EU Single Market for Goods: policy updates during 2019 – 2020

October 2020

Accessibility of products and services

Directive (EU) 2019/882 on the accessibility requirements for products and services[1]

Directive aims to harmonise **accessibility requirements for certain products** and **services** so the EU's internal market operates smoothly by eliminating and preventing any free-movement barriers that may exist because of divergent national legislation.

Products covered by Directive:

- computers and operating systems;
- payment terminals and certain self-service terminals such as ATMs, ticketing and check-in machines, interactive self-service information terminals;
- smartphones and other equipment for accessing telecommunication services;
- TV equipment involving digital television services;
- e-readers.

Services covered by Directive:

- telephony services;
- services to access audiovisual media services;
- certain elements of air, bus, rail and water transport services such as websites, mobile services, electronic tickets, information;
- consumer banking;
- e-books;
- e-commerce;
- answer to emergency calls to the single European number '112'.

Mutual recognition in the EU's single market

Regulation (EU) 2019/1020 on market surveillance and compliance of products[2]

Regulation aims to improve how the free movement of goods principle works **by strengthening market surveillance of products covered by EU hamonisation legislation**. This must ensure a high level of protection of health and safety, in general and in the workplace, and protect consumers, the environment, public security and other public interest. It lays down rules and procedures for economic operators* and establishes a system for their cooperation with supervisory authorities, establishes controls on products imported into the EU.

Regulation deletes and replaces Articles 15 to 29 of Regulation (EC) No 765/2008 (see summary on Accreditation and market surveillance) and amends Directive 2004/42/EC and Regulation (EU) No 305/2011 (see summary on Construction products).

According to the Regulation EU countries shall, among other, appoint **a single liaison office** to represent the surveillance authorities and communicate the country's national strategy. Draw up an **overarching national market surveillance strategy** every 4 years from 16 July 2022 to promote a *consistent*, *comprehensive* and *integrated* approach to market surveillance — this must include:

- data on non-compliant products;
- priority areas for enforcing the EU legislation;
- enforcement activities to reduce non-compliance;

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32019L0882
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32019R1020

- assessment of cooperation between authorities in other EU countries.

Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008[3]

Regulation aims to strengthen the functioning of the internal market by improving the application of the principle of mutual recognition and by removing unjustified barriers to trade.

Regulation lays down rules and procedures concerning the application by Member States of the **principle of mutual recognition in individual cases in relation to goods** which are subject to Article 34 TFEU and which are lawfully marketed in another Member State, having regard to Article 36 TFEU and the case-law of the Court of Justice of the European Union.

Regulation also provides for the establishment and maintenance of **Product Contact Points** in Member States and for cooperation and exchange of information in the context of the principle of mutual recognition.

Technical harmonisation

Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/20034

Regulation lays down common rules on safety, quality and labelling requirements for fertilising products.

Regulation covers 7 categories of fertilising products, namely:

1) fertilisers:

inorganic fertilisers,
organo-mineral fertilisers,
organic fertilisers;

2) soil improvers,
3) liming materials,
4) growing media,
5) inhibitors,
6) plant biostimulants, and
7) fertilising product blends.

Commission Recommendation (EU) 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat[5]

Recommendation provides for:

the notified bodies under Regulation (EU) 2016/425 should **prioritise** and **swiftly conduct** the conformity assessment activities in the framework of all newly submitted requests by economic operators of PPE necessary for protection in the context of the COVID-19 outbreak;

market surveillance authorities in the Member States should **as a matter of priority** focus on non-compliant PPE or medical devices raising serious risks as to the health and safety of their intended user;

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R0515
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1009
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32020H0403

market surveillance authorities should inform **immediately** the Commission and other Member States of any temporary arrangement they have granted to specific PPE or medical devices.

Commission Recommendation (EU) 2020/518 on a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning mobile applications and the use of anonymized mobility data[6]

Regulation provides for the COVID – 19 approach **for mobile applications and the use of anonymized mobility data**. The approach consists of:

specifications to ensure the effectiveness of mobile information, **warning** and **tracing applications for combating COVID-19 from the medical and technical point of view**;

measures to prevent proliferation of applications that are not compatible with Union law, to support requirements for accessibility for persons with disabilities, and for interoperability and promotion of common solutions, not excluding a potential pan-European application;

governance mechanisms to be applied by public health authorities and cooperation with the ECDC;

the **identification of good practices and mechanisms for exchange of information** on the functioning of the applications; and

sharing data with relevant epidemiological public bodies and public health research institutions, including aggregated data to ECDC.

EU type-approval legislation with regard to the UK withdrawal due to Brexit

Regulation (EU) 2019/26 — complementing EU type-approval legislation with regard to the withdrawal of the United Kingdom from the EU[7]

Regulation establishes new rules to ensure a **smooth transition for the type-approval of motor vehicles**, as well as of systems, components and separate technical units intended for these vehicles, when the UK (1) leaves the EU.

Interaction of technical harmonisation with environmental policy

Regulation (EU) 2019/631 — setting CO2 emission performance standards for new passenger cars and for new light commercial vehicles[8]

Regulation establishes CO2 emissions performance requirements for new passenger cars and for new light commercial vehicles in order to contribute to achieving the Union's target of reducing its greenhouse gas emissions, as laid down in Regulation (EU) 2018/842, and the objectives of the Paris Agreement and to ensure the proper functioning of the internal market.

Standardisation

ISO/IEC 17000:2020[9]

The main changes compared to the previous edition are as follows:

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32020H0518
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32019R0026
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32019R0631#PP2Contents
[9] https://www.iso.org/obp/ui/#iso:std:iso-iec:17000:ed-2:v1:en

- ✓ addition of new terms: **"object of conformity assessment**" (see 4.2), **"owner"** (see 4.13), **"impartiality"** (see 5.3), **"independence"** (see 5.4), **"validation"** (see 6.5), **"verification"** (see 6.6), **"decision"** (see 7.2), **"expiry"** (see 8.4) and **"restoration"** (see 8.5);
- ✓ **change of concept of conformity assessment system**;
- ✓ **deletion of the definition of the term "product"** from the body of the document and addition to Annex B;
- ✓ **editorial revision of Annex A** limited to changes in the terms and definitions in Clauses 4 to 9;
- ✓ **extension of Annex B.**

CEN-CENELEC Guide 36:2020 - Guidance on the rules for drafting and presentation of candidate harmonized product standards for construction products[10]

Guide 36 has been prepared by CEN-CENELEC BT WG 9 'Strategy for the construction sector. This document intended for use by Technical Committees drafting candidate harmonized European Standards in the **Construction Sector**. It gives the rules for the presentation of standards for construction products drafted following a standardization request issued in the framework of **Regulation (EU) 305/2011 (CPR)**. Other EU Directives/Regulations may also apply to construction products.

CEN and CENELEC responses to COVID-19

In response to the coronavirus outbreak, CEN and CENELEC agreed, in collaboration with all their Members and after an urgent request from the European Commission, to make **freely available** *a series of European standards (ENs)* **for medical devices and personal protective equipment** used in the context of the COVID-19 pandemic. **Read Press Release issued on 20 March 2020**[11]: "Providing free access to the national adoptions of this set of European standards facilitates the work of the many companies within the European Economic Area which are reconverting their production lines to deliver tangible results quickly and ensure that healthcare professionals and patients have access to the equipment they urgently need. The 11 standards developed by CEN and potentially 3 additional ones developed jointly with ISO made available cover common filtering masks, medical gloves and protective clothing. They are the fruit of a collective European effort. These European standards were developed and adopted by different Technical Bodies, taking into account the contributions of hundreds of experts and stakeholders in the personal protective equipment and medical field all around Europe. The standards are available for free download from the websites of CEN national members[12].

The list of the standards follows:

EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

This European Standard specifies minimum requirements for filtering half masks as respiratory protective devices to protect against particles except for escape purposes. Laboratory and practical performance tests are included for the assessment of compliance with the requirements.

EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

This document specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms. This European Standard is not applicable to masks intended exclusively for the personal protection of staff. NOTE 1 Standards for masks for use as respiratory

[10] https://www.cencenelec.eu/standards/Guides/Pages/default.aspx
[11] https://www.cencenelec.eu/News/Press_Releases/Pages/PR-2020-003.aspx
[12] https://standards.cen.eu/dyn/www/f?p=CENWEB:5:::NO:::

personal protective equipment are available. NOTE 2 Annex A provides information for the users of medical face masks.

EN 166:2001 Personal eye-protection – Specifications

This European standard specifies functional requirements for various types of personal eye-protectors. The transmittance requirements for various types of filter oculars are given in separate standards (see clause 3).

EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

This standard specifies requirements and test methods for re-usable and limited use protective clothing providing protection against infective agents. Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions, are not covered by the scope of this standard.

EN 14605:2005+A1:2009 Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

This document specifies the minimum requirements for the following types of limited use and reusable chemical protective clothing: - Full-body protective clothing with liquid-tight connections between different parts of the clothing (Type 3: liquid-tight clothing) and, if applicable, with liquid-tight connections to component parts, such as hoods, gloves, boots, visors or respiratory protective equipment, which may be specified in other European Standards. Examples of such clothing are one-piece coveralls or two-piece suits, with or without hood or visors, with or without boot-socks or over-boots, with or without gloves; - Full-body protective clothing with spray-tight connections between different parts of the clothing (Type 4: spray-tight clothing) and, if applicable, spray-tight connections to component parts, such as hoods, gloves, boots, visors or respiratory protective equipment, which may be specified in other European Standards. Examples of such clothing are one-piece coveralls or two-piece suits, with or without hood or visors, with or without boot-socks or over-boots, with or without gloves; - Partial body protection garments offering protection to specific parts of the body against permeation of chemical liquids. Examples of such garments are e.g. laboratory coats, jackets, trousers, aprons, sleeves, hoods (not air-supplied) etc. As partial body protection leaves some parts of the body unprotected this document specifies only the performance requirements for the clothing material and the seams. NOTE Partial body chemical protective garments which offer only protection against penetration of chemical liquids are within the scope of EN 13034 (Type PB [6] clothing).

EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns

his European Standard specifies information to be supplied to users and third party verifiers in addition to the usual labelling of medical devices (see EN 1041 and EN ISO 15223-1), concerning manufacturing and processing requirements. This European Standard gives information on the characteristics of single-use and reusable surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment, intended to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. This European Standard specifies test methods for evaluating the identified characteristics of surgical drapes and gowns and sets performance requirements for these products. EN 13795-1 does not cover requirements for resistance to penetration by laser radiation of products. Suitable test methods for resistance to penetration by laser radiation, together with an appropriate classification system, are given in EN ISO 11810. EN 13795-1 does not cover requirements for incise drapes or films. EN 13795-1 does not cover requirements for antimicrobial treatments for surgical gowns and drapes. Antimicrobial treatment may cause environmental risks such as resistance and pollution. However, antimicrobial treated surgical gowns and drapes fall under the scope of this standard with respect to their use as surgical gowns and drapes.

EN 13795-2:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits

This European Standard specifies information to be supplied to users and third party verifiers in addition to the usual labelling of medical devices (see EN 1041 and EN ISO 15223-1), concerning manufacturing and processing requirements. This European Standard gives information on the characteristics of single-use and reusable clean air suits used as medical devices for clinical staff, intended to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. This European Standard specifies test methods for evaluating the identified characteristics of clean air suits and sets performance requirements for these products.

EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

This part of this Standard specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes. NOTE Attention is drawn to EN 374-1 "Protective gloves against chemicals and micro-organisms - Part 1: Terminology and performance requirements".

EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties

This European Standard specifies requirements and gives test methods for physical properties of single-use medical gloves (i.e. surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain in use an adequate level of protection from cross contamination for both patient and user. This European Standard does not specify the size of a lot. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

This part of EN 455 specifies requirements for the evaluation of biological safety for medical gloves for single use. It gives requirements for labelling and the disclosure of information relevant to the test methods used.

EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

For labelling and the disclosure of information relevant to the test methods used. This European Standard applies to existing, new and significantly changed designs. Existing designs that do not currently have ageing data available should generate that data within a reasonable period of time. This European Standard does not specify the size of a lot. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

In addition, upon CEN's request the following **EN ISO standards are made available as read-only**:

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks (ISO 374-5:2016)

ISO 374-5:2016 specifies the requirements and test methods for protective gloves intended to protect the user against micro-organisms. NOTE If other protection features is to be needed, e.g. chemical risks, mechanical risks, thermal risks, electrostatic dissipation etc., the appropriate specific performance standard is to be used in addition. Further information on protective gloves standards can be found in the EN 420.

EN ISO 13688:2013 Protective clothing - General requirements (ISO 13688:2013)

ISO 13688:2012 specifies general performance requirements for ergonomics, innocuousness, size designation, ageing, compatibility and marking of protective clothing and the information to be supplied by the manufacturer with the protective clothing. ISO 13688:2012 is only intended to be used in combination with other standards containing requirements for specific protective performance and not on a stand-alone basis.

EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

ISO 10993-1:2009 describes: the general principles governing the biological evaluation of medical devices within a risk management process; the general categorization of devices based on the nature and duration of

their contact with the body; the evaluation of existing relevant data from all sources; the identification of gaps in the available data set on the basis of a risk analysis; the identification of additional data sets necessary to analyse the biological safety of the medical device; the assessment of the biological safety of the medical device.

Metrology

EURAMET Calibration Guide No. 21 Version 2.0 (05/2020) (updated calibration guidelines for standard capacity measures)[13]

Calibration Guideline No. 21 in particular details information and advice concerning standard capacity measures for tanks that utilise a volumetric calibration method. To monitor the domestic and industrial consumption of water and fuels, for example, it is essential to have accurate measurement systems and volume standards in place – where the volume standards here are referred to as 'standard capacity measures'.

[13]https://www.euramet.org/index.php?eID=tx_securedownloads&p=40&u=0&g=0&t=1633898548&hash=4be4d4729b87539f8ef4c00b40b4c6e449e5feef&file=Media/docs/Publications/calguides/I-CAL-GUI-021_Calibration_Guideline_No._21_web.pdf