realised by the manufacturer, preferably in the described order:

a) specification of the product, its purpose, for whom it is intended, its intended use etc. – this being the **base for successful completion** of all next steps;
b) identification of all legislative acts applying to the product (Chapter 4);
c) identification of requirements relating to the product performance (usually as a result of risk analysis) as well as to conformity assessment procedures laid down in the legislative acts (Chapter 5);
d) identification and use of technical specifications (in the design phase of the product – in particular of harmonised European standards) related to the legislative acts and applicable to the product (Chapter 6);
e) design of the product so that it meets requirements of the legislative acts (profiting from use of up-to-date technical specifications, in particular harmonised European standards if they exist);
f) identification of the applicable conformity assessments procedures prior to placing of the product on the internal market (Chapter 7);
g) choice of an appropriate (notified) conformity assessment body if its involvement in conformity assessment is laid down (Chapter 8);
h) realisation of the conformity assessment procedures (Chapter 9);
i) mandatory marking of the product (Chapter 10);
j) and supply of the accompanying documentation (Chapter 11);
k) production, possible conformity assessment procedures in the production stage and placing of the product on the internal market;
l) monitoring of information concerning use of the product including findings of market surveillance authorities and, if applicable, consequent measures related to design and following production of the adapted product.

3.4.3 It is useful to realise activities **a) to h)** during the **pre-production stages**; if realised later, additional costs may arise caused by changes of the product, the production process etc.

3.4.4 Experience derived from results of activities **a) to g)** can to a large extent be **utilised repeatedly** even for other types/models of the same sort of similar products. If the manufacturer is adopting such procedures consistently during the first use, their subsequent use will proceed a lot more smoothly.

3.4.5 If the separate parts of products are manufactured in more countries, then it might be useful to realise activities **a) to h)** in the manufacturer's country. Tests, inspections etc. of a product specimen in the EU (for example in the Czech Republic) might also be taken into consideration.

3.4.6 Conformity of the product with essential requirements of the legislative acts has to be ensured for all products (pieces, batches etc.) during the whole period of their placing on the market. The measures ensuring fulfilment of this principle have to be performed in the production place (also in more places if substantial parts of the product are manufactured there). This applies similarly for services of notified bodies if their compulsory activities at conformity assessment cover also the production stage (see also Chapter 9.6).

3.4.7 Activities described under **h)** and **i)** have to be realised prior to placing of the product on the market.

3.4.8 Support of an "authorised representative" established in a Member State (i.e. also in the Czech Republic) may be used in all cases.

3.4.9 If anybody makes any changes of the product after its placing on the market (or during its distribution etc.), he becomes the manufacturer. He is then obliged to realize all manufacturer's activities concerning possible consequences of the carried out changes for compliance with the legislative acts, results of conformity assessment, archived documentation of the product and production, accompanying documentation for product's use, marking of the product etc. This has to comply with requirements of regulations applicable to the product.

4 Identification of legislative acts that apply to the product

4.1 There is no document or list for assigning a particular EU legislative act(s) to a particular product. This cannot be done even after transposition into the national legislation of a Member State, for example of the Czech Republic. Such an assignment can only be made (especially if it is for the first time) by analysing the system of existing legislative acts in force. Necessary conditions for it are among others identification of the product in question, intentions and aims of its development, future production and placing on the internal market, intended use etc. (see 3.4.2a above).

4.2 One or more pieces of legislation regulating its placing on the internal market may apply to one product simultaneously. The manufacturer has to fulfil and the product has to meet **all** relevant requirements **of all** applicable legislative acts.

4.3 For the first preview, whether the product in question is a specified product, the list of specified product sectors in Chapter 5 of **Annex A** of this publication can be used, with possibility of opening the **full texts** of legislative acts and harmonised standards. These sections are linked with the **ÚNMZ Information Portal – Regulations and Standards** [A6.2]. For further information, see the ÚNMZ website **Sectors of specified products** [A5.1]. The relevant legislative acts can be identified by titles of the directives or regulations (on the EU website) or sectors and consequently of government orders on the ÚNMZ website.

4.4 The result of such survey is the **preliminary** list of the EU (or Czech) regulations (legislative acts) which **might be** applicable to the product.

4.5 **Detailed study** of opening sections of individual legislative texts identified in the previous step has to follow next.

4.6 The scope of application of a sectoral legislative act, i.e. definition of the range of products to which the **act applies**, is always declared in the opening sections of the text. This might serve for indication whether the legislative act applies to the product or not.

4.7 In general, exclusions of some products (types of products) from the scope of the legislative act are also laid down in the text. If this is the case and the product in question is covered by such exclusion, then the act **does not apply** to it.

4.8 This analysis has to be performed systematically **for all** identifiable sectoral legislative acts (according to 4.5 above) which might possibly apply to the product.

4.9 The result of this analysis is the **complete list of sectoral legislative acts** applying to the product in question.

Note 1: *The scope of EU legislative acts laying down essential requirements for a product and rules for its placing on the internal market is in the Member States generally known in each professional sector. The relevant information can therefore be obtained also from the Member States (incl. the Czech Republic) or from professional groups in these countries.*

Note 2: *Other legislative acts, even outside the New Approach area, can apply to the product in question – for example the legislative acts concerning general safety (see Note to 2.1), consumer protection, REACH etc. The manufacturer and other economic operators in the supply chain have to fulfil relevant requirements of such legislative acts as well.*

4.10 The responsibility for correct assignment of all applicable legislative acts to the product **lies with the manufacturer**. In doubt, he may contact the **regulation's administrator [**A6.17] (in the Czech Republic) and ask for non-binding consultation. Such consultation may be provided also by Czech notified bodies (see the list in [A3.1.1] or [A3.2.1] or [A6.6]/[A6.6.1]) or professional groups acting in the relevant product area/sector.

Note: *Any consultation with a notified body cannot be extended to expert cooperation how to fulfil the requirements – such activity of these subjects is regarded as guidance and as such* ***prohibited****.*

5 Identification of requirements of legislative acts

5.1 Each relevant sectoral legislative act specifies in its either body or annexes the "**essential requirements**" applying to all products covered by it. The requirements for the product in question have to be **identified**.

5.2 The essential requirements must be applied proportionately to risks connected with the product. Therefore, the manufacturers have to perform the risk analysis (obligatory in some sectors, useful in all) and specify all possible risks the product may cause and identify accordingly the essential requirements concerning the product. This analysis must be documented and included into the (archived) technical documentation especially when required by the relevant legislative act.

5.3 In addition, the manufacturer has to document how he solves the found risks in order to ensure the conformity of the product with applicable essential requirements and thus safety of the product (for example by fulfilling requirements of harmonised standards, if they exist).

5.4 If only a part of a harmonised standard is used or if such a standard does not cover all applicable essential requirements, then the way of solving of those relevant essential requirements not covered by that standard has to be documented (this applies similarly in the case when no harmonised standard exists for the product in question [A7.6]).

5.5 Only evidently irrelevant requirements (in respect of the product's purpose, intended use etc. – see 3.4.2a above) **may be excluded**. All other requirements have to be fulfilled. Their fulfilling has to be ensured by adequate measures applied to the product, its production, the accompanying documentation of the product, instructions for use especially for the user. This fact has to be consecutively **demonstrated and documented** by the following conformity assessment and documents resulting from it.

5.6 This analysis has to be repeated for **all legislative acts** applying to the product in question and identified according to the list in 4.9 above.

5.7 In the Czech Republic – for products to which some government orders implementing **Act 22** [A4.1] or a directly applicable EU regulation implemented by **Act 22** apply, **also** the relevant provisions of **Act 22** apply.

5.8 In the Czech Republic – for products to which some government orders implementing **Act 90** [A4.2] or a directly applicable EU regulation implemented by **Act 90** apply, also the relevant provisions of **Act 90** apply.

Note to 5.7 and 5.8: *For identification of requirements according to 5.1, Act 22 [A4.1] and Act 90 [A4.2] have to be taken into account as well.*

5.9 A (structured) **list of all requirements** for the product's performance (possibly manufacturer's activities) identified/specified **from all legislative acts** applying to the product is the result of this step.

Note: *For identification of legislative acts applying to the product in question, the database of harmonised European standards can also be used – see [A6.4]*

6 Identification of technical specifications related to legislative acts

6.1 The New Approach introduced the principle of "**presumption of conformity**". If a requirement of a harmonised European/Czech standard (hEN/hČSN) is fulfilled, the corresponding "essential requirement" of the relevant legislative act is considered to be fulfilled as well.

Note: *but* ***nothing more!!!*** *Fulfilling of requirements of a standard (even if it is harmonised and clearly related to the product in question) does not mean automatically that* ***all*** *relevant essential requirements of the legislative act are fulfilled. The act may contain other essential requirements not dealt with by the standard (especially when new technologies, constructions etc. are involved).*

6.2 The harmonised European standards (hEN) give presumption of conformity only after **publishing of their references in the Official Journal of the European Union – OJEU** [A6.3]. Since March 2019, only new or withdrawn references of harmonised standards have been published in the OJEU (series L) by means of Commission implementing decisions related to the EU harmonisation legislative act in question.
The harmonisation of a European standard is always related to the relevant EU harmonisation legislative act. One European standard can be harmonised to one or more EU harmonisation legislative acts.

6.3 The harmonised Czech standards (hČSN) are transposed harmonised European standards. They are labelled ČSN EN, their number is identical with the relevant European standard – see [A3.4].

Note: *A harmonised Czech standard is fully compatible with the harmonised European standard of the same title and number; references to both are equivalent.*

6.4 The harmonised **Czech and European** standards can be effectively searched by using the monthly updated **database of all harmonised European standards** [A6.4]. Standards can be searched by parts of their title or by their numbers or by other criteria. For the given sector, the section Harmonised standards grouped **by spheres** can be used [A6.5].

Note: *The same source of information [A6.5] covers also spheres outside the placing of specified products on the market for which harmonised standards are also issued (chemical substances, air traffic, cosmetic products, packaging and packaging waste, inspection of pesticide application equipment, postal services, accessibility of the websites and mobile applications of public sector bodies).*

6.5 To some EU harmonisation legislative acts and their corresponding Czech legislative acts, harmonised standards **have not been issued yet** [A7.6]. A manufacturer (in specified cases with participation of a notified subject) has to ensure and demonstrate conformity with the essential requirements of the legislative act by using (if appropriate) for example:
- non-harmonised technical standards;
- other sectoral or manufacturer's own technical specifications;
- proven sectoral or manufacturer's own practices;
- known sectoral or manufacturer's own technical solutions;
- applicable scientific and technical knowledge;
- etc.

Note: *See also 9.5.3 to 9.5.5 below.*

In all such cases the conformity with all relevant essential requirements of the legislative acts identified in 4.9 above must be "directly" ensured and demonstrated (where the conformity is not demonstrated by use of harmonised standard/s).

Note: *If more legislative acts apply to the product, then harmonised standards might exist (or might be used by the manufacturer) only in relation to some of them.*

6.6 Although the use of harmonised standards for design, production and consequent conformity assessment of a product is not mandatory, it is very **advantageous** to the manufacturer. Of course, the manufacturer has (at least for the first time) to carry out an analysis as to whether the used harmonised standard covers all essential requirements of the applicable legislative act. Even those requirements that are not covered by the harmonised

standard are to be **met** and their fulfilling **demonstrated**. Therefore, using of more harmonised standards or possibly other technical specifications within the conformity assessment of one product is by no means exceptional.

6.7 The cases when a harmonised standard exists but the manufacturer does not use it (especially in parts of guides concerning construction or other technical solutions) are uncommon. Even such solution is possible, because technical standards including harmonised ones are generally **non-binding**. For ensuring compliance with essential requirements of the legislative acts, documents and knowledge identifying the up-to-date state of the art and technical possibilities (see 6.5) can be used.
Presumption of conformity with a harmonised standard cannot be used (logically). Nevertheless, the harmonised standard can be used for conformity assessment in parts identifying the required parameters, final requirements level, i.e. in general safety goals which are to be achieved during design and production.

6.8 If a manufacturer uses an existing harmonised European standard, he should always use the standard's latest issue reference to which is published in the OJEU [A6.3]. Such issue a.o. legally reflects the state of the art (Decision of the Court of Justice of the European Union C-300/95).
It is therefore necessary for the manufacturer to monitor continuously updating of the harmonised standards/specifications he uses. He should react to their changes by changing the design or production and by updating the conformity assessment – for products newly placed on the market after the update of the formerly used harmonised standard/specification.

6.9 When a harmonised standard is concerned reference of which has been withdrawn from the OJEU due to the fact that some requirements of it do not ensure compliance with relevant essential requirements, available information on reasons of the withdrawal (especially in the relevant Commission implementing decision published in the OJEU [A6.3]) can be used for identifying the necessary level of technical requirements for the product.

Note: *Harmonised standards are subject to revisions and are continuously replaced by new versions. If a reference to a new version of a European standard has not been published yet in the OJEU [A6.3] (see 6.2) as a harmonised European standard, only the superseded version of the standard can be used for design of the product, its conformity assessment and CE marking until the reference to the new European standard is published in the OJEU as the harmonised European standard; for details, see also Statement of the ÚNMZ [A6.3.1]. During the transition period after the publication, both versions of the standard can be used for conformity assessment. The date on which the presumption of conformity of the superseded version of the standard ceases is usually indicated in the OJEU.*

6.10 Distribution of texts of standards in the Czech Republic – for reading and for printing – is ensured by their publisher – since 2018 the Czech Standardization Agency [A3.4] – together with authorised dealers. For basic information – see the service **ČSN On-line** on the website of the Czech Standardisation Agency.

6.11 The **ÚNMZ Information Portal – Regulations and Standards** [A6.2] contains monthly updated lists of harmonised European standards and corresponding Czech harmonised standards for individual sectors (including full texts of relevant legislative acts of the Czech Republic and the EU). Users of the service **ČSN On-line** (A6.10) may open **fulltext versions of harmonised European standards** directly from these updated lists.

Monthly updates of the portal can be followed in the **archive of updates** [A6.2.1].

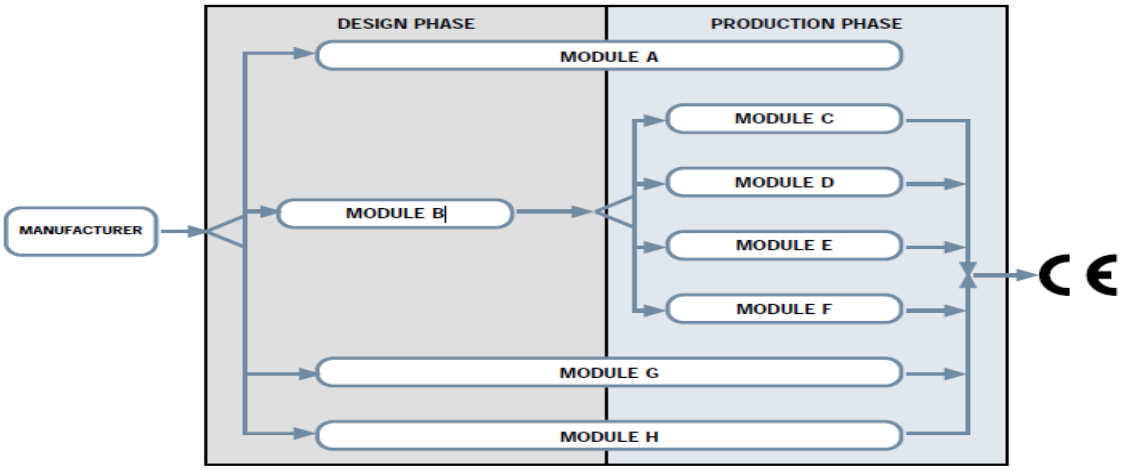
7 Identification of conformity assessment procedures before placing of the product on the internal market or putting into use

7.1 Each legislative act contains in its either "body" or annexes the description of procedures (**modules**) for assessment of conformity of the product with essential requirements laid down in the act.
There exist 8 basic modules A to H, with their modifications together 16, named A1 to H1. Their systematic identification can be made in principle in the same way as identification of the essential requirements (see Chapter 5 above).

7.2 All modules and their variants are listed in Annex II of Decision 768 [A2.4]. This Annex II contains also the scheme of relations between the modules as well as their detailed description. The following topics are described there:

- module features;
- variants for various products and for various input conditions of the same type of products (for example using/non using of a harmonised standard, lists of products with specific mode);
- technical documentation on conformity assessment which the manufacturer/installer is obliged to draw up, keep and present to the notified body if he uses its services;
- involvement of a notified body, application for its services, results, information, communication;
- approval of a batch, production, quality system;
- controls of products, production, quality system, surveillance;
- declaration of conformity and conformity marking;
- keeping of documents and documentation;
- authorized representative;
- or other.

It is necessary to **repeat** the detailed analysis for each legislative act identified according to Chapter 4 of this publication as applying to the product in question.
The result is the (structured) **list of all conformity assessment procedures (modules)** and detailed inventory of partial activities which must be carried out during conformity assessment of the product.



7.3 The **crucial procedure** – independently of Decision 768 [A2.4], Act 22 [A4.1] and Act 90 [A4.2] – is the **procedure laid down in the concrete legislative act(s)** applying to the

product, as identified according to 4.9 above. For the legislative acts, see product sectors [A5.6].

Note: *In a concrete sectoral legislative act, a conformity assessment procedure need not be indicated by the code from Decision 768 [A2.4] nor references to text of Decision 768 are used.*

7.4 Where more legislative acts apply to the product, the conformity assessment procedures may vary according to the individual acts. In such a case, the procedures have to be identified and then realised with respect for such variability.
And vice versa – if different legislative acts require the same procedure/module or the same partial activities within the modules (for example tests, inspections, certification etc.) then this procedure/module (including outputs) will be carried out only once but with differences in details if they are laid down in the individual acts.

7.5 The principal output from this analysis has to be also the identification of **mandatory involvement of services of notified bodies** (NB) in the conformity assessment process. Scope of such mandatory involvement of an NB may be:
- substantial to total;
- partial;
- none – basic variant of module A (or C).

7.6 Nevertheless, expert services (testing, inspection, certification etc.) of a subject serving for mandatory activities as an NB can be used even for realisation of those parts of the assessment that are not mandatory but only as services carried out by an accredited (or non-accredited) subject.

7.7 Both types of services are provided on a **commercial basis**.

7.8 This analysis provides a.o. the **outline of mandatory conformity assessment procedures**.
The formalised result may be a list of required activities in the prescribed and logical order including competences, sources, outputs, documents etc. etc. (recommendable is for example a manufacturer's internal regulation).

Note: *The conformity assessment procedures specify in the relevant module obligations of the manufacturer (see 3.2.1 above). This concerns especially cooperation with the notified body if its activity in the conformity assessment process is required.*

8 Choosing the appropriate notified body

8.1 For realisation of mandatory services of a notified body (if laid down in the legislative act(s)), the manufacturer can choose any body notified for activities under the relevant **legislative act, product and module**. Generally there are more bodies notified under one legislative act. The scope of activities under one or more legislative acts can be different for each notified body.
The notified bodies are listed in the EU information system database **NANDO** (New Approach Notified and Designated Organisations) [A6.6] enabling searching of bodies by countries, directives and other criteria.

In the Czech Republic, the following sources can be used:

- the list of Czech notified bodies in **NANDO** (with their scope of activity) [A6.6.1];
- the list of notified bodies in the Czech Republic on **ÚNMZ** websites [A3.1.1].
- the list of **AAAO** members [A3.2.1] and their websites;

8.2 The notification in the Czech Republic is realised by ÚNMZ [A3.1], the Czech notified bodies (see definition 020) being published in the electronic EU database **NANDO** [A6.6.1].

ÚNMZ – Czech Office for Standards, Metrology and Testing [A3.1] – is a state administration body acting a.o. in the area of activities described in this publication. Within its responsibility in the Czech Republic in relation to notified bodies, ÚNMZ among others:
- assesses [A3.1.2] competence of applicants for authorization and notification (according to Act 22 [A4.1]), Act 90 [A4.2], and Act 206 [A4.3];
- notifies the assessed bodies to the European Commission and other EU Member States;
- publishes authorizations and notifications in the Journal of the Office [A6.7];
- creates conditions for their uniform procedures;
- monitors their activities;
- solves some offences, administers sanctions etc. at breach of Act 22 [A4.1], Act 90 [A4.2];
- cooperates internationally in these areas.

For details, see **Act 22** [A4.1] and **Act 90** [A4.2].

For an outline of all ÚNMZ activities, see [A3.1].

8.3 Applicants seeking authorization and notification demonstrate their expert competence for the conformity assessment activities preferably by means of accreditation in compliance with **Regulation 765** [A2.3], together with Regulations 1020 [A2.8], if applicable. Accreditation in the Czech Republic is performed in accordance with Regulation 765 by the only Czech accreditation body – **Czech Accreditation Institute (CAI)** [A3.3]. Rules for accreditation as well as the scope of accreditation of individual organizations can be seen on the CAI website [A3.3.1].

Note: *On 16 July 2021, Regulation 765 [A2.3] was amended by Regulation 1020 [A2.8]. The amendment concerns both the title and some provisions – see Article 39 of Regulation 1020.*

8.4 Outputs of conformity assessment carried out by notified bodies established in the Czech Republic are **valid** within the whole EU/EEA.

8.5 The expert competence and offer of services of notified bodies, members of the AAAO [A3.2.1] and others, is in general broader than their activity in the position of notified bodies. It is demonstrated among others by means of accreditation but in particular for activities **outside the frame of notification** also in other ways – long tradition, customer references, membership in international groups of similar subjects, leading role in standardisation activities etc. etc.
This is the reason for use of the same subject even for non-mandatory tests, inspections and certifications. The manufacturer may in this manner, for example, demonstrate the conformity with requirements of a legislative act in the cases where involvement of a notified body is not mandatory. Moreover, he may demonstrate to his customers the performance of his products, credibility of his procedures etc. even beyond the scope of obligations derived from the legislative acts.
Such activities comprise, for example, certification of management systems according to the ISO 9000 and 14000 series of standards etc. – see the **list of AAAO members** [A3.2.1] and detailed information (names of these subjects also in English and Russian) on their respective websites.

9 Realisation of conformity assessment procedures

9.1 It is always the **manufacturer, irrespective of the country where is established**, who **is responsible** for correct and complete realisation of conformity assessment procedures in compliance with the applicable legislative acts.

9.2 The conformity assessment procedures and their variants for different situations relating to the same product are described in detail in the individual legislative acts. Legislative acts reflecting **Decision 768** [A2.4] use various types of modules (see 7.1 above).

9.3 Risk analysis

9.3.1 Some modules prescribe the **risk analysis** with regard to the product safety. It is most useful also when using other modules.

9.3.2 Irrespective of sector and product differences, the first step of the analysis is **identification of all risks** with potential possibility of substantial **damages**. By means of a "dialogue" between the essential requirements of the applicable legislative acts plus consequential specifications/harmonised standards and design/construction/performances of the product, the relevant requirements (ca = risks) are identified including those not solved by these documents (see also Chapter 5).

9.3.3 The next step is the evaluation of importance of each risk from the point of view of damages that might happen at a loss incident. This importance depends on

a) probability of realisation of the risk to loss;
b) supposed amount of loss;
c) and – by more sophisticated analysis – vice versa on the probability and possible scope of averting of realisation of the risk to loss.

9.3.4 According to this importance, the differentiated measures are to be accepted for elimination of the risk. It is (formally/methodically) outside the analysis but this is the **goal of the whole activity**, so separation or termination would be contradictory. For the product itself it means:

a) to eliminate sources of **unacceptable risk** or by means of concrete measures prevent possible realisation of the risk to loss, independently of specified/approved/expected use of the product;
b) to solve **residual risks** by means of safety marks (pictograms) and inscriptions on the product, safety instructions in the accompanying documentation for use of the product, laying down and fulfilling requirements for qualification of personnel, training of personnel etc.;
c) not to solve (after careful evaluation) **negligible risks** (or only mention them in the accompanying documentation to the product for the user).

9.3.5 All measures have to be subjected to validation with checking of their efficiency and possibly (according to the result of the validation) repeated or modified. The final goal is to prevent damages in real life of the product (during its intended, specified or usual time of use).

9.3.6 It is also useful to start the analysis as soon as possible (in the pre-production stages) and subsequently make it more precise.

9.3.7 The higher level of the analysis is its "extension" to the period of expected long-term **use** of the product. The result is then for example the program of planned preventive measures during use. This may be for example planned monitoring/checks/controls/revisions, planned maintenance and repairs carried out according to either plan or monitored state, with renovation/exchange of risky parts of the products with shorter service life than the whole product etc.

Note 1: *For some products/sectors, the risk analysis is described in technical standards/specifications; various procedures are used with special terminology etc. (e.g. ČSN EN ISO 12 100). The above mentioned principles are the same and applicable also in other situations and are generally described for example in ČSN ISO 31 000.*

Note 2*: Practical experience has shown that the measures resulting from the risk analysis may/must concern not only the product itself. Then, a useful guidance for a manufacturer can be detailed risk analysis in relation to measures in the market surveillance area where cooperation of economic operators is required as laid down in Regulation 1020 (in force since 16 July 2021) ([A2.8] and definition 012.1).*

According to Regulation 1020 ([A2.8] and definition 012.1), products are (in relation to risks) specified as follows:

a) *"**product presenting a risk**" – a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests, protected by the applicable EU harmonisation legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;*

b) *"**product presenting a serious risk**" – a product presenting a risk, for which, based on a risk assessment and taking into account the normal and foreseeable use of the product, the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate;*

Although a "product" is mentioned here, the examination has apparently cover individual qualities/risks.

Note 3: *According to Regulation 1020 [A2.8], the corrective action to be taken by the economic operator may include, among others:*

a) *bringing the product into compliance, including by rectifying formal non-compliance as defined by the applicable EU harmonisation legislation, or by ensuring that the product no longer presents a risk;*
b) *preventing the product from being made available on the market;*
c) *withdrawing or recalling the product immediately and alerting the public to the risk presented;*
d) *destroying the product or otherwise rendering it inoperable;*
e) *affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks that it might present, in the language or languages determined by the Member State in which the product is made available on the market;*
f) *setting prior conditions for making the product concerned available on the market;*

g) alerting the end users at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the Member State in which the product is made available on the market.

Corrective actions referred to in points e), f), and g) may only be required in cases where the product is liable to present a risk only in certain conditions or only to certain end users.

Market surveillance authorities ensure that products presenting a serious risk are withdrawn or recalled, where there is no other effective means available to eliminate the serious risk, or that their being made available on the market is prohibited. Market surveillance authorities notify the European Commission of this action immediately, in accordance with Article 20 of Regulation 1020 [A2.8] (Rapid Information Exchange System).

A decision whether or not a product presents a serious risk is based on an appropriate risk assessment that takes account of the nature of the hazard and the likelihood of its occurrence.

9.4 Conformity assessment without participation of a notified body

9.4.1 A substantial part of praxis in conformity assessment is covered by "**module A**", which **does not prescribe involvement** of an NB in the conformity assessment process. Similarly for the basic variant of module C.
The technical activities (tests, inspections etc.) may be then:
- either carried out by the manufacturer himself, provided he is technically, personally etc. equipped for doing so;
- or carried out with utilisation of external services of competent organisations. These should be first of all the organisations accredited [A3.3.1] according to globally united rules, published on the website of **CAI** [A3.3].

9.4.2 It is the manufacturer's choice and responsibility whom he will use. Accreditation of the organisation used at conformity assessment according to module A (or C) is not mandatory but poses an indisputable argument of demonstration of competence and impartiality.

Note: *This can, to a certain degree, be applied even if the organisation's accreditation does not cover its concrete used services. This is because the accreditation requirements apply not only to a concrete "accredited activity" but to the whole organisation, thus influencing credibility of its "non-accredited activities" as well.*

9.4.3 The organisation with a notified body status can also provide non-mandatory services but not as a notified body – only as an accredited subject (within the scope of its accreditation) or, in extreme case, as a competent but not accredited subject (see 8.5). In such a case, increased attention should be paid to impartiality risks.

9.4.4 Any activity of an organisation with the notified body status **must not** have the character of guidance with **instructions** how to fulfil the relevant requirements on product performance or how to eliminate discrepancies in fulfilling these requirements.

9.5 Conformity assessment with participation of a notified body

9.5.1 Most modules lay down **mandatory involvement** of a notified body in the conformity assessment process. These modules require that the manufacturer asking for the notified body's service deliver to the notified body, with his application, also the technical

documentation (its scope according to the relevant module) including a.o. the test/inspection protocols acquired by the manufacturer.
The tests or inspections at this stage, i.e. prior to manufacturer's application for the notified body's conformity assessment service, have to be handled in principle in the same way as described in 9.4 above.

9.5.2 The notified body has to carry out (or make carry out) these tests and activities which are prescribed by the relevant module (and possibly specified in the specifications, especially in the harmonised European standards or harmonised Czech standards). If the notified body plans to subcontract (with mandatory agreement of the client) tests or inspections to another organisation, this organisation must as a **subcontractor** fulfil practically the same requirements on competence, impartiality etc. as the subcontracting notified body. The full responsibility for the work of the subcontractor lies with the subcontracting notified body.

9.5.3 Where the **harmonised standards do not exist** or the manufacturer **has not used** them or has used them only **partly** the notified body applies specific procedures. This situation requires very close cooperation with the manufacturer.
The notified body examines the solution and technical specifications – checks whether all relevant essential requirements have been fulfilled and stated in the technical documentation file and whether the solutions and technical specification used meet the essential requirements. Doing it, the notified body takes the current state of the art into account.

9.5.4 In general – the technical solution for fulfilling the essential requirements of the legislative act, if a harmonised standard **is not used**:

a) may be laid down in a technical standard (non-harmonised) or in other technical specifications;
b) or drawn up by the manufacturer (or association of manufacturers of the same product, qualified subjects acting in the sector etc.) in compliance with the general technical and scientific knowledge stated in technical and scientific literature;
c) or drawn up by the manufacturer (or association of manufacturers of the same product, qualified subjects acting in the sector etc.) from experience of development, production and use of similar products, of safety proved in praxis etc.

Such flexibility enables manufacturers to choose own way how to fulfil the requirements. It enables for example to adjust materials and design of the product to technical state of the art. In these cases, the manufacturer cannot use the presumption of conformity but has to prove compliance with the legislative act on his own. It means that he demonstrates in detail in the technical documentation to the product how the technical specifications he uses ensure the conformity with essential requirements. For more information, see Article 4.1.3 in Blue Guide 2016 [A6.1.1].

9.6 Conformity assessment in mass production

9.6.1 The manufacture has the general obligation to ensure that **every piece** of the product he is placing on the market meets all relevant requirements of legislative acts. The frame for conformity assessment of products from repeated/mass production is based on the modular structure (see 7.1 above):

- either on "**EU-Type examination**" in the pre-production stage (module B) together with one of other modules ensuring compliance with this type in the production stage (module C and variants, modules D, E and F); or

- on operating of a "**quality assurance system**" in the pre-production and production stages (modules D1, E1, F1, G, H and H1); or
- on "**internal production control**" (module A and variants).

9.6.2 In the first two consequent cases not only the product itself (its specimen as the representative of the product type/model) is assessed but also the production (possibly also pre-production stages) according to various modules and their modifications even with participation of a notified body. The extent can be from assessment/approval of the production process (in the production place) to taking samples of products from mass production, often with the following supervision, either planned or random.

9.6.3 In the third case, the manufacturer ensures the compliance of the manufactured products with the technical documentation by means of internal production control.

9.6.4 The provisions from the **concrete legislative acts** applying to the product according to Chapters 4 and 5 are binding.

9.7 Archiving of conformity assessment results

9.7.1 Individual legislative acts lay down which documents on conformity assessment the manufacturer has to draw up or collect. The documents can be systematically identified similarly to Chapter 5 above.

9.7.2 Important is the obligation to **archive** these documents even after placing on the market of the last item of the relevant product. Act 22 [A4.1], Section 13, subsection 7 lays down the general period of 10 years which may be laid down by concrete government orders differently. Act 90 [A4.2], Section 6, subsection 2 does not lay down any general period of time leaving it to the government orders. In general – see the sectoral legislative acts [A5.6].

9.7.3 Traceability of documentation is also very important. For every **piece/batch/packing** of the product, the concrete relevant version of documents (incl. the declaration of conformity – see later) must be enabled to be searched out, if possible within the required period.

9.8 Declaration of conformity

9.8.1 After accomplishing all required conformity assessment procedures with positive results, the **manufacturer draws up** the "**EU declaration of conformity**" (or "EC declaration of conformity" according to the still valid old legislative acts), the form and content of which are laid down by the provisions with which the conformity is assessed and declared.

9.8.2 Where a notified body is involved in the conformity assessment procedures, the certificates and other documents issued by it serve (together with other documents) the manufacturer as materials for drawing up the declaration.
However, they **cannot substitute** this declaration!

9.8.3 The product's "**admission ticket**" to the market from the point of view of requirements laid down by the EU harmonisation legislation is the **EU/EC declaration of conformity**, not a certificate or any other document issued by a notified body, even if it looks "officially"!!

9.8.4 According to the New Legislative Framework, the manufacturer draws up only **one single (common) EU declaration of conformity** even if more legislative acts apply to the

product. The single declaration of conformity can be made up of a dossier containing all relevant individual declarations of conformity provided the concrete legislative act enables it.
Where the final usable product is assembled on the spot from components of various origins, the relevant legislative acts lay down how the declaration of conformity should be drawn (including responsibility for it), its form, content etc,

9.8.5 Some legislative acts require **each item of the product** to be accompanied by the "EU/EC declaration of conformity".

9.8.6 The rules for conformity assessment and the declaration of conformity do not affect the possibility for the manufacturer to order, on commercial base, from an organisation which has also status of the notified body even other non-NB supporting documents (for example voluntary test protocols, inspection reports/protocols, certificates etc.). The organisation has to perform this as an accredited subject outside the scope of the notified body's activities.

9.8.7 According to Regulation 515 [A2.6], it is possible to draw up a declaration of lawful marketing of goods for the purposes of mutual recognition ("**mutual recognition declaration"**). It concerns situations when a product is placed on the market according to the EU-non-harmonised national regulations. This declaration demonstrates to the competent authorities of any Member State of destination that the product is lawfully placed on the market in the Member State of manufacturer or importer.
This declaration has to comply with provisions of Article 4 of Regulation 515 [A2.6], follow the structure set out in Part I and Part II of the Annex of Regulation 515 and contain all the information specified therein. If an EU legislative act requiring a declaration of conformity applies to the product, the mutual recognition declaration may be attached to the declaration of conformity.
The mutual recognition declaration shall be drawn up in one of the official languages of the EU, and, if applicable, with translation into a language required by the Member State of destination.

10 Mandatory marking of the product

10.1 The **CE marking** is the common visual information on the product declaring that the requirements of EU harmonisation legislative acts are fulfilled. It means that compliance of the product with the relevant EU harmonisation legislative acts requiring or enabling the CE marking has been **verified and confirmed** prior to placing of the product on the market and therefore the product can be placed on the internal market.

10.2 The CE marking, if affixed rightly, declares that the manufacturer/installer respected all applicable legislative acts and made everything what was his obligation (and maybe even within his power at current state of the art) for the safety of the product.
Relevant EU procedures enable operative reaction to changes in the situation by adaptation of harmonisation legislative acts, harmonised specifications as well as activities of economic operators, notified bodies and surveillance authorities.

10.3 General principles for the **CE marking** (see the picture at the beginning of this publication) are laid down in Annex II of **Regulation 765** [A2.3] (see also definition 012 in Chapter 0), further details are specified in the concrete legislative acts applying to the product. Following the New Legislative Framework [A1.13], conditions for affixing the CE marking are also described in Decision 768 [A2.4] and in the relevant legislative acts and in the

corresponding harmonised standards/specifications (details may differ in various product sectors).

10.4 For products assembled at the manufacturer's site, the CE marking is attached, prior to placing of the product on the market, by the manufacturer himself or by his authorized representative. For products assembled on the site of their use, the CE marking is attached, prior to putting of the product into use, by the installer of the product, with support of the decision of the notified body concerned.

10.5 The CE marking is to be affixed to the product itself, its label or packaging.
Electronic CE marking **is not** allowed.

10.6 Some pieces of legislation require the CE marking to be accompanied by the identification number of the notified body involved in the conformity assessment.

10.7 Apart from the CE marking, other marks and markings (both mandatory connected with CE and voluntary) can be affixed to the product.
Some pieces of legislation provide for **special conformity marking** (instead of CE), for example:

a) the wheel mark (directive on marine equipment [A5.6.3]);
b) the "Pi" symbol (π - directive on transportable pressure equipment [A5.6.24]);
c) the "3" symbol (inverted epsilon – ε – directive on aerosol dispensers [A5.6.16]).

10.8 According to some directives, the CE marking can be followed by other compulsory markings, for example:

a) the pictogram with indication of the guaranteed sound power (

– directive on the noise emission in the environment by equipment for use outdoors [A5.6.18]);
b) the supplementary metrology marking consisting of a rectangle with capital "M" and last two digits of the year in which the marking was affixed (directive on measuring instruments and directive on non-automatic weighing instruments [A5.6.4] and [A5.6.10]);
c) the specific marking of explosion protection ( – directive on equipment and protective systems intended for use in potentially explosive atmospheres [A5.6.14]).

10.9 Also other markings not connected with CE may be placed on the specified products. However it is forbidden to affix marks, markings or inscriptions which could confuse third party as to the meaning or form of the CE marking. Any other marking may be affixed to the product provided its affixing does not impair the visibility, legibility and meaning of the CE marking.

10.10 Further details concerning marking of the concrete product are laid down in the relevant sectoral legislative acts. These were, logically, use also for the conformity assessment of the product. Unfortunately, it must be said that in this part the legislative acts (even the harmonisation ones) still differ.

10.11 Obligation or possibility of use of the CE marking is also laid down in other pieces of EU legislation (and in transposed legislation of the Member States incl. the Czech Republic), though they cannot be regarded legislative acts from the area of placing of specified products on the market. Provisions contained in these acts may differ from the rules described in this publication (for example the **ecodesign** of products) [A7.8].

11 Accompanying documentation

11.1 This documentation accompanies the product from its production (even from its pre-production stage) till its liquidation after the end of its life. The author of the accompanying documentation is mainly the manufacturer.
Requirements for the accompanying documentation are specified in the legislative acts and harmonised technical specifications. The documentation reflects also the results of design/development of the product, tests and verification of prototypes/first samples, preparation of production as well as results of conformity assessment of the product. So it is original from the point of view of the product as well as of the manufacturer.

11.2 The **first big group** of possible documents is predominantly an internal concern of the manufacturer and is connected with construction of the product which is important at its placing on the market and putting into operation. The aim to preserve operating and safety performance invested into the product during its development and production, its further "technical life" etc.

11.3 Examples of topics in the first group – instructions for:

a) storage after the production;
b) adjustment (before transport);
c) packing;
d) transport;
e) storage at distributors;
f) assembling and putting into operation, testing in operation etc. (if it is in responsibility of the manufacturer/supplier as part of delivery);
g) pre-sell service (in responsibility of the manufacturer/supplier, his contractors etc.);
h) guarantee service (in responsibility of the manufacturer/supplier, his contractors etc.);
i) expected replacements of worn-out parts (in responsibility of the manufacturer/supplier, his contractors etc.);
j) diagnostics including HW and SW (in responsibility of the manufacturer/supplier, his contractors etc.);
k) system and distribution of spare parts (in responsibility of the manufacturer/supplier, his contractors etc.);
l) expected troubleshooting (in responsibility of the manufacturer/supplier, his contractors etc.);
m) etc. – the list need not be exhaustible and is not limited, contains also non-actual items for some products.

11.4 The **second** possible or rather **necessary** group of documents is intended for end users of the products (both legal and private persons). It is connected primarily with use of products and activities of users. It is derived from requirements of the legislative acts and connected technical specifications, with substantial and reasonable sectoral and product differences. It reflects results of the risk analysis, conformity assessment etc.
The aim is to ensure safety of users in the sense of life and health protection as well as protection of the environment and property. An important factor for manufacturers and other economic operators is also protection against damages caused by using the product and protection against sanctions resulting from non-fulfilling the requirements of legislative acts (i.e. incorrect placing of the products on the market, their lawless distribution, improper accompanying documentation, losses caused by faulty product etc.).
These documents in general reflect information and guidance for efficient use of the product in compliance with the purpose for which the manufacturer the product developed, produced and placed on the market.

11.5 "**Instruction for use**" is a typical document from the second group. Its name may vary, it may consist of more documents etc. but this document must contain everything which is for the product required, necessary and sufficient. Complementing of the text with pictures, schemes etc. makes it more effective and attractive.

Note 1: *Generally – in many situations it is necessary to distinguish between the "owner" of the product and its actual "user/operator". The owner has towards the user/operator (and vice versa) of the concrete product many obligations and responsibilities, often resulting from conditions set by the owner.*

Note 2: *For example, for technical equipment the "Instructions for use" is the most important document which informs the owner about WHO, WHEN and HOW may possibly change its construction without loss of guarantee rights and liability (10 years) of the manufacturer/installer for possible damages caused by the defect product to the owner/user/third party.*

11.6 Examples of topics in the second group:

a) general specification of the product, its purpose, to whom it is intended, way of use etc. (see also 3.4.2a);
b) method of identification of type, variant, item, production date of the product (a.o. for communication with manufacturer, distributor, service, supplier of spare parts, for complaints etc.);
c) description of the product, its technical, using and safety parameters;
d) supposed, recommended and prohibited use;
e) required qualification of the user, (possibly compulsory) training provided by the manufacturer/supplier/distributor etc.;
f) assembling, installation and putting into operation (if in responsibility of the owner/operator/user);
g) proper using, handling, adjustment, maintenance (in responsibility of the owner/operator/user);
h) safety principles for using, adjusting, maintenance, repairs, incl.:
   ha) residual risks and measures for their elimination (see also 9.3.4b);
   hb) negligible risks (see also 9.3.4c);
   hc) meaning of safety inscriptions, pictures and pictograms on the product/packaging;
   hd) use of personal protection equipment, parameters for its consequent purchase;
   he) and others;
i) monitoring of operation and wear and tear, mandatory preventive replacement of parts etc. (see also 9.3.7);
j) mandatory use of contracted manufacturer/supplier's service;
k) troubles and troubleshooting (in responsibility of the user/operator/owner);
l) available repair shops and services, spare parts distribution;
m) guarantee conditions; exclusion of construction changes (not only loss of guarantee – the original manufacturer is absolved from all his responsibility for the product, and person who made the changes becomes the manufacturer with all consequences (see also definition 029 in Chapter 0, 3.4.9 and Note 2 in 11.5));
n) disposal of the product;
o) etc. – the list need not be exhaustible and is not limited, some items overlap; the list contains also non-actual items for some products.

11.7 Material intended for propagation, presentation, training etc. will have rather different character. Even these materials must correspond to other documentation and reflect the reality.

12 Conclusion

12.1 This publication contains only the **basic principles** which a manufacturer has to follow if he wants to place his products on the market in the EU/EEA (incl. in the Czech Republic).

12.2 Concrete (especially sectoral) legislative acts [A5.6] lay down, for concrete situations and concrete products, details as well as further procedures and differences from the general principles described here. For specific area of construction products, see Appendix 2.

12.3 Due to its restricted extent, this publication cannot cover all specificities of concrete products or types of products. The principles described in the text have been chosen in order to cover, as much as possible, the situations common for various products and manufacturers.

12.4 A much more detailed document is the **Blue Guide 2016** [A6.1.1]. An update of this publication (the Blue Guide updated) is currently under preparation – see [A6.1.2]. *It will be available on the website of the European Commission [A1.2] and the ÚNMZ [A3.1] after publication of the official text by the Commission.*

Note: *Some information about what the "new" Blue Guide will contain is indicated in document [A6.1.3]:*
The structure will not be changed substantially from the 2016 version. Some topics are added:
- *the digital economy, software, e-commerce;*
- *the circular economy such as the remanufacturing and treatment of used goods;*
- *implications of Brexit;*
- *enhancement of market surveillance;*
- *clarification of some problematic topics.*

12.5 In the Czech Republic, the entrepreneurs may use the **ÚNMZ Information Portal – Regulations and Standards"** [A6.2] including monthly updates [A6.2.1].

12.6 In relation with Regulation 1020 [A2.8] which entered into force on 16 July 2021 and whose aim is to eliminate growing amount of non-conforming products, bad traceability of non-conforming products imported into the EU via online means, insufficient border control of imported products etc., a number of new provisions concerning economic operators is being prepared. The economic operators should familiarize themselves with these provisions and their application.

12.7 A useful source of information for entrepreneurs and public is also the information portal of ITC Zlín, a. s. "**Zákony a normy**" [A6.1.15] on laws and standards. It is very wide-ranging in areas of placing of products on the market, their conformity assessment, standardisation and standards from various countries, market surveillance, management systems and other useful links. The portal covers not only the area of specified products; its scope is much wider. Its full version is subject to payment but a lot of information is accessible for free.

12.8 Other recommended **sources of information in the EU**:
- **EUR – Lex** [A1.3] – access to the EU law in all EU official languages;
- **Portal Your Europe** [A6.1.11] – for orientation of entrepreneurs and citizens in the European legislation and various national legislations of the EU Member States;

as well as the following websites:

- **EU/European Union** [A1.1] – general information/Newsroom;
- **European Commission** [A1.2] – European Commission – Internal Market, Industry, Entrepreneurship and SMEs (GROWTH)**;**
- **EUROLAB** [A1.21] – European Federation of National Associations of Measurement, Testing and Laboratories**;**
- **EA – European Accreditation** [A1.22];
- **CEOC [**A1.23] – International Confederation of Inspection and Certification Organisations.

Links to information sources

The following links are numbered identically as in the previous text. However, the list contains also other links useful chiefly for placing a product on the internal market of the EEA including the market in the Czech Republic. Responsibility for the content of documents linked lies with their owners.

Abbreviations of the links' language versions:

- *EU – official version from the EU website, all official languages of the EU (incl. CS) can be chosen;*
- *EN – official version in English;*
- *CS – official version in Czech;*
- *EN/CS – both official versions in English (prior) and in Czech can be used;*
- *CS/EN – both official versions in Czech (prior) and in English can be used;*

WARNING: Automatic translation (if allowed in the browser settings) may lead to incorrectness or even faults in terminology. Therefore it is recommended to disable it especially when using the CS/EN or EN/CS links and use only the official versions.
***Note:** Items "free" are reserved for future.*

No	Name	Address
1	**Institutions, standardisation in the EU, international organisations**	
1.1	European Union – Newsroom (EN)	**EN:** *http://europa.eu/newsroom/home_en*
1.2	European Commission – Internal Market, Industry, Entrepreneurship and SMEs (EU)	**EN:** *http://ec.europa.eu/growth/*
1.3	EUR – Lex – website providing access to the EU legislation (EU)	**EN:** *http://eur-lex.europa.eu/*
1.4	European Commission (EU)	**EN:** *http://ec.europa.eu/priorities/internal-market_en*
	free	
1.11	Internal Market – market of the EU/EEA countries (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:internal_market*
1.12	New Approach Directives (EU harmonisation) (EN)	**EN:** *https://www.cenelec.eu/aboutcenelec/whatwestandfor/supportlegislation/newapproachdirectives.html*
1.13	New Legislative Framework (EU – European Commission website / CS – ÚNMZ [3.1] website)	**EN:** *https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en* **CS:** *https://www.unmz.cz/statni-zkusebnictvi/informacni-portal-unmz/pravni-predpisy/novy-legislativni-ramec/*
1.14	Goods Package: Reinforcing trust in the single market (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX:52017DC0787*
1.15	PCP – Product Contact Points (EN)	**EN:** *http://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition/contacts-list/*

1.16	ProCoP – Product Contact Point at Ministry of Industry and Trade of the Czech Republic (CS/EN)	**CS:** *https://www.mpo.cz/cz/zahranicni-obchod/podnikani-v-EU/sluzby-pro-podnikatele-na-vnitrnim-trhu-eu/procop/default.htm* **EN:** *https://www.mpo.cz/en/foreign-trade/business-in-the-eu/services-for-entrepreneurs-in-the-eu-internal-market/product-contact-point/default.htm*
1.17	Implications of Brexit (EU)	**EN:** *https://ec.europa.eu/info/relations-united-kingdom/new-normal/consequences-brexit_en*
	free	
1.21	EUROLAB aisbl (EN)	**EN:** *https://www.eurolab.org/*
1.22	EA – European Accreditation (EN)	**EN:** *http://www.european-accreditation.org/*
1.23	CEOC - International Confederation of Inspection and Certification Organisations (EN)	**EN:** *https://www.iso.org/organization/8898.html*
2	**EU legislative acts and documents**	
2.1	Directive 2001/95/EC on general product safety (EN/CS)	**EN:** *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0095:20100101:EN:PDF* **CS:** *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0095:20100101:CS:PDF*
2.1.1	Proposal of Regulation (revision of Directive 2001/95) from 5 August 2021 – basic information (EN/CS)	**EN:** *https://ec.europa.eu/info/business-economy-euro/product-safety-and-requirements/product-safety/consumer-product-safety_cs* **CS:** *https://www.mpo.cz/cz/ochrana-spotrebitele/bezpecnost-vyrobku/navrh-narizeni-o-obecne-bezpecnosti-vyrobku---262748/*
2.2	Regulation 764 Regulation (EC) No 764/2008 (on 19 April 2020 repealed and replaced by Regulation 515 – see 2.10) (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0764*
2.3	Regulation 765 Regulation (EC) No 765/2008 on 16 July 2021 amended by Regulation 1020 – see 2.12) (EN/CS)	**EN:** *https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02008R0765-20210716&qid=1629274158782&from=CS* **CS:** *https://eur-lex.europa.eu/legal-content/CS/TXT/HTML/?uri=CELEX:02008R0765-20210716&qid=1629274158782&from=CS*
2.4	Decision 768 Decision No 768/2008/EC (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008D0768*
2.5	Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (consolidated version) (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/cs/TXT/?uri=CELEX%3A32013L0029*

2.6	Regulation 515 Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R0515*
2.6.1	Guidance document (23 March 2021) for the application of Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2021.100.01.0016.01.ENG&toc=OJ%3AC%3A2021%3A100%3ATOC*
2.7	Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/SK/ALL/?uri=CELEX:31985L0374*
2.8	Regulation 1020 Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 Applicable from 16 July 2021 (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1020*
3	**Organisations and institutions in the Czech Republic** *(incl. their information systems and databases)*	
3.1	ÚNMZ – Czech Office for Standards, Metrology and Testing (CS)	**CS:** *https://www.unmz.cz/obecne/o-uradu/*
3.1.1	ÚNMZ – list of notified bodies in the Czech Republic (CS)	**CS:** *https://www.unmz.cz/statni-zkusebnictvi/autorizovane-osoby-oznamene-subjekty/seznam-ao-os-a-uno/*
3.1.2	Applications for authorisation and notification of conformity assessment subjects 2020 (CS)	**CS:** *https://www.unmz.cz/files/zku%C5%A1ebnictv%C3%AD/Pokyn%20P1_01.01.2020.pdf*
3.2	AAAO – Association of Accredited and Authorised Organisations (CS)	**CS:** *http://www.aaao.cz/*
3.2.1	AAAO – list of AAAO members (CS)	**CS:** *http://www.aaao.cz/clenove/*
3.3	CAI – Czech Accreditation Institute (CS/EN)	**CS:** *https://www.cai.cz/?page_id=23* **EN:** *https://www.cai.cz/?page_id=12864&lang=en*
3.3.1	CAI – database of accredited subjects (CS/EN)	**CS:** *https://www.cai.cz/?page_id=4499* **EN:** *https://www.cai.cz/?page_id=12902&lang=en*
3.4	Czech Standardization Agency (CS/EN)	**CS:** *https://www.agentura-cas.cz/* **EN:** *https://www.agentura-cas.cz/en/*
4	**Czech Legal Acts**	

4.1	Act 22 Act No. 22/1997 Coll., on Technical Requirements for Products and on Amendments to Some Acts, as amended (version effective from 1 January 2021 to 31 December 2021) (CS/EN working consolidated text of ÚNMZ [3.1])	**CS:** *https://www.zakonyprolidi.cz/cs/1997-22/zneni-20210101* **EN:** *https://www.unmz.cz/en/office/legislation-in-force/working-consolidated-text-of-act-no-22-1997-coll-on-technical-requirements-for-products/*
4.2	Act 90 Act No. 90/2016 Coll., on Conformity Assessment of Specified Products when Made Available on the Market, as amended (version effective from 1 January 2021) (CS/EN working consolidated text of ÚNMZ [3.1])	**CS:** *https://www.zakonyprolidi.cz/cs/2016-90/zneni-20210101* **EN:** *https://www.unmz.cz/en/office/legislation-in-force/act-90_16_en_working-translation/*
4.3	Act 206 Act No. 206/2015 Coll., on pyrotechnics (CS)	**CS:** *https://www.zakonyprolidi.cz/cs/2015-206*
4.4	Act 102 Act No. 102/2001 Coll., on general safety of products (CS)	**CS:** *https://www.zakonyprolidi.cz/cs/2001-102*
4.5	Act 263 Act No. 263/2016 Coll., the Atomic Act (CS)	**CS:** *https://www.zakonyprolidi.cz/cs/2016-263*
4.5.1	Decrees for implementation of the Atomic Act (Decrees No. 358, 359, 360, 361, 362/2016 Coll.) (CS)	**CS:** *http://www.unmz.cz/files/zku%C5%A1ebnictv%C3%AD/sb0143-2016.pdf*
4.6	Government Order 173 Government Order No. 173/1997 Coll., that specifies selected products for the conformity assessment, as amended (CS)	**CS:** *https://www.zakonyprolidi.cz/cs/1997-173*
4.7	Government Order 208 Government Order No. 208/2015 Coll., on technical requirements for pyrotechnical articles and their making available on the market (CS)	**CS:** *https://www.zakonyprolidi.cz/cs/2015-208*
4.8	Draft of Czech market surveillance act (CS)	**CS:** *https://www.psp.cz/sqw/historie.sqw?o=8&t=1131*
4.9	Act 64 Act No. 64/1986 Coll., the Czech Trade Inspection Authority Act (CS)	**CS:** *https://www.zakonyprolidi.cz/cs/1986-64*
4.10	Act 526 Act 526/2020 Coll. amending Act 22 and Act 90 (CS)	**CS:** *https://www.zakonyprolidi.cz/cs/2020-526*
5	**Product sectors**	
5.1	Specified products (ÚNMZ) [A3.1] (CS)	**CS:** *https://www.unmz.cz/statni-zkusebnictvi/stanovene-vyrobky/*

5.1.1	Ditto – Harmonised standards by sectors (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti* **EN:** *https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti*
5.2	Product sectors under Act 22 (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=2* **EN:** *https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=2*
5.3	Product sectors under Act 90 (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=133* **EN:** *https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=133*
	free	
5.6	**Product sectors** *For each sector:* - *outline of harmonised standards based on last references in the OJEU (EN/CS); outline of specified standards for selected products* - *EU harmonisation legislative act (EN/CS);* - *Czech legislative act (CS);* - *Slovak legislative act (in Slovak);* - *link to valid references of harmonised standards in the OJEU (CS);*	
5.6.1	Low voltage equipment (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/89* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/89*
5.6.2	Simple pressure vessels (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/105* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/105*
5.6.3	Marine equipment (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.czehn/kategorie/184* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/184*
5.6.4	Measuring instruments (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/104* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/104*
5.6.5	Personal protection equipment (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/210* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/210*
5.6.6	Radio equipment (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/193* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/193*
5.6.7	Recreational craft and personal watercraft (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/135* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/135*
5.6.8	Appliances burning gaseous fuels (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/213* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/213*

5.6.9	Pressure equipment (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/195* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/195*
5.6.9.1	Pressure equipment (transitional period) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/110* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/110*
5.6.10	Non-automatic weighing instruments (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/103* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/103*
5.6.11	Explosives for civil uses (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/97* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/97*
5.6.12	Electromagnetic compatibility (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/90* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/90*
5.6.13	Lifts (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/109* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/109*
5.6.14	Equipment and protective systems intended for use in potentially explosive atmospheres (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/134* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/134*
5.6.15	Cableway installations (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/211* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/211*
5.6.16	Aerosol dispensers (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/187* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/187*
5.6.17	Ecodesign requirements for household refrigerating appliances (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/113* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/113*
5.6.18	Noise emissions (NOI) (CS/EN)	**EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/186* **CS:** *https://www.nlfnorm.cz/ehn/kategorie/186*
5.6.19	Emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/188* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/188*
5.6.20	European rail system (high-speed and conventional) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/112* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/112*
5.6.21	Toys (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/85* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/85*
5.6.22	Restriction of the use of certain hazardous substances in electrical and electronic equipment (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/93* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/93*

5.6.23.1	Personal protective equipment (placed on the market by 20 April 2019) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/86* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/86*
5.6.23.2	Personal protective equipment (NLF) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/210* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/210*
5.6.24	Transportable pressure equipment (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/185* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/185*
5.6.25	Appliances burning gaseous fuels (placed on the market by 21 April 2018) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/107* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/107*
5.6.26	Construction products CE marked (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/84* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/84*
5.6.27	Machinery (CS/EN)	**EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/106* **CS:** *https://www.nlfnorm.cz/ehn/kategorie/106*
5.6.28	Efficiency requirements for new hot-water boilers (BED) (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/183* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/183*
5.6.29	Medical devices (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/95* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/95*
5.6.30	Active implantable medical devices (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/94* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/94*
5.6.31	In vitro diagnostic medical devices (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/96* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/96*
5.6.32	Pyrotechnic articles (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/100* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/100*
5.6.33	Sector of construction products – Selected construction products not CE marked (CS)	**CS:** *http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/1_5_vybran.htm*
5.6.34	National sector in the Czech Republic – Selected products for conformity assessment (CS)	**CS:** *https://www.unmz.cz/urad/vybrane-vyrobky*
6	**Internet portals and databases, information publications**	

6.1	Guide to the implementation of directives based on the new approach and the global approach (Blue Guide 2000) (EU/CS/CS) *(OUT OF DATE – only for information – for up-to-date version see [A6.1.1] and [A6.1.2])*	**EN:** *https://op.europa.eu/cs/publication-detail/-/publication/4f6721ee-8008-4fd7-acf7-9d03448d49e5#* **CS:** *http://www.old.unmz.cz/sborniky_th/14/1400.pdf* **CS:** *http://www.old.unmz.cz/urad/prirucka-pro-zavadeni-smernic-zalozenych-na-novem-pristupu-a-globalnim-pristupu*
6.1.1	Blue Guide on the implementation of EU products rules 2016 – Blue Guide 2016 (EU/EN/CS)	**EN:** *https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules_en* **EN:** *http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_272_R_0001&from=CS* **CS:** *http://eur-lex.europa.eu/legal-content/CS/TXT/PDF/?uri=OJ:JOC_2016_272_R_0001&from=CS*
6.1.2	Blue Guide updated – *It will be available on the website of the European Commission [A1.2] and the ÚNMZ [A3.1] after publication of the official text by the Commission.* (EN/CS)	**EN:** **CS:**
6.1.3	EU product compliance: what to expect from the revised Blue Guide (EN)	**EN:** *https://www.reedsmith.com/en/perspectives/2020/11/eu-product-compliance-what-to-expect-from-the-revised-blue-guide*
6.2	ÚNMZ Information Portal – Regulations and Standards (CS)	**CS:** *https://www.unmz.cz/urad/informacni-portal-unmz*
6.2.1	Ditto – outline of monthly updates (CS)	**CS:** *http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/aktualizace.htm*
6.3	OJEU – Official Journal of the EU – quick search (EU)	**EN:** *https://eur-lex.europa.eu/homepage.html?locale=en*
6.3.1	Statement of the ÚNMZ about revision of harmonised European standards issued by CEN (CS)	**CS:** *https://www.unmz.cz/wp-content/uploads/Zru%C5%A1en%C3%A9-harmonizovan%C3%A9-normy-stanovisko-%C3%9ANMZ.pdf*
6.4	Database of harmonised standards (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/475/databaze-harmonizovanych-norem-477* **EN:** *https://www.nlfnorm.cz/en/normy/475/databaze-harmonizovanych-norem-477*
6.5	Harmonised standards grouped by sectors and areas (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti* **EN:** *https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti*
6.6	NANDO – New Approach Notified and Designated Organisations – information system of notified bodies (EN)	**EN:** *http://ec.europa.eu/growth/tools-databases/nando/index.cfm*

6.6.1	Ditto – list of Czech notified bodies in NANDO (EN)	**EN:** *http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=203*
6.7	ÚNMZ – Journal of the Office (CS)	**CS:** *https://www.unmz.cz/urad/vestnik-unmz*
6.8	ÚNMZ – Program for Development of Testing (CS)	**CS:** *https://www.unmz.cz/statni-zkusebnictvi/program-rozvoje-zkusebnictvi/*
	free	
6.11	Portal "Your Europe" (EU)	**EN:** *https://europa.eu/youreurope/citizens/index_en.htm*
6.12	Portal "Zákony pro lidi" ("Laws for people") (CS)	**CS:** *https://www.zakonyprolidi.cz/*
6.13	Portal "Esipa" (CS)	**CS:** *https://esipa.cz/*
6.14	Portal of Czech public administration (CS)	**CS:** *https://www.mvcr.cz/clanek/portal-verejne-spravy.aspx*
6.15	Information portal ITC Zlín "Zákony a normy" ("Laws and Standards") (CS)	**CS:** *https://www.nlfnorm.cz/informacni-portal*
6.16	Information system for implementation of EU legislation (CS)	**CS:** *https://isap.vlada.cz/homepage.nsf/verejnost*
6.17	Authorities responsible for implementation of EU legislation into the Czech legislation – central authorities of the Czech Republic (CS)	**CS:** *https://isap.vlada.cz/dul/dirtaiii.nsf/gestor?OpenView*
6.18	Commission decisions based on objections against publication of harmonised European standards in the OJEU (EN)	**EN:** *https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/formal-objections_en*
7	**Harmonisation outside the specified products**	
7.1	Horizontal legislative acts – NLF (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=3* **EN:** *https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=3*
7.2	General safety (CS/EN)	**CS:** *https://www.nlfnorm.cz/ehn/kategorie/87* **EN:** *https://www.nlfnorm.cz/en/ehn/kategorie/87*
7.3	Other selected sectors (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=5* **EN:** *https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=5*
7.4	Services (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=105* **EN:** *https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=105* *h*

7.5	Accessibility of websites and mobile applications (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=217* **EN:** *https://www.nlfnorm.cz/en/normy/556/harmonizovane-normy-rozdelene-podle-oblasti?s=217*
7.6	EU harmonisation legislative acts WITHOUT issued harmonised European standards (CS)	**CS:** *http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/sektor_dalsi%20_22.htm*
7.7	Specified Czech standards (CS)	**CS:** *http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/nehen.htm*
7.8	ECO – regulations and standards for ecodesign and energetic labels of appliances (CS)	**CS:** *http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/eko.htm*
8	**Construction products**	
8.1	ÚNMZ Information Portal – Construction Products (CS/EN)	**CS:** *https://www.unmz.cz/statni-zkusebnictvi/informacni-portal-unmz/informacni-portal-unmz-specializovany-na-pravni-a-technicke-dokumenty-v-oblasti-uvadeni-stavebnich-vyrobku-na-jednotny-evropsky-trh-c233/* **EN:** *https://www.unmz.cz/statni-zkusebnictvi/informacni-portal-unmz/information-portal-construction-products/*
8.1.1	Ditto – outline of monthly updates (CS)	**CS:** *http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/aktualizace.htm*
8.2	CPR Regulation (EU) No 305/2011 – Construction Products Regulation (consolidated version with amendments of 16 July 2021 by Regulation 1020) (EU)	**EN:** *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0305-20210716*
8.3	Database of harmonised European standards / harmonised Czech standards to the CPR (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/70/prehled-harmonizovanych-norem-k-cpr* **EN:** *https://www.nlfnorm.cz/en/normy/70/prehled-harmonizovanych-norem-k-cpr*
8.4	Database of European Assessment Documents (EAD) to the CPR (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/1402/databaze-evropskych-dokumentu-pro-posuzovani-ead-k-narizeni-ep-a-rady-eu-c-305-2011-cpr-* **EN:** *https://www.nlfnorm.cz/en/normy/1402/databaze-evropskych-dokumentu-pro-posuzovani-ead-k-narizeni-ep-a-rady-eu-c-305-2011-cpr-*
8.5	Groups of harmonised standards and EAD's according to Annex IV of the CPR (CS/EN)	**CS:** *https://www.nlfnorm.cz/normy/71/harmonizovane-normy-rozdelene-do-skupin-vyrobku* **EN:** *https://www.nlfnorm.cz/en/normy/71/harmonizovane-normy-rozdelene-do-skupin-vyrobku-podle-prilohy-iv-k-cpr*
8.6	Government Order 163 Government Order No. 163/2002 Coll., that lays down technical requirements for selected construction products, as amended (CS)	**CS:** *https://www.zakonyprolidi.cz/cs/2002-163*

8.7	Specified standards to Government Order 163 (CS)	**CS:** *http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/tech_poz/cr/pp_cr/vybr_stav/un_163_2002/un_163_2002.htm*
8.8	Technical guides to Government Order 163 (CS)	**CS:** *http://koordinacesv.tzus.cz/technicke-navody*
8.9	EU brochure "CE marking of construction products step by step" (EN/CS)	**EN:** *https://ec.europa.eu/docsroom/documents/12308/attachments/1/translations/en/renditions/native* **CS:** *http://www.unmz.cz/files/zku%C5%A1ebnictv%C3%AD/CE-marking_CS_150622%20final.pdf*
8.10	CPCP – Contact point for CE-marked construction products (harmonised and non-harmonised) according to Regulation (EU) No 305/2011 (CPR) (EN/CS)	**EN:** *https://www.mpo.cz/en/construction-and-raw-materials/contact-point-for-construction-products/product-contact-point-for-construction--147314/* **CS:** *https://www.mpo.cz/cz/stavebnictvi-a-suroviny/kontaktni-misto-pro-stavebni-vyrobky/kontaktni-misto-pro-stavebni-vyrobky-s-oznacenim-ce-podle-narizeni-c--305-2011-eu--o-stavebnich-vyrobcich--147227/*
8.11	Information from the Coordinating institute in the field of construction products authorized by the ÚNMZ (CS)	**CS:** *http://koordinacesv.tzus.cz/koordinacni-pracoviste*
8.12	Technical assessment bodies (TABs) in the EU (incl. the Czech Republic) (EN)	**EN:** *https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=33*
8.12.1	Technical assessment bodies (TABs) in the Czech Republic (CS)	**CS:** *1) https://www.tzus.cz/sluzby/subjekt-pro-technicke-posuzovani* *2) http://www.csias.cz/posuzovani_shody.php*
8.13	ETA – European technical assessment (EN/CS)	**EN:** *https://www.eota.eu/what-is-an-eta* **CS:** *http://www.sgpstandard.cz/editor/unmz/?u=stav_vyr/1_7_eta.htm*
8.14	EAD – European assessment document (EN)	**EN:** *https://www.eota.eu/eads*

End of Annex A

Appendix 1

Identification of changes of EU and Czech legislative acts

The changes concern horizontal topics of this publication.
The table includes EU harmonisation legislative acts and Czech legislative acts in force as well as their revisions (both expected and under way).
Selected links to information sources are listed in Annex A of this new version (2021) of the publication.
As construction products area is concerned, only the basic information is listed in Appendix 2 of this "Version 2021".
The following table reflects changes of legislation done between years 2019 (after 31 July 2019) and 2021 (by 31 July 2021 or 31 August 2021, when possible, even by the latest date).

Item	**Basic legislative acts regulating placing of products on the market**	**Main changes as against 2019** *Current state of legislative acts – see the ÚNMZ Information Portal "Regulations and Standards" [A6.2]*
1	NLF – Regulation 764 [A2.2]	Regulation 764 [A2.2] – on 19 April 2020 repealed and replaced by Regulation 515 – see Item 2
2	Regulation 515 [A2.6]	Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 [A2.6]. The regulation lays down rules and procedures concerning application of the mutual recognition principle by Member States in relation to goods which has been placed on the market in another Member State in compliance with the latter's legislative acts. It also provides for establishment and operation of product contact points in Member States as well as cooperation and exchange of information in relation to the mutual recognition principle. It is one of two new regulations of the so called "Goods Package: Reinforcing trust in the single market" [A1.14]. The regulation has been applied since 19 April 2020, before that date Regulation 764 [A2.2] was applied, see Item 1. *(some changes were taken into account in "Version 2020" of the publication)*
2.1	Guidance to Regulation 515 [A2.6.1]	Guidance document (dated 23 March 2021) for the application of Regulation (EU) 2019/515 of the European Parliament and of the Council on the mutual recognition of goods lawfully marketed in another Member State This guidance document aims to help enterprises as well as relevant national authorities apply Regulation 515 [A2.6].
3	NLF – Regulation 765 as amended [A2.3]	Regulation 765 was amended on 16 July 2021 – partly repealed and replaced with Regulation 1020 [A2.8] – see Item 4
4	Regulation 1020 [A2.8]	Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 [A2.3] and (EU) No 305/2011 [A8.2]. The aim of this regulation is to ensure that only the products compliant with the regulations and fulfilling requirements for high level of protection of

		justified concern are made available on the market. The regulation lays down rules and procedures for economic operators concerning products covered by some EU harmonisation legislative acts, and creates the framework of cooperation with economic operators as well as for control on products entering the EU market. It is the second of two new regulations of the so called "Goods Package: Reinforcing trust in the single market" [A1.14]. The entire regulation has been applied since 16 July 2021. *(according to amendments in Regulation 765 [A2.3], some changes were already taken into account in "Version 2020" of the publication; as far as the market surveillance area is concerned, this publication only refers to relevant obligations of economic operators)* *(For implementation of this directly application piece of legislation, a draft act on market surveillance [A4.8] is under preparation in the Czech Republic – see Item 10.)*
5	NLF – Decision 768 as amended [A2.4]	No changes
6	Other EU horizontal harmonisation legislative acts	Following the issue of harmonisation legislative acts mentioned in Items 2 and 4, changes in the horizontally applicable legislative acts are announced – Items 10, 11 and following. Concurrently some directives or regulations (EU) concerning concrete product sectors are being amended or completed (not within the scope of this publication). See also Item 9 below.
7	Act 22 – Act No. 22/1997 Coll. as amended by Act No. 91/2016 Coll., Act No. 183/2017 Coll., Act No. 265/2017 Coll., and Act No. 526/2020 Coll. [A4.10]	On 1 January 2021 Act 526/2020 Coll., [A4.10] amending Act 22 [A4.1] and Act 90 [A4.2] entered into force. Its part concerning Act 22 [A4.1] reflects the "sponsored access" to standards as well as changes in the accreditation process. *The changes do not affect the topic of this publication.* Its part concerning Act 90 [A4.2] represents adaptation to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices. *The changes do not affect the topic of this publication.*
8	Act 90 – Act No. 90/2016 Coll., as amended by Act No. 183/2017 Coll., Act No. 265/2017 Coll., and Act No. 526/2020 Coll. [A4.10]	Another amendment of Act 90 – see Item 7.
9	Government orders implementing Act 22 and Act 90	Update on harmonisation legislative acts and relevant harmonised standards – see (in Czech) *http://www.sgpstandard.cz/editor/unmz/?u=tech_poz/aktualizace.htm* Reduction of harmonised sectors to Act 22 – concerns the sectors transferred to Act 90.

		Updates on national Czech government orders not harmonised with the EU. *(All these changes are reflected in the links (Annex A), if they have any impact on the publication's text.)*
10	Preparation of an act on market surveillance and compliance of products with legislation [A4.8]	A separate **act on market surveillance act and on compliance of products with legislation...** [A4.8] is being prepared aiming at implementation of Regulation 1020 [A2.8] (see Item 4 above). The draft act appoints the central liaison authority, lays down some competences and obligations of authorities responsible for market surveillance (hereinafter "market surveillance authority"), regulates the cooperation between the central liaison authority, the market surveillance authority and the Customs organisation of the Czech Republic. It also regulates some rights and obligations of economic operators (in the Czech Republic). This act will be used for application of the regulation on market surveillance (Regulation 1020 [A2.8]) as well as for market surveillance of products to which EU legislative acts mentioned in Annex I of Regulation 1020 apply. Consequently, those Czech legislative acts containing provisions concerning the market surveillance will be amended. Those concerned are Act No. 634/1992 Coll., on Consumer Protection as amended, Act 22 [A4.1], Act No. 156/1998 Coll., on fertilizers as amended, Act No. 406/2000 Coll., on Energy Management as amended, Act 102 [A4.4], Act No. 477/2001 Coll., on Packaging as amended, Act 206 [A4.3], Act 90 [A4.2]. *The legislative procedure started in mid-2020 and has not been finished yet (by 31 August 2021).*
11	Revision of the General Safety Directive [A2.1] [A2.1.1]	On 30 June 2021, the European Commission published the Proposal for a Regulation on Product Safety [A2.1.1]. The proposal reflects changes on the market with products, updates and modernises the general framework for the safety of non-food consumer products, preserving its role as a safety net for consumers in the products' area. To ensure continuity with the current legislation [A2.1] the proposal: - requires that only safe products be placed on the market; - sets certain obligations for economic operators aimed at ensuring the products' safety; - contains provisions for the development of standards in support of the products' safety; The proposal also aligns the market surveillance rules for products falling outside the scope of the EU harmonisation legislation ("non-harmonised products") with those applying to products falling under the scope of the EU harmonisation legislation ("harmonised products"). *The legislative procedure in the EU (and in the Czech Republic) has not been finished yet (by 31 August 2021).*
End of Appendix 1		

Appendix 2

Specific features of construction products

This publication does not cover the area of construction products because of (a. o.) their specific features, some general examples being as follows:

- **different** definitions with different meaning are used (e.g. essential characteristics, performance, levels, classes, threshold levels, product type, intended use etc.); nevertheless basic **principles** for making available / placing on the market are **analogous**;
- not only characteristics of a product itself but especially its influence on fulfilling the **basic requirements for the construction work** in which it has to be installed is taken into account; only such construction product can be placed on the market whose performances (after its correct installation in the construction work) do not represent risk for fulfilling the basic requirements for the construction work;
- the "harmonised" area is regulated by Regulation (EU) No 305/2011 – Construction Products Regulation – **CPR** [A8.2] (see definition 014 in Chapter 0);
- harmonised technical specifications for the CPR are harmonised European standards (see the database in [A8.3]) and European Assessment Documents (see the database in [A8.4]);
- according to Annex IV of the CPR, construction products are divided into product areas (see the database [A8.5]);
- for products to which a harmonised European standard does not exist but EAD's do, a "technical assessment body" (TAB) [A8.12]/[A8.12.1] may be asked to issue a "**European Technical Assessment – ETA**" [A8.13];
- modules used in other sectors (Decision 768, Annex II) [A2.4] are not used in the CPR; "**systems of assessment and verification of constancy of performance**" (AVCP) are used, called 1, 1+, 2+, 3, and 4;
- in the "harmonised" area, the manufacturer does not issue an "EU/EC declaration of conformity" but a "**Declaration of performance**";
- for all construction products to which a harmonised European or Czech standard applies or for which an ETA has been issued, the **CE marking is the only marking**; it declares that the construction product is in **conformity** with performance stated in the "**Declaration of performance**" issued by the manufacturer in relation to essential characteristics according to the harmonised European or Czech standard or the ETA in question;
- affixing of the **CE marking is then obligatory** for all construction products for which the manufacturer has drawn up the "**Declaration of performance**";
- products without any harmonised European or Czech standard applicable to them are in the "non-harmonised" area and are regulated by national regulation of the EU Member States;
- in the Czech Republic, the "non-harmonised" area is regulated by **specified technical standards** [A8.7] and **technical guides** [A8.8];
- even in the "non-harmonised" area in the Czech Republic there are specific conformity assessment procedures laid down in Government Order 163 [A8.6], sections 5 to 12; for further details, see the ÚNMZ Information Portal – Construction Products [A8.1] + outline of monthly updates [A8.1.1];
- the European Commission published an **information brochure** "CE marking of construction products step by step" [A8.9] containing a.o. many links to other information sources;
- further information can be seen on the website of the **Coordinating institute** in the field of construction products authorized by the ÚNMZ [A8.11];
- information sources for the sector of construction products are listed in Chapter 8 of Annex A;

More specific features are possible.

Accompanying data:

This publication was written with the support of the Czech Office for Standards, Metrology and Testing (ÚNMZ) under Project No PRZ 21/5.1/AAAO.
Contractor: Association of Accredited and Authorised Organisations (AAAO)
Author: Josef Šenk
Based on the publications:
"**Uvádění stanovených výrobků na trh** *(verze 2019)*" and "**Placing of products on the Internal Market of the European Economic Area**" *(version 2020)*
drawn up by AAAO with support of ÚNMZ in 2019 and 2020.

End of the publication incl. annexes.
Prague, 10 November 2021