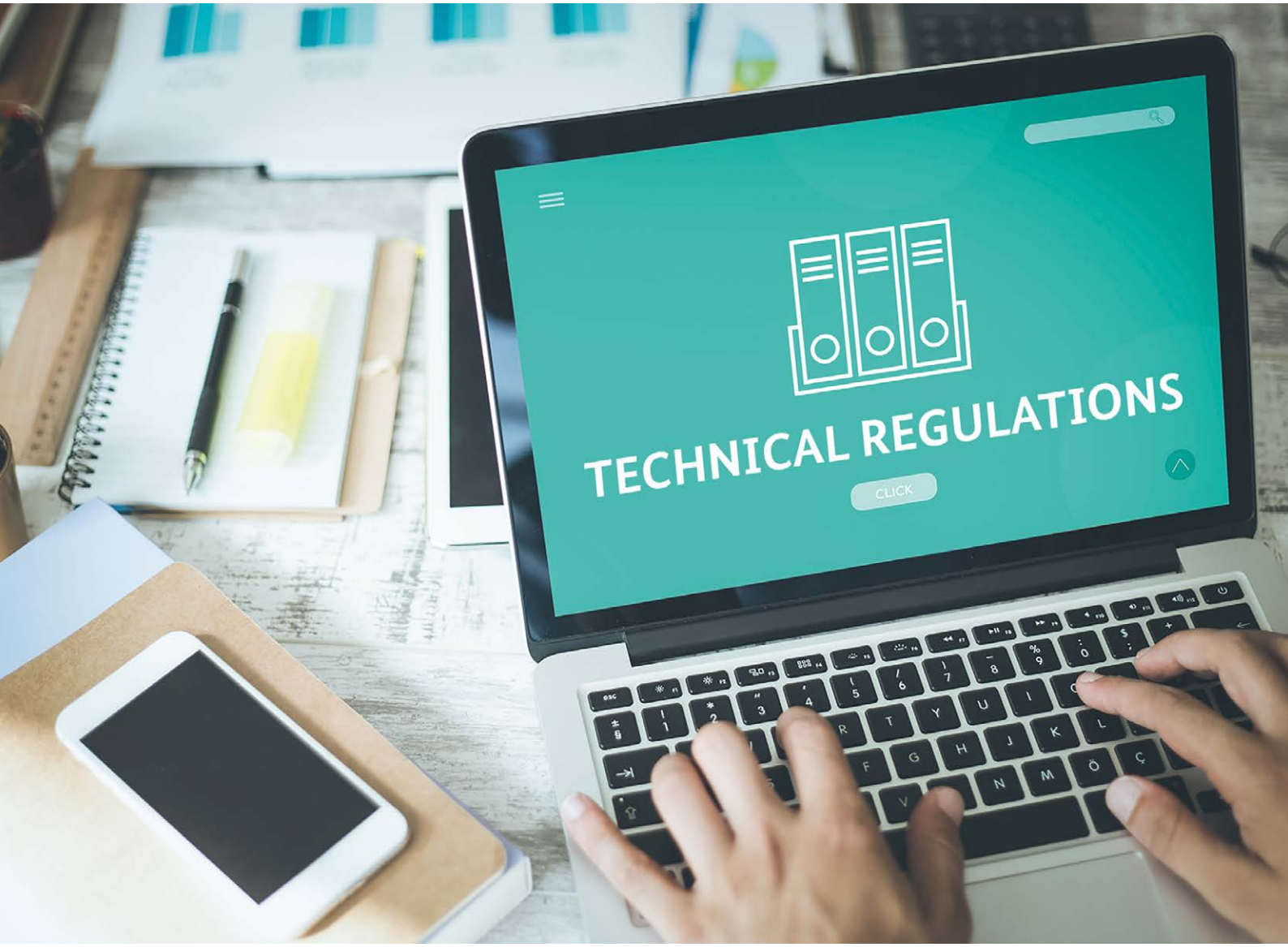
Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
National Metrology Institute

International
Trade
Centre



Technical Regulations

Recommendations for development and enforcement

Alex Inklaar, Elisabeth Stampfl-Blaha, Elisabeth Sperlich

german
cooperation
DEUTSCHE ZUSAMMENARBEIT

On behalf of

Federal Ministry
for Economic Cooperation
and Development

On behalf of the Federal Government of Germany, the Physikalisch-Technische Bundesanstalt promotes the improvement of the framework conditions for economic, social and environmentally friendly action and thus supports the development of quality infrastructure.

Authors:
Alex Inklaar, Elisabeth Stampfl-Blaha, Elisabeth Sperlich

Alex Inklaar, the author of the 1st edition of this Guide, died on 6 December 2018. With his passing, PTB lost one of its most important experts in the field of standardization and technical regulation. The aspiration of Alex Inklaar to convey international good practices based on the perspective and challenges of development partners was also a guiding factor for this publication.

We will continue to build upon his contributions as we carry on this work in his spirit.

Foreword by ITC and PTB

Manufacturers and distributors in any given market should not have free rein for their products because they could endanger the health and safety of consumers or damage the environment. Consequently, governments need to decide on interventions to prevent market failures and protect consumers as well as the environment by establishing technical regulations. In short, technical regulations are documents prepared by government authorities that lay down product characteristics or their related processes and production methods, with which compliance is mandatory.

Technical regulations, however, can at the same time unnecessarily impede trade if they are not properly developed or are established for illegitimate objectives. There is thus a need for a framework to minimize obstacles that could arise from technical regulations in trade. This need is met by the WTO Agreement on Technical Barriers to Trade (TBT) which provides rules for the development of technical regulations in a transparent manner. One of the main principles is that technical regulations should, as far as possible, be based on international standards so that various markets are open to the same product.

The WTO Agreement on TBT does not have specific provisions for *good regulatory practices* although there have been discussions on the subject in the TBT Committee at WTO. One of the means to ensure good regulatory practices is using regulatory impact assessments. These have been increasingly used as policy instruments by governments in various countries to determine and assess the impact of proposed technical regulations and to ensure that they are necessary, cost effective, and in the best interest of society.

Technical regulations need enforcement. However, this should be done in such a manner that their legitimate objectives are fulfilled without putting an unnecessary burden on businesses. This can be achieved through an effective market surveillance system which can be combined with pre-market controls if necessary. Market surveillance should be organized in such a way that the – often limited – resources are deployed specifically to high-risk areas and that there are no additional costs to businesses.

The information contained in this booklet is helpful for regulators in developing and transition countries who are working towards implementing an improved regulatory process. This should lead to enhancing trade among these countries as well as with developed countries.

This booklet, a revised version of the booklet published in 2009, is intended to continue to fill the void that still exists despite the various documents that are available on the development and enforcement of technical regulations. PTB and ITC are grateful to Alex Inklaar, who passed away in December 2018, that he as the author of the first edition saw the need to explain the subject in a simple manner. The updated version presented here has been prepared with the kind support and contributions of Dr Elisabeth Stampfl-Blaha and Dr Elisabeth Sperlich, Austrian Standards Institute, as well as of Ms Siglinde Kaiser, consultant of PTB.

PTB and ITC hope that this booklet will be useful for policy makers as well as regulators in developing and transition countries in their efforts towards achieving improved regulation and enhanced exports.

Khemraj Ramful
Senior Adviser for Export Quality Management , ITC

Dr. Marion Stoldt
Head of International Cooperation Group, PTB

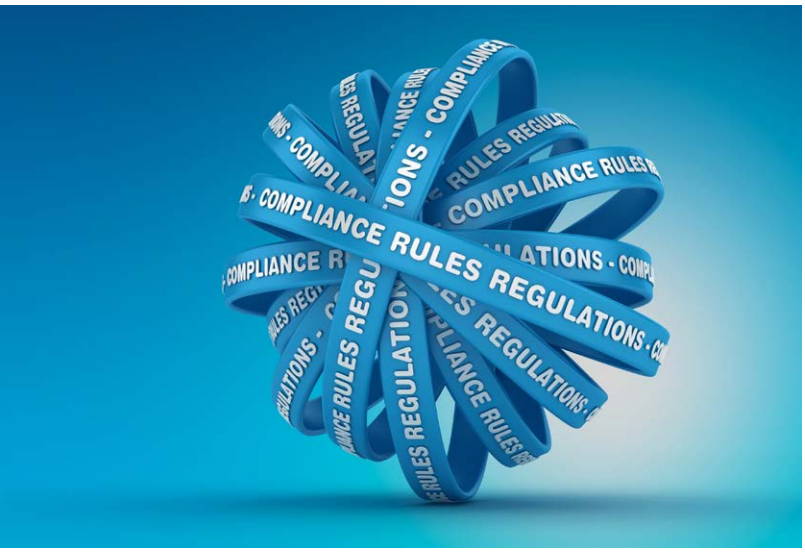
1. Why Regulation is Necessary

Governments nowadays are confronted with the need to protect their citizens and the environment from serious challenges arising, for instance, from rapidly evolving new technologies, globalization, digitalization, and climate change.

New technologies can have effects in terms of safety, but also of economic, environmental, and societal impact. The interplay of various technologies and their cross-sectorial use is complex and requires a thorough understanding of technical details and their implications.

Globalization requires markets that are fit to compete regionally and globally, demanding harmonization of frameworks on a larger scale. Barriers to trade need to be avoided, using approaches on trade that are based on a common identification and understanding of environmental and societal objectives as well as safety.

The digitalization of processes and products, e.g., based on artificial intelligence, raises both technological and societal questions (e.g., privacy), while climate change is an overarching global challenge requiring a joint international approach based on commonly agreed goals. These goals must be translated into regional and national actions that governments can enforce to reach the globally defined goals.



© iStock

Technical regulations are an instrument that governments can apply to tackle the challenges they are confronted with on a national, regional, and global level. The development of technical regulations is a multi-facetted task. Competent authorities are to draft technical regulations, put them into force, and to survey compliance.

Compliance with technical regulations is considered mandatory[1] and it is important to clearly distinguish between technical regulations and standards, the latter being voluntary, and to be aware of their different functions and objectives.[2]

> The focus of the WTO TBT Agreement lies in the voluntary nature of a standard. The standard must be approved by a recognized body and in the context of the Agreement, consensus for the approval is not a necessary requirement. International standards bodies, such as ISO and IEC, use the term *mandatory standard* and consider consensus within the international standardization community as a prerequisite.

Technical regulations and standards can complement each other, if carefully balanced. Regulations should be limited to areas where they are needed to achieve goals of a national, regional, or international nature and where the objectives cannot be reached by other means, i.e., by voluntary standards that cover market needs and when a regulatory intervention is not needed.

To support regulators in this complex task, various good regulatory practices (GRP) have been developed, i.a. by the Organisation for Economic Co-operation and Development (OECD).

1 Refer to the WTO TBT Agreement Annex 1 (Terms and their Definitions for the Purpose of this Agreement) *https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm#annexI*, query 2022-05-02.

2 Ibid

2. Good Regulatory Practices (GRP)

2.1. Key considerations

Good regulatory practices are internationally recognized processes, systems, tools, and methods for improving the quality of regulations and ensuring that regulatory outcomes are effective, transparent, inclusive, and sustained. More and more trade agreements contain good regulatory practices to promote the effectiveness and efficiency of regulations and, therefore, facilitate safe trade. In 2012, the Council of the Organisation for Economic Co-operation and Development (OECD) adopted the Recommendation of the Council on Regulatory Policy and Governance. The Recommendation was the first international instrument to address regulatory policy, management, and governance as a whole-of-government activity.

Key considerations of good regulatory practices are:

- Clarity as to the policy rationale, the objectives, and the institutional framework
- Prevention of undue influence and maintaining of trust
- Transparency, consistency, and accountability
- Promotion of stakeholder engagement and participation
- Ensuring that the regulation produces benefits that justify costs
- No distortion of markets
- Regular performance evaluation (as to relevance, effectiveness, and efficiency)

2.2. Regulatory impact assessments (RIAs)

A regulatory impact assessment (RIA) is an essential element of good regulatory practices; it is a policy instrument for the determination and assessment of the impact of a proposed regulation regarding its costs, benefits, and adverse effects.

Worldwide, a rapidly growing number of countries have introduced the obligation to carry out such assessments for different types of regulations – especially for proposed technical regulations.

> It is important to note that not every planned and proposed technical regulation automatically requires a complete RIA. It is recommended to define and describe different forms of an RIA, varying in stringency and required investment of resources, to be applied in relation to the expected impact of the proposed regulation.

Consultation with selected potentially affected parties is an important element of every RIA. The RIA provides the structure for discussion papers and the results of the discussions/consultations are fed into the RIA process.[3]

A complete RIA should contain the following components:

Purpose and intended effect

- What problem needs to be solved and which effects shall be achieved?

Risk analysis

- What are the current risks that the regulation shall address?

Target group analysis

- Which target groups will be affected by the technical regulation and to what degree?
- Will certain target groups be affected in a disproportionate way? (For instance, micro, small, and medium-sized enterprises?)
- Will it be necessary to provide relief to certain parties?

3 A useful description of the RIA approach applied in the United Kingdom can be found at *https://www.gov.uk/government/publications/impact-assessment-template-for-government-policies*, query 2022-05-02. An overview and OECD studies of RIAs are available at *https://www.oecd.org/regreform/regulatory-policy/ria.htm, query 2022-05-02*.

Options

- What are the alternatives to a technical regulation?

Cost-benefit analysis

- Do the benefits of the regulation justify the total costs of the regulatory exercise?
- What are the types and amounts of costs arising for the government, to the specialized authorities involved in the process, to the economic actors, and to consumers, including indirect costs?
- What would the costs (types and quantities) be for alternative options?

Feasibility studies

- Will the primarily affected economic parties be able, from a technical and economic point of view, to comply with the requirements of the technical regulation?
- Will supportive technological measures be required and possible?
- Is the total investment on the part of the respective affected parties still justified?
- Are the implementation costs on the part of the affected parties still acceptable against the background of their overall regulatory burden?

Compatibility checks

- Is the regulation compatible with existing national legislation?
- Will it be necessary to withdraw or amend other national regulations?
- Is the regulation compatible with regional and international treaties and agreements?

Finally, after the regulator has taken all decisions related to the contents of the technical regulation and has formulated the corresponding provisions, an editorial check should be implemented, taking the following into consideration:

- Does the legal text use simple and clear language?
- Does the document have a clear structure?
- Are all provisions formulated in a clear and unambiguous manner and are they free of contradictions?
- Are all key terms defined?
- Are all definitions recognized and agreed both nationally and internationally?

2.3. Guiding questions to the regulator for the preparation of technical regulations

The following tables present questions that can be used to address the above components in detail at the different development stages of a technical regulation. Table 1 provides questions to be asked before a decision for a technical regulation is taken. Table 2 lists questions to be asked once a decision was taken to develop such a regulation.

Table 1 – Topics and questions to consider when in the process of deliberating a technical regulation

Topics	
Problem addressed *A clear identification of the problem is essential for all further steps and must not be omitted from the RIA process.* *If a detailed description is not yet available, it must be developed.*	**Guiding questions** ■ What is the problem? ■ Who identified the problem? ■ Is a detailed description of the problem available? ■ How urgent is the problem? ■ Which parties will be affected by the regulation and how exactly will they be affected?
Risks *A risk-based approach will help to find the right balance when deciding on the depth of regulation, compliance measures, sanctions, etc.*	**Guiding questions** ■ What type of risks are involved? ■ Do we have any documented results of a risk analysis? ■ Is it necessary to carry out our own risk analysis or should another party be engaged to carry out the risk analysis? ■ Does compliance with the regulation confront the affected enterprises with problems of financial nature?
Responsibilities *Very often more than one authority should be responsible for developing a regulation. Sometimes non-public actors can also play a decisive role in contributing to the solution.*	**Guiding questions** ■ Who is responsible for solving this problem? ■ Who should be responsible for the development of a technical regulation? ■ Do we already know the most important actors who can contribute to the solution?
Decision on Regulatory Instruments *Today there is a strong demand for deregulation. Therefore co-regulation (regulatory framework plus additional measures) and non-mandatory approaches (standards, self-binding agreements, etc.) and/or promotion campaigns need careful consideration.*	**Guiding questions** ■ Do we need a technical regulation to solve the problem or are there other options? ■ Would a voluntary standard be sufficient or at least a quick solution to start with? ■ Could voluntary measures by economic actors other than standards solve the problem? ■ Could other options such as awareness-raising, education, or information solve the problem? ■ Could economic and tax incentives solve the problem? ■ Should we go for co-regulation (regulatory framework, but details left to standards)?

Table 2 – Topics and questions to consider if the need for regulation was confirmed

Topics	
Aims and objectives of the technical regulation *The aims and objectives, which are based on a clear and concise problem description, have both the function of a political vision and of an instrument for measuring effects.*	**Guiding questions** ■ What are the aims and objectives of the technical regulation? ■ Do we have a detailed description of the aims and objectives? ■ Are the objectives in line with WTO TBT requirements?
Process *Frequently there is a trade-off between speed and openness of the development process. This must be balanced in the design of the process. Risks such as a lack of sufficient knowledge of the issue or strong resistance of stakeholders will also influence the decision on process design.*	**Guiding questions** ■ Can we already take a decision concerning the adequate development procedure for the technical regulation? ■ To what degree should the procedure be consensus-based? ■ How many consultations should take place with stakeholders and how frequently? ■ Should we set up an experts' group? ■ Who will prepare the draft?
Documents available *In most cases, the problem is not unique to the respective country. Therefore, it is strongly recommended to systematically check the availability of documents (regulations, standards) which deal – at least partially – with the problem to be solved. They can serve as inspiration or even be taken over with minor or no changes.*	**Guiding questions** ■ Is there an international standard on which the technical regulation could be based? ■ Are there any regional standards, national standards, or foreign national standards on which the technical regulation could be based? ■ Do any foreign technical regulations address similar problems? ■ Is the relevant standard or regulation suitable for application under our specific national conditions (geographical/geological conditions, climate, technical/technological feasibility)?
New standards needed as part of the solution *If a standard needs to be developed (as the solution or as part of the solution), international standards must be given priority. As a fall-back, regional, foreign, or national standards or foreign regulations can be helpful. The way that the standard (stand-alone or used by regulation) will be applied needs to be decided.*	**Guiding questions** ■ Could a newly developed standard (national, regional, or international) support the regulation? ■ Should the national (or regional) standards organization preparing the standard receive an official mandate for this task? ■ Should the standards organization managing the preparation of the standard receive financial support for this task? ■ In exactly what way do we want to use the standard in combination with the technical regulation: incorporation of the standard into the regulation (only if copyright allows this) or reference to the standard? – Exclusive reference? – Indicative reference? – Dated reference? – Undated reference?[4]

4 Refer to chapter 4.2 for an explanation of these terms

Evidence base *There might be a lack of evidence on which decisions on regulatory measures can be based. In this case, conducting dedicated studies must be considered.*	**Guiding questions** ■ If no adequate standards or regulations are available yet, or if we are in doubt about the adequacy of the existing standards or regulations, do we see a necessity to carry out our own studies, examinations, tests, analyses? ■ If yes, which authority or (scientific) institution could carry out the required studies? ■ Should these studies also include product and/or materials testing? ■ If yes, which laboratories would be competent to carry out the required tests? ■ Should these laboratories be internationally accredited?
Compliance with legal requirements *Potential hurdles for compliance with the legal requirements (or the standard) must be considered.*	**Guiding questions** ■ How do we ensure that the legal requirements are sufficiently known and understood by all the affected parties? ■ How do we ensure that the affected parties are capable of compliance? ■ How do we ensure that the legal requirements are complied with? ■ How do we create incentives for the affected parties to comply with the legal requirements? ■ Do we have enough national bodies which can offer the required testing, analysis, inspection, and calibration services? ■ Are there ways to support the affected micro, small, and medium-sized enterprises in their compliance efforts by means of education and training activities and/or financial support?
Conformity Assessment *The conformity assessment measures must be considered based on the risk assessment, the costs involved, and the available infrastructure.*	**Guiding questions** ■ Which conformity assessment procedure(s) will the regulation foresee? ■ Which bodies will be authorized to carry out the conformity assessment procedure(s)? ■ What are the criteria for the authorized bodies? ■ Who assesses and confirms the competence of the authorized bodies? ■ What is the role of accreditation? ■ Will a product marking scheme be introduced? ■ Are there any explicit arrangements for the recognition of foreign test results and certificates? ■ Are there any explicit arrangements for market surveillance based on the regulation? ■ Will there be a clear separation between conformity assessment (pre-market) and market surveillance (post-market) activities? ■ Have the responsibilities for market surveillance been allocated in a clear and unambiguous manner? ■ Have we planned and can we mobilize adequate human, technical, and financial resources for market surveillance?
Review *After a defined period, the regulation needs to be reviewed based on the situation as of after the implementation of the regulation, the experiences gained, and the degree of achievement of the goals and objectives.*	**Guiding questions** ■ Does the problem still exist or has the situation changed? ■ Has the regulation achieved its goals (or to which extent)? ■ Are new instruments available to solve the initial problem? ■ What do data on (non-)compliance and experiences with conformity assessment and market surveillance teach us?

3. Technical Regulations and Standards

The complexity of technology, the speed of change, and globalization go hand in hand with fast-changing regulatory needs. Because flexibility is key, it is very attractive to use (preferably international) standards when developing regulations. The WTO/TBT Agreement even requires regulators to use international standards (Art. 2.4).[5]

It is therefore important to be clear about the terms *technical regulation* and *standard*, their differences, and their common features.

The following table shows the differences:

Table 3 – Differences

Legal character	
Technical regulations ■ Technical regulations are **legally binding** prescriptions. ■ They must be applied by all parties, be they large or small, regardless of the introduction costs. ■ This implementation obligation can be a substantial threat to the existence of micro, small, and medium-sized companies.	**Standards** ■ Standards are considered to be **recommendations**. ■ Companies and organizations apply them on a voluntary basis. Users decide for themselves which standards are relevant for them and if the benefits would be greater than the expected costs of their implementation into the company's or organization's practice. ■ Standards often reflect market expectations – in some cases, compliance with certain standards can even be a precondition for competitiveness and market access.
■ If a technical regulation prescribes a specific product design in detail, this tends to create a real hindrance to innovation which in turn may cause substantial damage to the competitiveness of the affected companies.	■ A product standard may also include detailed technical solutions regarding the design and construction of a product (although today a performance-based approach is preferred).
■ A technical regulation must be complied with in its totality.	■ Users of the standard are free to choose to observe the standard or to use other technical solutions and innovations. ■ All users may pick and choose aspects and solutions that are relevant to them out of the total content of the standard.
■ Technical regulations, which are difficult to understand or even misleading (ambiguous), must nevertheless be applied and complied with.	■ Standards which are badly written, difficult to understand, or even misleading (ambiguous) are seldomly used. Potential standards users will rarely apply a standard which they cannot read and/or understand.

5 "Where technical regulations are required and relevant international standards exist or their completion is imminent, members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."

Purpose

Technical regulations	Standards
■ The main focus of technical regulations is on the **safety – and not quality – of products** (including foodstuffs and services), plants, installations, and set-ups of all kinds. They primarily focus on safety objectives and values. ■ Technical regulations aim to achieve the protection of human beings, animals, and the environment against dangers and negative influences of all kinds. Many technical regulations deal with safety at the workplace, the protection of consumers against dangerous products, and the general health of human beings and animals. ■ Another possible objective of technical regulation is the regulation of market issues in the case of market failure. If the play of forces between market actors leads to a significantly unequal treatment of one or several parties, the issue of adequate technical regulations may help to establish a level playing field for fair competition and ensure access to justice for all players.	■ Standardization is an instrument for **optimization**, which was originally developed by and for manufacturers, for the benefit of manufacturers and their clients. ■ Nowadays standards are used not only by the economic actors but by practically all organized groups of civil society as well as the state and its authorities. ■ Standards are agreements between all relevant interest groups. The establishment of these agreements in technical standardization committees is based on the consensus of all participants as per good standardization practices of the standardization bodies. ■ Standards are usually detailed and describe how safety objectives can be put into practice. ■ The subjects of standardization are as varied as the groups that use them. Standardization bodies address the needs of the interested parties in recognized standards. ■ The aims and objectives of standardization are manifold, too. They also include the aim of contributing to the safety of the respective subject of standardization.

Responsibility

Technical regulations	Standards
■ The **responsibility** for the development and issuing of technical regulations lies with the **state and its competent authorities**. ■ Technical regulations are part of the total collection of legal norms of a country or a region. The **enforcement** of technical regulations, too, is the sole responsibility of the state and its authorities. ■ Ultimately, these tasks are embodied in the constitution of each state. How the tasks are to be accomplished is the sovereign decision of each state.	■ The **responsibility** for the production and publication of standards lies with the respective (public and private) **stakeholders** and the **recognized standards bodies**. ■ The standardization process follows internationally agreed and recognized principles such as openness, consensus, and transparency. ■ The stakeholders cooperate in technical committees and can also contribute to the content of a standard during the public enquiry.
■ The way in which a state fulfils its regulatory tasks cannot be prescribed regionally or internationally. ■ There are many good reasons, however, to study – and where possible – adopt tried and tested international practices and good regulatory practices (GRP) described and published by organizations such as the Organisation for Economic Co-operation and Development (OECD).	■ Principles for the standardization processes are defined in Annex 3 of the WTO/TBT Agreement (Code of Good Practice for the Preparation, Adoption and Application of Standards[6]) and the respective rules of procedure of recognized standards bodies.

6 *https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm#annexI* (query 2022-05-02)

Table 4 – Similarities

The following elements are relevant for both regulations and standards.

Common aspects of technical regulations and standards
Necessity ■ For a technical regulation, following the good regulatory principles, this shall be done by means of a Regulatory Impact Assessment – within the realm of possibility of the authority and with a reasonable investment of resources. ■ With regards to standards, a cost-benefit analysis should be carried out before accepting the proposal for a standard.
Evaluation of effects ■ The first step towards the elaboration of a technical regulation/standard should be to examine the necessity for it. The costs of state intervention and of the stakeholders caused by the technical regulation or standard should be a factor when evaluating the need.
Exemptions and exceptions ■ The possibility of exemptions and exceptions for the benefit of severely affected parties should always be examined. ■ This is of course more important for regulations (in view of their mandatory character). ■ In a standard the chapter *Scope* takes into account possible exceptions.
Transition ■ Adequate transitional periods should be introduced. ■ This is vital for regulations (as the law has to be complied with as soon as it is entered into force). ■ Standards offer more flexibility in view of their voluntary nature.
Performance criteria ■ Instead of requirements concerning the design and construction of a product, performance criteria should be defined. ■ For regulations, the selection of the relevant performance characteristics that need to be regulated should be carried out with great care. In principle, only those characteristics which are relevant to safety or other legitimate objectives should be included in the regulation. ■ Standards may be more detailed, and the performance approach will avoid excluding new products due to stringent design requirements.
Integration of regulation and standards ■ The decision to integrate an existing standard into a technical regulation, for example by means of reference to the standard, should only be taken after the determination of the compatibility of the standards with the objectives pursued by the regulation. However, the authority maintains full responsibility of the content which it makes mandatory.
Delegation of responsibilities ■ There is no doubt that it is possible and useful to delegate certain tasks in connection with the elaboration of drafts for technical regulations to Non-Governmental Organisations or Third Parties. ■ A standards body may for instance receive a mandate to prepare standards which will be complementary to technical regulations.
Editing ■ The texts shall be carefully edited for – Clear and simple language – Unambiguous statements – Complete statements – Minimum number of references to other regulations/standards

4. Reference to Standards in Technical Regulations

4.1. Background

The adequate development of technical regulations requires expertise in the most varied fields, which usually is not or not sufficiently available in state authorities. Incorporating or referencing standards permits the legislator to focus on the key objectives concerning safety, etc., of a technical regulation and refrain from entering into details.

Standards are based on an open process that involves all stakeholders and asks for contributions and provision of technical expertise from all parties involved; therefore, they offer a wealth and depth of technical knowledge, agreed upon in a broad consensus-based process.

Against this backdrop, referencing standards offers significant advantages:

- The legislator can rely on recognized solutions and does not need to invest in the reinvention of the wheel.
- The overall development process is highly cost-effective.
- The main characteristics of the standardization process – consensus, openness, and transparency – often guarantee a high degree of acceptance of the technical regulation.
- Good standards describe the state of the art.

4.2. Methods for referencing to standards

One option to use standards in regulation is the incorporation of the text of a standard – the word-by-word reproduction of a standard or excerpts of a standard in a regulation. However, this will not only raise copyright problems (standards are usually protected by copyright legislation), but also cause a lack of transparency as to the source of the text. If the incorporated material from a standard is revised and the legislator wants to update the regulation, the full text of the regulation must be revised.

The other option is referencing to standards. If the legislator decides to refer to standards for the purpose of technical regulation, there are fundamentally different methods for exclusive and the indicative referencing.

In addition, references may be dated or undated. This differentiation becomes particularly relevant in the case of exclusive reference to standards.

Exclusive reference to standards
Through exclusive reference, the standard becomes part of the technical regulation and compliance with the standard becomes mandatory. There are no alternative options to demonstrate compliance with the technical regulation.

Example
Article 4 (1) of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations, and administrative provisions of the Member States concerning the manufacture, presentation, and sale of tobacco and related products and repealing Directive2001/37/EC (OJ 2014 L 127, p. 1) stipulates that
The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide.
The accuracy of the tar, nicotine and carbon monoxide measurements shall be determined in accordance with ISO standard 8243.

Using dated references
In the case of a dated reference, the technical regulation contains the number, title, and date of the referenced standard. As result, only this specific version of the standard may be used for compliance purposes.

The advantage of this method lies in its clarity and the resulting high degree of legal certainty. The legislator is the master of the procedure and decides which specifications are relevant for the purposes of the regulation. The users of the regulation know exactly with which standard(s) compliance is mandatory.

The disadvantage of the dated reference is just as clear: Every revision of the cited standard in order to adjust it to the state of the art must necessarily result in a revision of the technical regulation as well (which, however, will normally mean just a change of the reference, nonetheless requiring a legislative process).

Using undated references
In the case of an undated reference, only the number and title of a standard are given, not the date of publication or availability of a standard. The result of this type of reference is that, at any given point in time, it will be the current version of the relevant standard which has to be complied with. Every update/revision of the standard automatically brings about a change in the material content of the regulation.

Using undated references to standards seems to be a very flexible and efficient method, but it holds substantial risks. After the first issue of the regulation, all later versions of the referenced standard will automatically become part of technical legislation as well. In fact, this constitutes the delegation of legislative competence to technical standardization committees where the standard is revised. Under some jurisdictions, such a delegation of competence is considered unconstitutional.

Indicative reference to standards
In the case of indicative references, the application of the standard is strongly recommended, but will remain voluntary. The preferred type of demonstration of conformity with the regulation is by means of compliance with the requirements of the standard. However, other options are not excluded.

Example
§ 30 (1) of Viennese Event Law *(Wiener Veranstaltungsgesetz)* 2020 stipulates that

At each event, basic medical equipment in good and perfectly hygienic condition must be available for first aid. This basic medical equipment has to comprise at least a first aid box type 2 according to ÖNORM Z 1020 or similar equipment.

Mandatory application of the standard

Exclusive reference
Demonstration of conformity is always to the standard

Dated reference
Only that particular version of the standard

Undated reference
The version of the standard referenced and all its subsequent versions

Danger!
Unauthorised delegation of competence

Voluntary application of the standard

Indicative reference
Demonstration of conformity is to the standard, with other options allowed

The method of indicative reference to standards is one of the central elements of the European New Approach (New Legislative Framework) for the harmonization of technical regulations.

Table 5 – Framework

The New Legislative Framework (formerly the New Approach) of the EU
The European method for referencing standards In accordance with this approach, harmonized technical regulations (EU directives or EU regulations) which are binding for all EU Member States contain only a few essential requirements, especially with regard to the safety of products and the health of consumers. The producers must comply with the essential requirements of the directive or regulation in a way he/she chooses. The preferable way is to use European Standards (EN) that have been developed to provide technical details on how those essential requirements should best be met. The number, title, and issue date of those standards which are deemed to detail the essential requirements are published in the Official Journal of the European Union.[7] Conformity to harmonized standards, whose application remains voluntary – offering one way of complying with the essential requirements – automatically brings about a presumption on the part of the competent authorities of all EU Member States that the legal requirements are complied with (principle of *presumption of conformity*).
Principles of the European method The New Legislative Framework is thus based on main principles that can be followed by legislators everywhere in the world: ■ Technical regulations lay down the main (safety) requirements for products or services. ■ Standards define the technical methods to be used to meet those main requirements. **If producers apply the standards, they can be sure that they are in line with the main requirements of the technical regulation.**

7 *https://eur-lex.europa.eu/content/help/oj/about-oj.html*

5. Enforcement of Technical Regulations through Effective Market Surveillance

5.1. Principles

The development and issue of technical regulations brings about the task and responsibility on the part of the competent authorities to ensure that the regulation's requirements are actually fulfilled by all economic actors. The primary objective of market surveillance is the protection of all citizens, especially where products can have an effect on health, safety, or the environment. Beyond this, it is of great significance to the interests of market players as an instrument to prevent unfair competition practices.

The authorities may carry out this task either before (conformity assessment) or after (market surveillance) the products are placed on the market. A combination of these two types is also possible and – as conformity assessment is seldomly in a position to cover 100 % of product tests – even necessary.

Market surveillance as a state task
Market surveillance is a state task. It needs a legal basis that ensures the existence and effective implementation of market surveillance. The ultimate responsibility must always lie with the public authorities. In no other way can the required impartiality and legitimacy in enforcement be achieved and the risk of conflicts of interest reduced to the minimum.

Market surveillance authorities must be vested with the powers, resources, skills, and knowledge necessary for the proper performance of their tasks: monitoring the market, initiating corrective action in the case of non-compliance, and enforcing conformity.

In terms of human resources, the authority should be able to rely on an adequate number of qualified and experienced employees adhering to high professional and ethical standards.

Performance of market surveillance tasks
The surveillance authority should be independent and perform its tasks in an impartial and non-discriminating manner. And finally, it should always observe the principle of proportionality, meaning, e.g., that any corrective action taken should correspond to the degree of risk and/or the nature of the detected non-conformity, and not be more stringent and trade-restrictive than necessary.

Market surveillance activities should be based on a market surveillance strategy. In the strategy, the overall goals of market surveillance should be defined as well as the general approach that should be taken (e.g., focus on proactive or reactive market surveillance, focus on products or businesses, or a combination thereof). Based on such a rather general strategy, detailed programmes for market surveillance can be developed, defining the scope of activities, the priority areas, product categories, and the allocation of resources.

Market surveillance authorities should perform appropriate checks of products to assess whether these comply with the relevant technical regulations. This can consist of document checks and physical and laboratory testing on the basis of adequate samples. The authorities can have their own testing laboratories, but they can also assign third-party conformity assessment bodies with this task.

Such conformity assessment bodies should be independent, impartial, and – ideally – accredited. Furthermore, there should not be any conflicts of interest between the market surveillance authority and the conformity assessment bodies. To ensure the quality and reliability of their work, the authorized conformity assessment bodies should preferably fulfil the criteria of the relevant international standards, such as ISO/IEC 17025 on general requirements for the competence of testing and calibration laboratories.

Financial resources
Experience shows that resources for market surveillance are extremely scarce. This state protection task is very costly and does not produce any substantial revenues. The well-intended market actors who already spend a lot of money on in-house testing and independent third-party inspections must not be burdened again and cannot be asked to pay for market surveillance as well. Thus, in the interest of efficient market surveillance, the available resources should be concentrated and deployed especially in higher risk areas, in fields with above-average non-conformity rates, and in other areas of special interest. In this connection, statistics should be kept and evaluated, and simple risk assessment procedures be applied.

Surveillance activities
In order to effectively monitor products in the market, market surveillance authorities should have adequate powers and resources to carry out the following activities and tasks:

- Demand that economic actors submit all necessary product-related information
- Arrange for random checks and (even unannounced) on-site inspections
- Conduct (regular) visits to premises
- Take product samples and submit them to examinations and tests

As per principle, market surveillance cannot take place during the design and production phase. It only starts after the product has been placed on the market. Nevertheless, it is important for the surveillance authority to have the right to carry out checks and examinations on the production site to determine if a detected non-conformity is of a systematic nature when defective products have been found on the market.

It is also very useful to monitor relatively high-risk products such as machinery at trade fairs and exhibitions to get a good overview of the market. This may also put the authority into a position to estimate the risks and/or likelihood of non-compliance. This represents an early opportunity for preventive educational measures. Thus, the operators/producers can be informed about the necessary legislative requirements and best practices which will lead to a better understanding and compliance with the requirements.

Corrective actions
In the event of the detection of non-conforming products, the authorities must order and enforce corrective action. Experience has shown that pure market policing by the surveillance authorities rarely produces any positive and sustainable results. It is certainly much more promising and effective to combine, wherever possible, stringent and consistent market monitoring with a cooperative approach to corrective action. In the interest of the protection of all citizens, the authorities should have all the necessary powers to take drastic action where required, including product withdrawal from the market, product recall from the consumer, or even destruction of the product. The adequate type of corrective action should, however, be determined with a lot of care and instinct, depending on the seriousness and the risk potential of the non-conformity.

Collaboration with consumer protection organizations
Market surveillance is an element of consumer protection in a wider sense. Surveillance authorities and consumer protection organizations should have a mutual interest in functioning and transparent cooperation: The authorities can benefit from the private associations' proximity to consumers to receive early and first-hand information about potential dangers in connection with consumer products. Private consumer organizations will benefit from technical data which can be provided by the authorities. And finally, without effective cooperation between authorities and private associations, neither of them will be able to contribute to the gradual increase of confidence in the effectiveness of the applied product safety policies and mechanisms.

5.2. Critical factors for an effective market surveillance

Due to its principles, market surveillance presents many challenges to authorities and market surveillance agencies.

The supervising authority must consider several critical factors to be able to implement effective market surveillance.

Responsibilities and organization

- Model of organizational structure:
  - One centralized authority for all sectors
  - One authority for foodstuffs, one for non-food items
  - Decentralized market surveillance by the competent authority issuing the technical regulation

Legal basis for market surveillance

- Framework legislation on general product safety
- Determination of powers of market surveillance authorities

Coordination and cooperation between national authorities

- Clear responsibility for overall coordination
- In case products fall into the scope of two or more regulations, or if different authorities are responsible for different aspects of a product, the government must organize market surveillance in such a way to avoid duplication of inspections.
- Typical tasks which should be centrally coordinated:
  - Establishment of databases
  - Creation of a national information and communication system for market surveillance
  - Participation in regional and international information and communication systems (e.g., RAPEX, which is a rapid alert system for dangerous consumer products operating across the European Union as well as in the non-EU countries of the European Economic Area [EEA]; ASEAN [Association of Southeast Asian Nations] Product Alerts, which is a one-stop portal compiling all information on recalled products which are traded within the region; and the OECD GlobalRecalls portal)
  - Cooperation with consumer (and other relevant) organizations

Strategy development

- Development of a unified national market surveillance strategy which can be communicated to all affected circles
- The national strategy serving as the basis for sector strategies

Financial resources

- Preparation of specific budget plans for market surveillance by the competent authorities, especially covering the following:
  - Personnel
  - Education and training
  - Cost of sampling
  - Cost of a minimum number of pro-active (preventive) monitoring projects
  - Public relations
  - Information and communication technology
  - Regional and international cooperation

Human resources development

- Training needs analysis
- Education and training plans, including on-the-job measures
- Study visits
- Regular exchanges of experience with foreign market surveillance authorities

Access to adequate testing facilities

- National resources and regional cooperation
- Creation of networks, preferably under the lead of an accredited laboratory
- Use of private testing facilities under clearly defined conditions and state supervision and responsibility

General market surveillance methodology

- Code of conduct for market inspectors
- Documented procedures and guidelines for the following:
  - Product sampling
  - On-site inspections
  - Communication with market actors
  - Assessment of non-conformities
  - Initiation of corrective action

Preventive market surveillance

- Introduction of unified procedures and tools for collecting, evaluating, and documenting data that is needed as a starting point for surveillance strategies (e.g. history of non-compliance, results of audits, market share, distribution of products)
- Introduction of simple risk assessment procedures and planning tools
- Harmonization of all procedures and tools for all authorities involved in market surveillance

Reactive market surveillance

- A mechanism to follow up complaints is in place
- Monitoring of accidents that are suspected to have been caused by relevant products

Information and education campaigns

- Awareness-raising among market participants on the mechanisms of market surveillance
- Awareness-raising among consumers concerning where to deliver complaints
- Awareness-raising of businesses on requirements of the technical regulations

6. Recommended Resources

OECD Best Practice Principles on the Governance of Regulators
https://www.oecd.org/gov/regulatory-policy/governance-regulators.htm

ASEAN Good Regulatory Practice (GRP) Guide
https://asean.org/wp-content/uploads/2017/09/ASEAN-Guidelines-on-Good-Regulatory-Practices2.pdf

European Commission: Better Regulation
https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en

UNECE Recommendation L, An International Model for Technical Harmonisation Based on Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the Use of International Standards
https://digitallibrary.un.org/record/467938

Manual of model procedures and guidance notes for the implementation of the WTO Agreement on Technical Barriers to Trade
https://digitallibrary.un.org/record/600838

New Legislative Framework (formally the "New Approach")
https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

Using and Referencing ISO and IEC Standards to support Public Policy
https://www.iso.org/publication/PUB100358.html

Regulatory Impact Analysis: A Tool for Policy Coherence
https://www.oecd.org/gov/regulatory-policy/ria-tool-for-policy-coherence.htm

Regulatory impact assessments: guidance for government departments
http://www.bis.gov.uk/policies/better-regulation/policy/scrutinising-new-regulations/preparing-impact-assessments

WTO Agreement on Technical Barriers to Trade (WTO/TBT Agreement)
https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

ISO/IEC GUIDE 2:2004 Standardization and related activities — General vocabulary
https://www.iso.org/standard/39976.html

7. Abbreviations and Acronyms

ASEAN	Association of Southeast Asian Nations *(https://www.asean.org/)*
EEA	European Environment Agency *(https://www.eea.europa.eu/)*
EU	European Union *(https://european-union.europa.eu)*
GRP	Good regulatory practice
IEC	International Electrotechnical Commission *(https://www.iec.ch)*
ISO	International Organization for Standardization *(https://www.iso.org)*
ITC	International Trade Centre *(https://www.intracen.org/)*
PTB	Physikalisch-Technische Bundesanstalt (*https://www.ptb.de; https://www.ptb.de/cms/en/)*
RIA	Regulatory impact assessment
TBT	Technical barrier to trade
OECD	Organisation for Economic Co-operation and Development *(https://www.oecd.org)*
ÖNORM	Austrian Standard (*https://www.austrian-standards.at/en)*
RAPEX	Rapid Exchange of Information System *(https://www.ec.europa.eu/safety-gate/#/screen/home)*
WTO	World Trade Organization (*https://www.wto.org*)

Annex: Glossary of Terms

1. Technical regulation

1.1. Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process, or production method.
Source: WTO Agreement on Technical Barriers to Trade, Annex 1.

1.2. Regulation that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice.
NOTE: A technical regulation may be supplemented by technical guidance that outlines some means of compliance with the requirements of the regulation, i. e. deemed-to-satisfy provision.
Source: ISO/IEC Guide 2:2004, Standardization and related activities – General vocabulary.

2. Standard

2.1. Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.
Source: WTO Agreement on Technical Barriers to Trade, Annex 1.

2.2. Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. NOTE: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.
Source: ISO/IEC Guide 2:2004, Standardization and related activities – General vocabulary.

3. Mandatory standard

3.1. Standard the application of which is made compulsory by virtue of a general law or exclusive reference in a regulation.
Source: ISO/IEC Guide 2:2004, Standardization and related activities – General vocabulary.

Note
For the purposes of the WTO Agreement on Technical Barriers to Trade, the category of *mandatory standard* does not exist. Standards are defined as documents of voluntary application. Should the application of a standard be rendered mandatory, the new document will immediately fall into the category of technical regulation, meaning that the authority rendering the standard mandatory will have to ensure that the transparency obligations for technical regulations are fulfilled.

4. Conformity assessment procedure

4.1. Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. EXPLANATORY NOTE: Conformity assessment procedures include, inter alia, procedures for sampling, testing, and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.
Source: WTO Agreement on Technical Barriers to Trade, Annex 1.

5. Regulatory cooperation

5.1. The range of institutional and procedural frameworks within which national governments, sub-national governments, and the wider public can work together to build more integrated systems for rule making and implementation, subject to the constraints of democratic values such as accountability, openness, and sovereignty.
Source: OECD: Regulatory cooperation for an interdependent world – 1994.

Note
Regulatory cooperation can be bilateral such as between Canada and the United States; regional such as among Member States of the European Union; or multilateral such as among signatories to World Trade Organization (WTO) agreements. Regulatory cooperation can also be unilateral, whereby one country acts to bring its regulatory approaches more in line with others, usually major trading partners.

Regulatory cooperation can take place at each stage in the act of regulating: at the early policy development stage; in designing or modifying enabling legislation, regulations, and standards; and, perhaps most importantly, in the regulatory policies, practices, and procedures carried out every day in ongoing compliance and enforcement activities.

6. Co-regulation

6.1. Co-regulation describes the mechanism whereby a legislative act entrusts the achievement of the objectives defined by the legislative authority to other, non-governmental parties which are widely recognized in the field. These parties may include economic operators, social partners, specialized non-governmental organizations and associations (such as standardization bodies).
Source: Authors own definition.

Note
In the European Union, co-regulation is one of the key elements of the New Legislative Framework.

7. Exclusive reference to standards (in legislation)

7.1. Reference to standards that states that the only way to meet the relevant requirements of a technical regulation is to comply with the standard(s) referred to.
Source: ISO/IEC Guide 2:2004, Standardization and related activities – General vocabulary.

Note
By means of exclusive reference, a standard becomes part of the legislation and thus loses its voluntary character.

8. Indicative reference to standards (in legislation)

8.1. Reference to standards that state that one way to meet the relevant requirements of a technical regulation is to comply with the standard(s) referred to.
Source: ISO/IEC Guide 2:2004, Standardization and related activities – General vocabulary.

Note
The use of the indicative reference to standards allows standards to retain their voluntary character. The indicative reference nevertheless constitutes a very strong recommendation to use the referenced standard for compliance purposes.

Indicative reference to standards is one of the main elements of the European Union's New Legislative Framework. Manufacturers using European harmonized standards benefit from a presumption of conformity to legislative requirements – and from simplified and much less costly conformity assessment procedures.

Notes

Imprint

Published by
International Trade Centre
54–56, rue de Montbrillant,
1202 Geneva Switzerland
Phone +41 22 730 0111
Fax +41 22 733 4439
ramful@intracen.org
www.intracen.org/eqm

Physikalisch-Technische Bundesanstalt
Phone +49 531 592-9030
friederike.stein@ptb.de
www.ptb.de/9.3/en

Responsible
Khemraj Ramful, ITC
Dr. Friederike Stein, PTB

Text
Alex Inklaar, Elisabeth Stampfl-Blaha, Elisabeth Sperlich

Title image
© istock

As of July 2009 | Updated edition from November 2023

Contact

Physikalisch-Technische Bundesanstalt
International Cooperation
Dr. Friederike Stein
Phone +49 531 592-9030
Fax +49 531 592-8225
friederike.stein@ptb.de
www.ptb.de/9.3/en