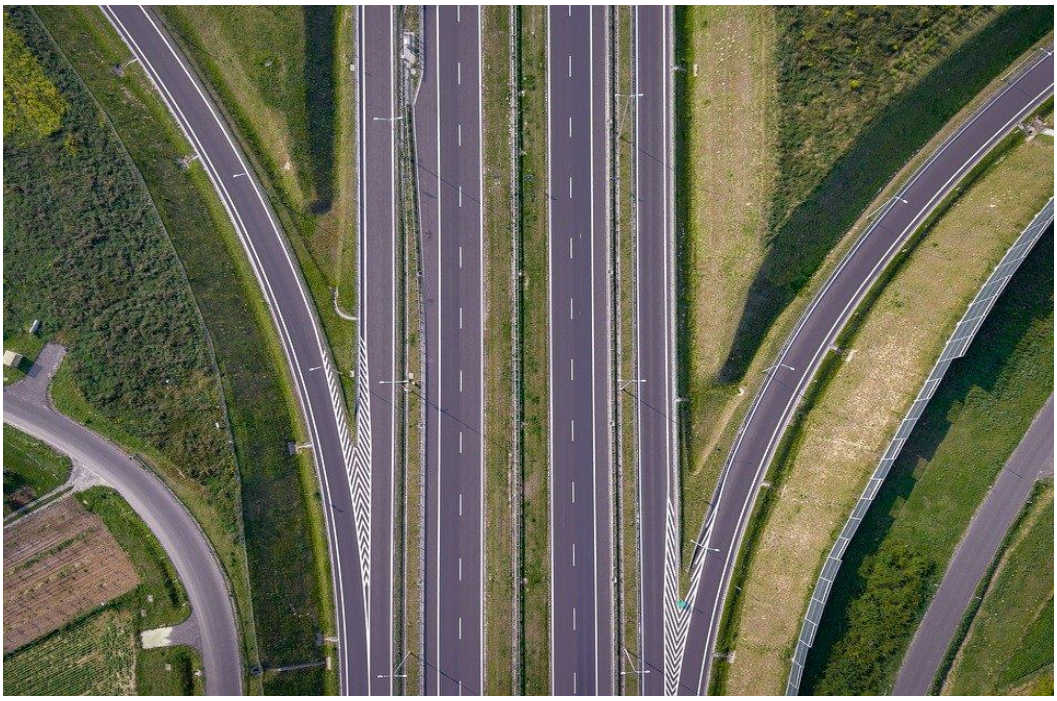
Guide to Products and Product Legislation (2021)



Preface

CEDR members are key stakeholders as they are both regulating authorities and public clients. These roles are governed by the transport policy goals set up by the national parliaments and governments. These policy goals have in common that they ask for road safety, environment protection, mobility and accessibility as well as appropriate use of public funds. CEDR WG Harmonisation and Standardisation's vision is therefore:

> *A common (single) market that increases the competition and by that decreases costs. For the members of CEDR this in turn leads to more efficient use of public money.*

The mission for CEDR WG Harmonisation and Standardisation is to monitor, support, understand and implement the Commission initiatives towards a European Common Market within the CEDR field of activities.

On this background this guide is an instrument to present the impact on and of the PPD, ETAs, product standards, design and execution standards, CEDR codes of practice, voluntary quality marking and the CPD as well as other Commission Directives. The Guide is to be used as a guideline on how to react in certain situations; i.e., what initiatives not to support, what initiatives to promote and what initiatives to act upon.

This Guide is intended for employees of public bodies assigned as experts by the national road authorities (NRAs) to act in the standardisation process. The outline is therefore based on the principle that the guide must describe the standardisation process as well as the harmonization process.

Disclaimer

For complex regulatory issues related to standards and product acceptance, individual members should ensure that decisions taken are aligned with national regulations and take legal advice where required.

Acronyms

AVCP - Assessment and Verification of Constancy of Performance
CEN - Comité Européen de Normalisation (European Committee for Standardization)
CENELEC - Comité Européen de Normalisation Électrotechnique (European Committee for Electrotechnical Standardization)
EAD - European Assessment Document
EC - European Commission (Administrative)
EN - EuroNorm
EOTA - European Organisation for Technical Assessment
ESO - European Standardisation Organisations
ETA - European Technical Assessment
ETSI - European Telecommunications Standards Institute
hEN - harmonised EuroNorm
NANDO - New Approach Notified and Designated Organisations
NB - Notified Body
NRA - National Road Authorities
OJEU - Official Journal of the EU
TAB - Technical Assessment Body
ATEX - Equipment for Explosive Atmospheres 2014/34/EU
CE - CE Marking 768/2008/EC
CPR - Construction Products Regulations EU 305/2011
EMC - Electromagnetic Compatibility Directive 2014/30/EU
LVD - Low Voltage Directive 2014/35/EU
PPD - Public Procurement Directive 2014/24/EU
RED - Radio Equipment Directive 2014/53/EU
TFEU - Treaty for the Functioning of the EU TFEU
TSRD - Technical Standards and Regulations Directive 2015/1535/EU

Contents

1. Introduction

1.1 Preface

CEDR members fulfil several roles, as policy setters in their own right, as well as regulating authorities and as public clients. These roles are often governed by the transport policy goals set up by the national parliaments and governments, and the EU. These policy goals focus on delivering road safety, environmental protection, mobility and accessibility for all users, as well as appropriate use of public funds.

1.2 Mission and strategy of CEDR

CEDR is an organisation of European national road administrations that promotes Excellence in the Management of Roads.

CEDR consolidates its position as the platform for Road Directors and National Road Administrations (NRAs) that facilitates, reliably and effectively:

1) Benchmarking and sharing of knowledge and best practices
2) Collaborations and sharing of resources in joint projects
3) Professional networking and competence building

1.3 Strategic Goals

Help NRAs to keep ahead of the curve, anticipate future trends and prepare them to face new challenges

Reinforce NRAs role as key providers of efficient and seamless mobility from an end user perspective within the transport system.

Facilitate and optimize the efficient use of resources, making the best use of existing infrastructures.

Improve the safety and sustainability of roads, and reduce their environmental impact and carbon footprint.

1.4 Intended Audience

This document is intended to assist anyone in the NRA's and/or people acting on behalf of NRA's in standardisation or procurement processes, and may be involved in developing European technical specifications and standards for the road transport sector.

This is not a definitive guide, there is no intention of repeating material that is available (and better written) elsewhere. Readers are recommended to engage with their respective government departments responsible for sponsoring the legislation in their Member States, and to read the guidance issued by the EU.

1.5 Other Documents

The reader may find it useful to read the following documents.

The Guide to the implementation of directives based on the New Approach and the Global Approach (Published by the Commission 2000), also known as the " Blue Guide 2016 [Ref 3.I]".

An overview of the standardisation procedure - *Guide to the implementation of directives based on the New Approach and the Global Approach (EU 2000 [Ref 2.I]).*

Manufacturers of construction products who are planning to CE-mark their products or seeking advice should read *CE marking - Step by Step [Ref 1.I]*. It also explains what to do if there are any changes to the product (its processes, raw materials, testing, etc.) which may make it necessary to revise associated documents. It is a useful document for those who need to understand the CE marking process as either specifiers or procurers.

1.6 Health warning

This document was written on the understanding of the product and procurement legislation at the time of writing. It is intended that the document is revised from time to time to reflect changes in processes and legislation, and the authors' understanding. You should always check that any comments or guidance in the document are still current.

This document assumes that your organisation is located within the European Union. For readers in countries that are not members of the European Union, or are subject to differing levels of integration - other rules may apply.

If you are in the UK, it will depend on whether you are in Great Britain (England, Scotland & Wales) or in Northern Ireland and subject to the Northern Ireland Protocol. It is recommended that you contact BEIS and or MHCLG for further information.

2. Legislative Environment

2.1 Introduction to EU legislation (Directives vs Regulations)

2.1.1 TFEU

The aims set out in the EU treaties are achieved by several types of legal act. The principle aim within the scope of this guidance is to provide a level playing field across the Member States for manufacturers and ensure that public procurers do not unduly favour domestic manufacturers or suppliers.

2.1.2 Regulations

Regulations are legal acts that apply automatically and uniformly to all EU countries as soon as they enter into force, without any need to be transposed into national law. They are binding in their entirety on all EU countries.

2.1.3 Directives

2.3 Directives require EU countries to achieve a certain result, but leave them free to choose how to do so. It is the responsibility of individual countries to devise their own transposing legislation on how to reach these goals.

2.2 Principles of product safety

The placing on the market of products is generally a strictly regulated process designed to ensure that "safe" products are made available on the EU market and meet certain characteristics or legal requirements. The legal provisions governing the placing on the market of products are in many cases European law and often lead to a CE marking of a product.

2.2.1 Directive 2001/95/EC General Product Safety

In order for products to be placed on the EU internal market, the requirements of Directive 2001/95 / EC [1]) on general product safety must be fulfilled. The purpose of this directive is to establish in Article 1

> *(1) "that the products placed on the market are safe".*

"Product" means a product that "is intended for consumers or could be used by consumers under reasonably foreseeable conditions, even if it is not intended for it, and is supplied or made available for consideration or free of charge in the course of a business activity, regardless of whether it is new, used or refurbished. "

Directive 2001/95 / EC defines what constitutes a "safe product" in Article 2 (b). It is "any product which, under normal or reasonably foreseeable use, including the period of use and, where applicable, commissioning, installation and maintenance requirements, has little or no compatibility with its use and maintains a high level of protection of health and safety of persons carries reasonable risks, "[...].

A product in accordance with Article 3 (2) is deemed to be "safe" if it complies with the legislation in an EU Member State or a harmonised European standard (hEN). An hEN is a European Standard produced by CEN, CENELEC or ETSI on the basis of a standardisation request (previously mandate) from the European Commission, which is cited in the Official Journal of the EU after its publication. The application of an hEN is voluntary (except construction products), but facilitates proof of compliance or that a product is "safe".

To assess whether a product meets certain requirements, a conformity assessment is carried out, and a Declaration of Conformance produced.

2.3 Public Procurement Directive [2014/24/EU].

The Public Procurement Directive is not a product directive, but has a direct impact on how the NRA sets out their contracts and ensures that they (the NRA) follow common rules when specifying products and services.

2.3.1 PPD Art 18 - Principles of procurement

2.5 Article 18 is a high-level requirement that ensures that the terms of a contract do not disadvantage economic operators by limiting the scope of products or suppliers, such as imposing prequalification lists or framing contract requirements in such a way that they can only be fulfilled by a specific manufacturer or country.

2.3.2 PPD Art 42 - Technical specifications

Article 42.3 sets out the hierarchy by which NRAs are permitted to specify products. Where a product falls within the scope of a higher category, the NRA is not permitted to use technical requirements from lower categories:

1) National standards transposing European standards (listed in OJEU);
2) European Technical Assessments (EADs), common technical specifications;
3) International standards;
4) Other technical reference systems established by the European standardisation bodies;
5) National standards, national technical approvals or national technical specifications relating to the design;
6) Local (NRA) rules.

All of which are “or equivalent”, where a product is legally placed on the market in another Member State.

2.4 The New Legislative Framework (NLF; Blue Guide 2016 [Ref 3.I])

The 'New Approach' framework Directives sets the framework for all of the “New approach” Directives and is intended to improve:

1) overall coherence and consistency;
2) the notification process;

3) accreditation; the conformity assessment procedures (modules);
4) CE marking and market surveillance (including revision of the safeguard clause procedures).

There are now a great many product directives under this framework, but the ones that are most likely to be encountered as part of the procurement of highway design and construction are:

1) Directive 2014/35/EU – Low Voltage Directive (LVD)
2) Directive 2014/30/EU – Electromagnetic Compatibility (EMC)
3) Directive 2014/34/EU – Equipment for explosive atmospheres (ATEX)
4) Directive 2014/53/EU - Radio Equipment Directive (RED)
5) Directive 2014/28/EU – Civil Explosives Directive (ATEX)
6) Directive 2006/42/EC - Machinery Directive (MD)

These have largely common clauses regarding conformity assessment and placing on the market. The key requirement is that they are do not endanger the health and safety of persons and domestic animals when properly installed and maintained and used in the applications for which it was intended.

2.5 CPR (Regulation (EU) No 305/2011)

The Construction Products Regulation places obligations on member states to remove barriers to trade of products that fall within the scope of a harmonised standards and ensure that construction products to have CE markings and are accompanied by a declaration of performance (DoP).

It sets out requirements and obligations for manufacturers, but the key articles for NRAs are:

1) Article 8 - obligations for member states to remove conflicting requirements
2) Article 17 - rules for harmonising standards
3) Article 18 - objections to harmonised standards CE marking penalties

In the EU, failure by the manufacturer to CE mark a product and provide a Declaration of Performance where the product falls within the scope of a harmonised standard is often an offence punishable with fines and/or prison.

Oddly enough, many manufacturers still believe that the NRA (client) can grant exceptions to the requirement to provide a Declaration of Performance and affix a CE Mark or that it is the responsibility to the client to enforce compliance. This is not the case, you as the client should report the product and the manufacturer to the Member States market surveillance body, who then enforce the non-compliance.

Some non-EU manufacturers have tried to avoid the need to CE mark their products by treating the purchaser as the importer, thereby passing on the responsibility for the CE marking and declaration of performance to the recipient.

On a small scale, this can be seen on Amazon where the product is shipped directly from the non-EU country to the buyer. As an NRA, this is not recommended, as it opens up the NRA to significant liabilities (and paperwork) making it uneconomic.

2.5.1 Placing on the market

"Placing on the market" is the stage defined in product legislation that defines the point at which product must have a CE mark and a Declaration of Performance.

Many NRAs conduct research as part of their duties, and the assessment of products that fall within the scope of a harmonised standard but are not CE marked may be used within the context of research activities such as pilots or trials provided they have not reached the stage of "placing on the market".

Once a product has reached the point of “placing on the market”, it is the responsibility of the manufacturer to CE mark their product, and it will be illegal for the NRA to continue to accept that product until the manufacturer has done so.

2.6 Recycling and circular economies

Products such as fill materials and recycled aggregate that fall within the scope of a harmonised standard, would be required to have a Declaration of Performance and a CE Mark, if they were to be supplied to site rather than reused.

Some civil engineering contracts (such as NEC 4 (Art 73.4)) state that any materials arising from excavation or demolishing belong to the Contractor.

The Contract Scope should be framed such that that the title for recovered material does not change hands until the end of the contract, ie it remains the client's property throughout its extraction, processing and reuse. By retaining ownership, there is no need to CE mark the product even though the product and its intended use fall within the scope of a harmonised standard.

3. Standards & Standardisation

3.1 Why we have harmonised standards

The starting-point of the standardisation process is the need for a common understanding between product manufacturers and their clients on the technical aspects of the products which need to be included in commercial transactions.

The Blue Book Blue Guide 2016 [Ref 3.I] provides information EU product legislation and the rules surrounding placing products on the market.

3.2 European Standardisation Organisations

CEN, the European Committee for Standardization is an association that brings together the National Standardization Bodies of European countries.

CEN is one of three European Standardization Organizations (together with CENELEC and ETSI) that have been officially recognised by the European Union and by the European Free Trade Association (EFTA) as being responsible for developing and defining voluntary standards at European level.

CEN provides a platform for the development of European Standards and other technical documents in relation to various kinds of products, materials, services and processes.

The two other European Standardisation Organisations (ESO):

1) CENELEC which is responsible for European standardisation in the area of electrical engineering
2) ETSI that develops applicable standards for ICT-enabled systems, applications & services.

EOTA is the European Organisation for Technical Assessment in the area of construction products, whose members (Approval Bodies) draft and issue European Assessment Documents (EAD) for specific products from specific/individual manufacturers in cases where the harmonised ENs do not (yet) cover such products

3.3 Standardisation Requests (Previously Mandates).

Standardisation Requests are the mechanism by which the European Commission (EC) and the secretariat of the European Free Trade Association (EFTA) request the European Standardization Organizations (ESOs) to develop and adopt European standards in support of European policies and legislation.

This mechanism involves several steps. Here is how it normally works for standardisation work in a field or sector that is covered by CEN:

1) The European Commission sends a provisional draft standardisation request to CEN;

2) The text is examined by the relevant Technical Body/Bodies within CEN;
3) CEN provides comments to the European Commission, including proposals for specific modifications to the text (with explanatory notes);
4) A draft standardisation request is submitted to the Standing Committee responsible for implementing the procedure described in Directive 98/34/EC, which ensures a wide consultation of national authorities and national standardization bodies in the EU Member States;
5) A standardisation request is formally submitted to CEN and examined by the relevant Technical Body or Bodies;
6) The CEN Technical Board makes a decision on whether or not to accept the standardisation request (with or without restrictions), taking into account the views of the relevant Technical Body or Bodies within CEN;
7) Once the Technical Board has made a decision, CEN informs the European Commission.

In each case where a standardisation request has been accepted, the relevant Technical Body (or Bodies) within CEN is/are entrusted with the task of undertaking the expected standardisation work.

As a member of an NRA, you may be invited to participate in working groups associated with a specific standardisation request to help develop new or amend existing European technical documents including Harmonised standards and other technical specifications.

3.4 Harmonised Standards

A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.

Not all EN Standards are harmonised and this can cause confusion. The list of harmonised standards is posted the OJEU website and the PPD requires NRAs to put their requirements in terms of the harmonised standard, which may not be the most recent / latest one.

A harmonised standard has an Annex (Annex ZA) which gives a set of essential characteristics against which the manufacturer states performance characteristics when CE marking the product. In order to get a CE mark, the manufacturer only needs to declare one characteristic.

National annexes which were produced to allow EU member states to provide a subset of the requirements of a harmonised standard have been judged to be a barrier to trade and are no longer permitted.

3.5 European Assessment Document (EAD)

A European Assessment Document (EAD) is standard in that applies to a specific products or group of products. It is based on an agreement between the manufacturer and the Technical Assessment Body (TAB) identifying those characteristics for which the manufacturer wishes to declare the performance, and which might be relevant for the intended use.

NRAs have to take EADs into account when developing standards to avoid discrimination and accept the CE mark and the Declaration of Performance arising out of the EAD as evidence of product performance.

EADs have a higher status than National standards and specifications and can be used to direct the development of either national requirements or future harmonised standards.

3.6 Eurocodes

Eurocodes are European Standards and should be used in accordance with the hierarchy defined in the PPD. This means that national codes may still be used for private works in parallel with the Eurocodes, but for public contracts (within the conditions of the PPD) the national design codes must be replaced by the Eurocodes.

3.7 Non-Contradictory, Complementary Instructions

Complementary documents that repeat requirements notified elsewhere as either "Regulations" or "regulations" are unlikely to require notification. Non-contradictory, complementary publications are often produced for complex harmonised standards, and are a way of making a complex standard more manageable both for the specifier and the manufacturer / supplier. They provide a carefully curated set of options / recipes that can be specified by the NRA and the industry, rather than developing solutions from scratch.

4. Governance, Conformity assessment, marking and labelling of Products

4.1 Notified Bodies

Notified bodies are third party organisations that have been appointed by a European Union (EU) Member State's competent authority following completion of an in-depth assessment. The primary role of a notified body is to provide services for conformity assessment on the conditions set out in the new approach directives in support of CE (conformity European) marking. Conformity assessment can be inspection, quality assurance, type examination or design examination, or a combination of these.

4.2 Capacities of a Notified Body

The obligations, tasks and requirements to meet for a Notified Body (NB) are as follows:

1) Notified bodies are expected to carry out the tasks pertaining to the conformity assessment procedures referred to in the applicable New Approach directives when a third party is required.

2) Member States are responsible for their notification. They may choose the bodies they notify from the bodies established in their territory which complies with the requirements of the directives and the principles laid down in Decision 93/465/EEC. As far as the CPD is concerned the basic criteria which the Notified Body must satisfy are mentioned in Annex IV of the CPD.

3) The assessment of the body seeking notification determines if it is technically competent and capable of carrying out the conformity assessment procedures in question, and if it can demonstrate the necessary level of independence, impartiality and integrity. Further, the competence of the notified body should be subject to surveillance, which is carried out at regular intervals and follows the practice established by the accreditation organisations.

4) The EN 45000 series of standards and accreditation are important instruments to help Member States authorities to judge if candidate Notified Body complies with the requirements of the applicable EU legislation.

4.3 General Responsibilities of a Notified Body

The general responsibilities of a Notified Body are the following:

1) Notified bodies shall provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies.

2) Notified bodies shall operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner.

3) Notified bodies shall dispose the appropriate equipment and employ the necessary personnel, which has sufficient and relevant knowledge and experience to carry out conformity assessment in accordance with the directive in question.

4) Notified bodies shall make adequate arrangements to ensure confidentiality of the information obtained in the course of conformity assessment.

5) Notified bodies shall be adequately insured to cover their professional activities, unless liability is assured under the national legislation of the notifying Member State.

6) Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or otherwise ensure that they know the situation of relevant standards.

4.4 Existing Notified Bodies

The EU NANDO web site (http://ec.europa.eu/enterprise/newapproach/nando) has regularly updated databases provided by the Commission and covering all New Approach Directives. The site gives information related to the Attestation of Conformity of products under the New Approach Directives. The information provided also comprises existing Notified Bodies that are relevant to different fields of activities.

4.5 Assessment and Verification of Constancy of Performance (AVCP)

AVCP is the level of oversight / quality control for a product that the EC / CEN has agreed that the product requires. This is a judgement regarding the consequences of failure of the product. For the most part it is driven by safety.

A simple product may only require self-certification by the manufacturer and an internal factory production control system (AVCP 4), whereas a product where the consequences of failure are more severe may require product testing by a third party and regular inspections by the Notified Body (AVCP 2+).

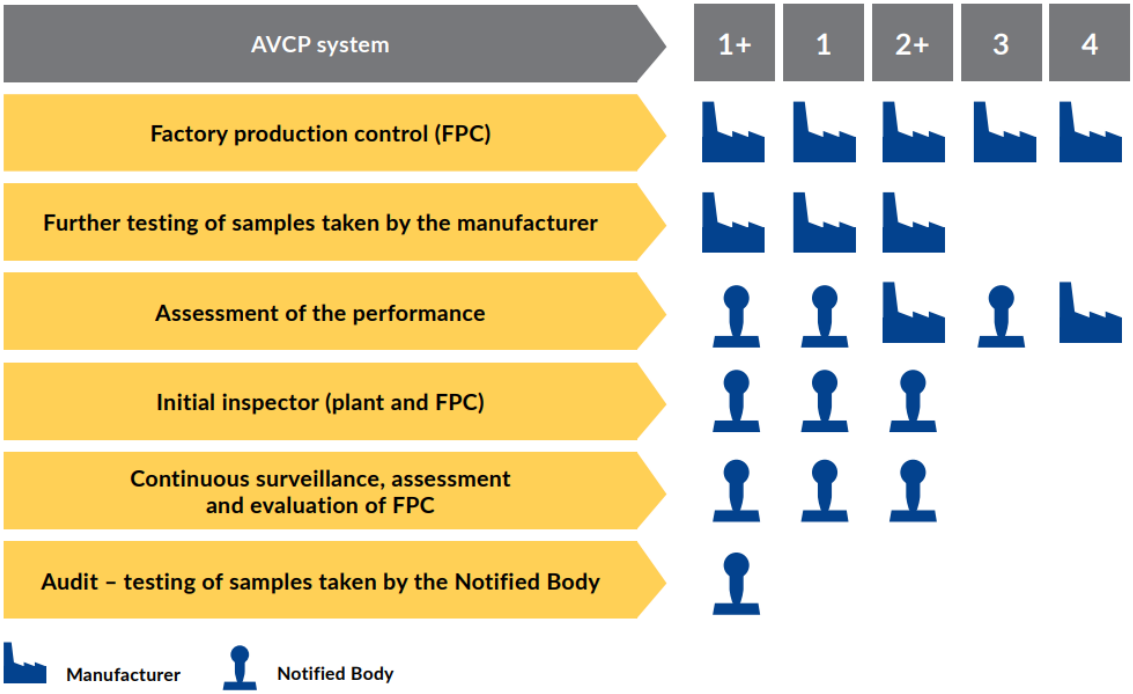


Figure 1 AVCP System *(CE Marking -Step by Step)*

The AVCP value is given in the Harmonised Standard in Z annex at the back of the harmonised standard. It is not something that can be varied by the NRA.

4.6 Evidence of compliance

CPR Article 8(3) sets the requirement that for any product covered by a harmonised standard, NRA of Member States can only specify the CE mark as a mark of conformity. While manufacturers may use other marks as added value when advertising their products, you (NRA) cannot require anything other than the DoP and CE-marks as evidence of compliance.

NRAs acting as either public bodies, or private bodies acting as a public body or acting under a public mandate (CPR Art 8.5) are not permitted to impose any additional rules to limit CE marked products, or preferentially select products. It also stops the imposition of pre-qualification requirements and "approved" lists.

4.7 Acting Under Mandate

"Acting under mandate" (CPR 8.5) means anyone working on the NRA's behalf is bound by the same rules as the NRA when it comes to specifying and/or accepting products.

Contract specific requirements are permitted, but as soon as the NRA provides any guidance or requirements that limit products, that guidance risks becoming general requirements and is therefore not permitted.

4.8 Market surveillance & non-compliance

4.8.1 General

Market Surveillance is closely linked with the Attestation of Conformity process. As far as Market Surveillance is concerned:

1) Market surveillance is an essential tool for the enforcement of CPR and New Approach directives.

2) The purpose of market surveillance is to ensure that the provisions of the applicable directives are complied with across the Community. Citizens are entitled to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.

3) Member States must nominate or establish authorities to be responsible for market surveillance.

4) These authorities need to have the necessary resources and powers for their surveillance activities, ensure technical competence and professional integrity of their personnel, and act in an independent and non-discriminatory way respecting the principle of proportionality.

5) Notified bodies should be excluded from the responsibility of market surveillance activities. This is to avoid conflicts of interest.

4.8.2 Basic Principle for Market Surveillance

The basic principles of Market Surveillance are:

1) National surveillance authorities shall monitor that products placed on the market comply with the provisions of the applicable national legislation transposing the New Approach directives;

2) Subsequently, when necessary, they shall take action in order to request manufacturer or his agent established in the EU to establish conformity.

3) Although market surveillance operations cannot take place during the design and product stages, enforcement usually requires that surveillance authorities act in collaboration with manufacturers and suppliers in order to prevent the placing on the market of non-compliant products.

4) The EC declaration of conformity and the technical documentation provide the surveillance authority with necessary information about the product.

4.8.3 Role of National Road Administrations

A DoP is presumed to be accurate and reliable (CPR Art 4.3), an NRA is not permitted to exclude a product or group of products from the procurement process, on the basis of a suspicion that a product or DoP is inaccurate. The assumption of conformity requires the NRA to accept the DoC / DoP, but compliance testing once the title for product has transferred to the NRA is entirely acceptable.

As an NRA, you are not directly responsible for enforcement, but where non-compliance with a harmonised standard, or declaration of performance arises, you are expected to alert the organisation responsible for market surveillance for your Member State. In reality, industry members are more likely to report competitors for non-compliance as a way of protecting their market share.

4.9 Manufacturers under CPR

A brief word on “manufacturers”. The definition scope is wider than just single products, and it can cause confusion. A manufacturer can fabricate a construction product or who has such a product designed or manufactured (fabricated), and markets that product under his name or trademark. A product from a manufacturer could be:

1. a single product with a DoP and a CE mark, or
2. a kit of parts with a DoP, a CE mark, and may include additional DoP and CE marks from the fabricators for the individual components.
3. a proprietary design, with no product, a DoP and a set of fabrication / installation instructions.

5. Processes

5.1 TSRD, Harmonised standards & EAD – The difference between technical regulations and standards

The difference between a standard and a technical regulation lies in compliance. While conformity with standards is voluntary for the manufacturer, technical regulations are by their nature mandatory. A standard can be made mandatory under a technical regulation.

5.2 Notification under TSRD

The Technical Standard and Regulation Directive (TSRD) is the legislation under which national regulations are subject to scrutiny by other member states to ensure that they do not affect the free movement of trade and create barriers to trade.

This directive is intended to establish transparency on national activities in the area of technical regulations and standardisation as well as setting up mechanisms to promote the harmonisation of technical regulations and standards at European level.

NOTE "Regulations" (capital "R") are different to "regulations" (small "r"). "Regulations" are statutory regulations, where as "regulations" are anything that has the effect of regulating. Depending on the country and method of procurement, the enforcement of regulations may be enforced by contract with no Statutory or Regulatory weight.

The requirements of an NRA may be considered "de facto regulations" if they refer either to:

1) technical specifications;
2) other (non-technical) requirements such as colour or markings;
3) rules on services;
4) professional codes or codes of practice which in turn refer to technical specifications or to other requirements;
5) rules on services, compliance with which confers a presumption of conformity with the obligations imposed by the national laws, regulations or administrative provisions.

As "de facto" regulations, NRA requirements may need to be notified under TRSD and spend some time languishing in Standstill on the Technical Regulation Information System (TRIS) website.

5.3 Notification

The submission process depends on the government department that sponsors the TSRD in your country, but the process usually requires you to complete a form with fields that mirror the information on the TRIS entry page and providing a copy of the "de facto" regulation in an editable (MS Word) format.

After three months standstill, there are several possible outcomes from the Notification process

1) Nothing (no comments), there is no response from anyone, either your document is compliant or no one cares enough about the subject to make a fuss. **Outcome – publish**

2) Comments - there are either some minor tweaks of the document are required, or there is some minor misunderstanding of the document. A misunderstanding can arise if either the document is part of a set, and general mutual recognition requirements are elsewhere. **Outcome - address and publish**

3) Opinions - the document has significant flaws and cannot be issued in its current state. You are given an additional three months to fix the problem and resubmit. **Outcome – fix and resubmit. (This can be repeated indefinitely)**

4) There is a fourth option, industry objects (for whatever reason), but the TSRD is only concerned by barriers to trade, and legislative non-compliance. **Outcome - publish and wait for the angry letters to the industry press.**

A word about consequences, the "no comments" option is not time-bound, if at any time in the future, there is a complaint regarding your "de facto" regulations, and it is upheld, you may be required to address any comments. Failure to do so can result in the EC taking action under TFEU 258 and TFEU 260, and the penalties imposed on your organisation are based on Member State GDP.

5.4 Participation in the TSRD process

As an NRA, it is likely that you will have been "volunteered" as a focal point as a competent authority and may be called upon to scrutinise other Member States regulations under the TSRD. See this as an opportunity to view other Member State approaches to your subject area and do not worry too much about the technical side, the EU is only interested if a requirement has an effect on the market.

6. Exceptions to CE Marking under CPR

6.1 CPR - Article 5 Manufacturer Derogations

The Construction Products Regulation permits situations where a product does not need to be CE Marked and gives the conditions under which the manufacturer can avoid having to CE mark their product. In the early years of CPR / CPD, many manufacturers believed that just because something is a custom size or shape it is exempt, but such products are usually caught by non-series production requirement.

In reality, derogations are intended to be used for bespoke and artisanal products, one-off designs produced in small workshops. However, highway professionals may encounter derogations for situations such as custom bridge bearings for older bridges, where the current practice of specifying and providing off the shelf bearings may not be suitable.

Experience has shown that manufacturers are wary of applying for derogations, as their product still has to demonstrate that it meets the required performance and none of their obligations regarding the performance are discharged, to the extent that they will prefer refurbishment of an old product over manufacture of new.

6.2 Client designed and client commissioned designs.

The client (NRA) may take the role of the “manufacturer” having designed or commissioned the design of a product, but choosing not to place the product on the market. Where this happens, the product falls outside of the definition of a “construction product” (CPR Art 2.1) and there is no need for CE marking and a DoP. Where the NRA subsequently choses to place the product on the market, the rules regarding “construction products” then apply.

The use of client designed and client commissioned products depends on what appetite the NRA (the client) or the designer commissioned by the NRA has for risk and what evidence the NRA requires to demonstrate that the "product" meets the published requirements as the client / overseeing organisation.

For some products such as road restraint systems, there are theoretical methods for calculating containment, which can be used to demonstrate that a product meets the requirements and could be used to validate a design.

There are NRA-designed products such as high containment concrete barriers where the NRA owns the design profile and is responsible for the risks associated with the design. High containment barriers are intended to protect bridge piers, and are unlikely to ever permitted for general use. Approval for their use is carefully controlled due to the associated risk. If the barrier is hit at speed, the consequences for the driver are severe, but this is accepted as part of the price for protecting bridge piers from vehicular impact.

Whether the NRA is responsible for the design if is used by third parties (eg Local Highway Authorities) is a question for legal representatives, and has not been tested in court. Where the NRA's requirements are enforced under contract, ie not a

national regulation, the use of the design and the outcome would be the responsibility of the third party.

If the NRA were to use the "client-designed" option too often or for commonly available products, manufacturers of CE marked equivalents may complain to the EU if they felt that the NRA was either excluding them or having an undue effect on the market.

6.3 Manufacturer (Proprietary) designs commercialised as products

These are not derogations. Proprietary designs commercialised as products are situations where the manufacturer owns the underlying design for a product, but either contracts or licences the manufacture or installation of the finished product to a third party. eg slip formed VRS (Britpave, Deltablock etc). Where these designs fall within the scope of harmonised standards, the manufacturer is responsible for the CE marking of the product and provision of Declaration of performance.

7. Informative references

The following documents are informative references for this document and provide supporting information.

Ref 1.I https://ec.europa.eu/growth/content/ce-marking-construction-products-step-stepguide-now-available-all-eu-languages-0_en. EU. CE marking - Step by Step, 'CE marking for construction products 'step-by-step' guide'

Ref 2.I https://op.europa.eu/en/publication-detail/-/publication/4f6721ee-8008-4fd7-acf7- 9d03448d49e5. EU 2000, 'Guide to the implementation of directives based on the new approach and the global approach (Warning - huge!)'

Ref 3.I https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_en. EU. Blue Guide 2016, 'The 'Blue Guide' on the implementation of EU products rules (2016)'

Appendix A. Landmark rulings of the EUCJ

These are just pointers, there is no intention to discuss the finer points of these rulings in this document. Their implications have not yet been integrated into the legislation.

A1 Case C-6/05, Medipac-Kazantzidis AE v Venizeleio-Pananeio (PE.S.Y. KRITIS)

Free movement of goods - Directive 93/42/EEC - Hospital purchase of medical devices bearing the CE marking - Protective measures - Public supply contract - Contract falling below the threshold of application of Directive 93/36/EEC - Principle of equal treatment and obligation of transparency.

A2 Case C-100/13, European Commission v Republic of Germany

Failure of a Member State to fulfil obligations — Free movement of goods — Rules of a Member State requiring that certain construction products bearing the 'CE' conformity marking conform to additional national standards — Lists of construction rules ('Bauregellisten')

A3 Case C-613/14, James Elliott Construction Limited v Irish Asphalt Limited

Reference for a preliminary ruling — Article 267 TFEU — Jurisdiction of the Court — Concept of 'provision of EU law' — Directive 89/106/EEC — Approximation of laws, regulations and administrative provisions of the Member States relating to construction products — Standard approved by the European Committee for Standardisation (CEN) pursuant to a mandate given by the European Commission — Publication of the standard in the Official Journal of the European Union — Harmonised standard EN 13242:2002 — National standard incorporating harmonised standard EN 13242:2002 — Contractual dispute between individuals — Method used to establish (non-) compliance of a product with a national standard transposing a harmonised standard — Date of establishing (non-) compliance of a product with that standard — Directive 98/34/EC — Procedure for the provision of information in the field of technical standards and regulations — Scope

A4 Case T-474/15, Global Garden Products Italy SpA (GGP Italy) v European Commission

Protection of the health and safety of consumers and workers — Directive 2006/42/EC — Safeguard clause — National measure of withdrawal from the market and prohibition of placing on the market of a lawn mower — Requirements concerning protective devices — Successive versions of a harmonised standard — Legal certainty — Commission Decision declaring the measure justified — Error of law