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TECHNICAL REGULATIONS

Recommendations for their elaboration and enforcement

Alex Inklaar

PTB Physikalisch Technische Bundesanstalt
Braunschweig und Berlin

International Trade Centre

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

Physikalisch-Technische Bundesanstalt
Bundesallee 100,
38116 Braunschweig, Germany
Phone: +49 531 592-82 00
Fax: +49 531 592-82 25
E-Mail: dieter.schwohnke@ptb.de
www.ptb.de/q5

Responsible: Shyam K. Gujadhur (ITC)
Dieter Schwohnke (PTB)

Text: Alex Inklaar
E-Mail: alex-inklaar@t-online.de

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Foreword

In any given market, manufacturers and distributors cannot be given a free rein for their products, especially for those that may endanger the health and safety of consumers or damage the environment. Consequently, governments intervene by establishing technical regulations to prevent market failures and protect consumers as well as the environment. However, technical regulations can impede trade if they are improperly elaborated or 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 elaboration of technical regulations in a transparent manner. Technical regulations should, as far as possible, be based on international standards so that in principle the same product could get access to various markets.

Good Regulatory Practice is essential for the elaboration and enforcement of technical regulations. However, the WTO Agreement on TBT does not have specific provisions for Good Regulatory Practice although there have been several discussions on the subject in the TBT Committee at WTO. One of the means to ensure Good Regulatory Practice is through the use of Regulatory Impact Assessments.

Various countries are increasingly using Regulatory Impact Assessments as policy instruments to determine and assess the impact of proposed technical regulations, to ensure that they are necessary, cost effective, and in the best interest of society.

The enforcement of technical regulations should be done in such a manner that their legitimate objectives are fulfilled without putting an unnecessary burden on business. This can be achieved by an effective market surveillance system, combined when required, with pre-market controls. Market surveillance should be organized in such a way that the limited resources are deployed in high-risk areas and there are no direct additional costs to business.

The information contained in this booklet should assist regulators in developing and transition countries to have an improved regulatory process. This should lead to these countries having enhanced trade between themselves as well as with developed countries. Although various documents are available on the elaboration and enforcement of technical regulations, this booklet fills a void by explaining the subject in a simple manner. PTB and ITC hope that it will be useful for policy makers as well as regulators in developing and transition countries in their efforts for improved regulation and enhanced exports.

Shyam K. Gujadhur
Senior Adviser on Standards
and Quality Management,
ITC

Dieter Schwohnke
Head Technical Cooperation Department,
PTB

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Preface

The preparation of technical regulations is a complex, multidisciplinary and delicate task. Inadequate regulations may cause substantial economic, social and even political damage. Not all the required expertise for the elaboration of well-balanced technical regulations can be made available within the competent authorities. Thus, active participation by the potentially affected parties in the elaboration process is imperative. Furthermore, it is highly recommended to use the results of standardization work – by and for the interested parties – for the purposes of technical legislation. Nevertheless, the competent authority should remain in absolute control of the procedure at all times in order to do justice to its mission and responsibility. These and other aspects of the balancing act called "Elaboration of technical regulations" are discussed in the booklet at hand.

In the context of Good Regulatory Practice, however, several important questions must be answered before the preparation of a specific item of technical legislation: Do we really need a regulation? What are the alternatives? And of course the work does not end with the issue of a regulation: How do we organise the implementation and the efficient enforcement of our technical legislation? These and similar issues are addressed as well.

No set of guidelines to technical regulations can ever be complete and the booklet at hand is by no means exhaustive – nor was it meant to be. The aim of this publication is rather to provide food for thought and offer examples,which may trigger the wish to continually improve one's own processes and instruments. We hope it will also contribute to keeping the dialogue and the exchange of experience between PTB, ITC and their partner institutions in the field of technical regulations and standards lively and relevant.

1. Standards and technical regulations from the point of view of users and affected parties

1.1. Standards are recommendations. Interested companies and organisations apply them on a voluntary basis. These standards users decide for themselves which standards are relevant for them and if the benefits are larger than the expected costs of their introduction into the company's or organisation's practice. In the case of high introduction costs (which may for instance result from the purchase of new equipment for production and testing purposes) micro, small and medium-sized companies often decide against the application of standards – if they are capable of making the required investments at all. Obviously, this type of decision against the application of a certain standard will not improve the productivity and competitiveness of a company, but it will not jeopardise its existence either.

1.2. Technical regulations are legally binding prescriptions. They must be applied by all parties, be they big or small, regardless of the introduction costs. This implementation obligation can certainly be a substantial threat to the existence of micro, small and medium-sized companies.

1.3. For the authority issuing the technical regulation this means:

- The possible effects of a technical regulation should be determined and evaluated by means of a Regulatory Impact Assessment - within the realm of possibility of the authority and with a reasonable investment of resources.
- The possibility of exemptions and exceptions for the benefit of severely affected parties should always be examined.
- Adequate transitional periods should be introduced.

1.4. If the interested parties participating in a technical standardization committee so wish and agree, product standards may also include detailed technical solutions with regard to the design and construction of a product. It is the decision of the users of the standard in which cases they want to observe the standard and in which cases they want to use other technical solutions and innovations. All users may make their choice of relevant aspects and solutions out of the total content of the standard.

1.5. If a **technical regulation** prescribes constructive, product-related solutions, this implies a real hindrance to innovation which in turn may cause substantial damage to the competitiveness of the affected companies. The technical regulation must be complied with in its totality.

1.6. For the authority issuing the technical regulation this means:

- Technical regulations should, wherever possible, refrain from the inclusion of requirements concerning the design and construction of a product. Instead, they should contain requirements
- 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 should be included in the regulation.

1.7. Standards, which are badly written, difficult to understand or even misleading (ambiguous) are seldom used. Potential standards users will rarely apply a standard which they cannot read and / or understand.

1.8. Technical regulations, which are difficult to understand or even misleading (ambiguous) must nevertheless be applied and complied with.

1.9. For the authority issuing the technical regulation this means:

Technical regulations need to be carefully edited for

- Clear and simple language
- Unambiguous statements
- Complete statements
- Minimum number of references to other regulations

2. Technical regulations and standards from the point of view of the state and its authorities

2.1. Technical regulations aim to achieve the protection of human beings, animals and the environment against dangers and negative influence of all kinds. Many technical regulations deal with safety at the work place, the protection of consumers against dangerous products and the general health of human beings and animals.
A further possible objective of technical regulations is the regulation of market issues in the case of market failure. If the play of forces between market actors leads to the 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. However, the main focus of technical regulations is definitely on the safety – and not the quality – of products (including foodstuffs and services), plants, installations and constructions of all kinds.

2.2. 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 all the economic actors but by practically all organised groups of civil society as well as the state and its authorities. Standards are agreements between all relevant interest groups, to their own benefit. The establishment of these agreements in technical standardization committees is based on the consensus of all participants.

The subjects of standardization are as varied as the user groups of standards: standardization in the context of recognised standardization bodies follows the needs of the interested parties. The aims and objectives of standardization are manifold, too. And they include the aim of contributing to the safety of the respective subject of standardization. However, it would not be correct to say that this is the main aim of standardization.

2.3. For the authority issuing the technical regulation this means:

- As the aims and objectives which were pursued with a certain standard may be very different from the protection oriented objective of the authority, it is seldom adequate and useful to simply "rename" a standard as a technical regulation.
- The first step towards the elaboration of technical regulations for a certain sector should be to examine the necessity for state intervention – and not to take stock of the already existing 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 objectives pursued by the regulation and the standard.

2.4. The responsibility for the elaboration 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.

2.5. The responsibility for the production and publication of **standards** lies with the recognised standards bodies. The steering councils of these organisations, often private, are – in accordance with international rules and practice – made up of representatives of all the interested parties, including the state.

The standardization process follows internationally agreed and recognised principles such as openness, consensus and transparency.

2.6. For the authority issuing the technical regulation this means:

- There is no doubt that it is possible and useful to delegate certain tasks in connection with the elaboration of technical regulations to Non-Governmental Organisations or "Non-Authorities". A standards body may for instance receive a mandate to prepare standards which will be complementary to technical regulations. Or the authority may decide to integrate existing standards into technical legislation by means of reference to these standards. However, due to the responsibilities mentioned above, it is the chief duty of the authority to remain in absolute control as "master of the procedure" at all times and to refrain from the delegation of legislative competence to unauthorized parties and circles – without constitutional and democratic legitimacy.
- As mentioned above, 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 described and published by organisations such as the Organisation for Economic Co-operation and Development (OECD) under the heading "Good Regulatory Practice" (GRP).

3. Reference to standards in technical regulations

3.1. Why?

The adequate elaboration of technical regulations requires expertise in the most varied fields, which normally is not or not sufficiently available in state authorities. The legislator/ the specialised authority has the possibility to mobilise the required experts and bring them together in technical committees for the preparation of technical regulations. In many cases, however, this would constitute a duplication of the efforts of the national standards body, whose task is to organise and support the collaboration of exactly these experts – in technical committees for standardization. It is certainly much more efficient to take the results of technical standardization committees – the standards – and use them for the purposes of legislation. This use would include the different methods of incorporation – the word-for-word reproduction of a standard or excerpts of a standard in a regulation – and especially of reference to standards.

The method of incorporation embodies a very static form of the use of standards, which has turned out to be impractical in many cases and may even be the source of legal uncertainty. In contrast, the method of reference to standards offers significant advantages:

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

3.2. How?

If the legislator decides to refer to standards for the purpose of technical regulation, he has the choice between the fundamentally different methods of the "exclusive" and the "indicative" reference. In addition, references may be "dated", or "undated". This differentiation becomes particularly relevant in the case of exclusive reference to standards.

3.2.1. Exclusive reference to standards

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

Dated reference

In the case of a dated reference, the technical regulation contains the number, title and date of the referenced standard. As a result of this, only this one 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 "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.

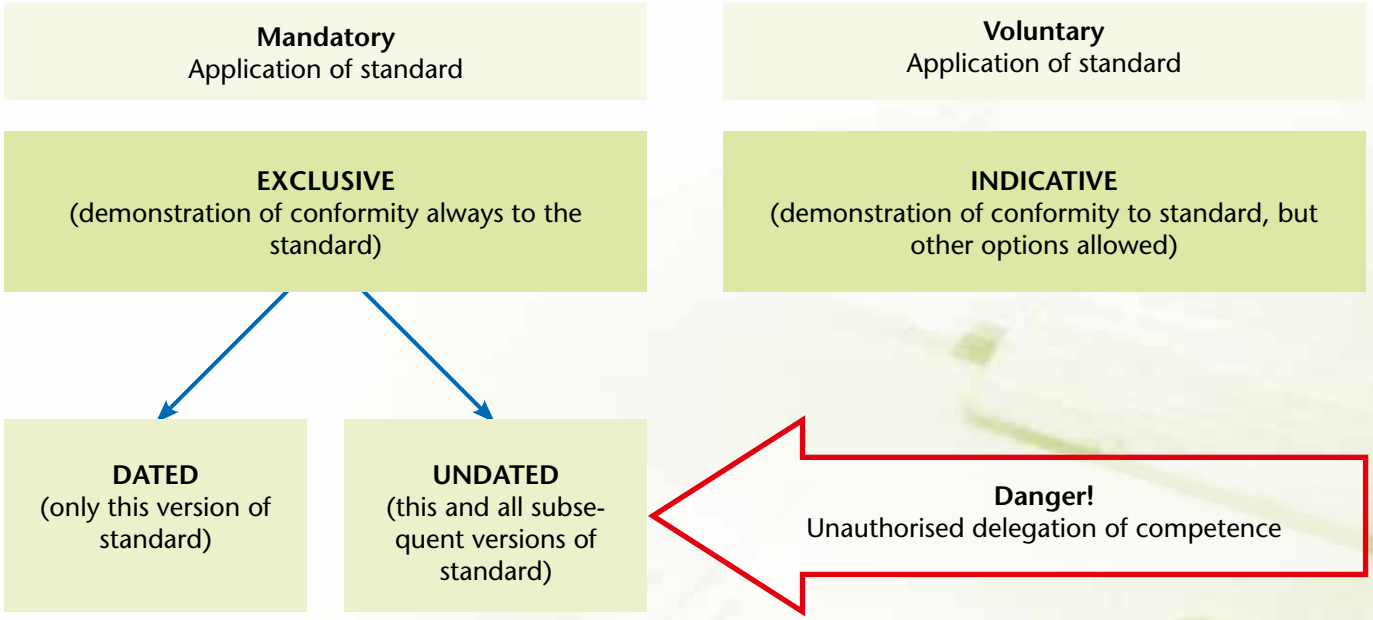
Unfortunately, the disadvantage of the dated reference is just as clear: Every revision of the cited standard in order to adjust it to the state of the art must necessarily result in a revision of the technical regulation as well.

Undated reference

In the case of an undated reference, only the number and title of a standard are given, not the date. The result of this type of reference is that, at any given point in time, it will always be the current version of the standard which is cited to complete the regulation or to demonstrate compliance with the legal requirements. Every update/revision of the standard automatically brings about a revision of the entire regulatory construct (= regulation + standard).

Although the undated reference to standards seems to be a very flexible and efficient method, 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 which may not have the capacity and certainly do not have the authority to carry out legislative tasks.

Direct reference to standards



3.2.2. Indicative reference to standards

In the case of indicative reference, the application of the standard is urgently recommended, but will always 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.

The method of indicative reference to standards is one of the central elements of the European "New Approach" to the harmonisation of technical regulations, standards and conformity assessment procedures. In accordance with this approach, harmonised technical regulations ("New Approach Directives") which are valid for all EU Member States, contain only few "essential requirements", especially with regard to the safety of products and the health of consumers. Technical solutions, which assist manufacturers in complying with the legal requirements, are offered in the form of harmonised European Standards which are referenced – indicatively – in the respective legal texts. Conformity to harmonised standards, whose application remains voluntary, automatically brings about a presumption on the part of the competent authorities of all the member states that the legal requirements are also complied with (The principle of "presumption of conformity").

3.3. Case example: Technical regulations and standards for bicycle helmets in the USA and Germany/Europe

USA

Already in the 1980s accident statistics in the USA provided evidence of the significant health risks inherent to bicycle riding in street traffic, especially for children. The authors of a widely cited study, the results of which were published in 1989, came to the conclusion that bicycle riders wearing helmets had an 85 % reduction in their risk of head injury and an 88 % reduction in their risk of brain damage. Further studies producing very similar results followed in the early nineties.

In 1994 the legislator reacted by issuing the Bicycle Helmet Safety Act. The Act stipulated that, as of March 1995, all bicycle helmets placed on the USA market must comply with one of three existing standards:

- ANSI Z90.4-1984,
- SNELL B-90,
- ASTM F1447- 1993.

Until that moment, the application of these three standards, which – in the very heterogeneous and decentralised American standardization system – had been prepared by different standards-setting organisations, had been voluntary.

The Bicycle Helmet Safety Act, however, declared the standards "interim mandatory standards" and rendered their application – or at least the application of one of the referenced standards – mandatory, for a certain transition phase. During this transition phase the "Consumer Product Safety Commission" was directed to initiate the following measures:

- Review the requirements of the interim standards described above and establish a final standard based on such requirements
- Include in the final standard a provision to protect against the risk of helmets coming off the heads of bicycle riders
- Include in the final standard provisions that address the risk of injury to children
- Include any additional provisions as appropriate

The definitive standard, CPSD 16 CFR Safety Standard for Bicycle Helmets, was published in 1998. Its application is mandatory – due to exclusive reference in the Bicycle Helmet Safety Act.

Germany/European Union

Until 1997 DIN 33954 was the valid German standard for bicycle helmets. The application of this test standard, which was also used for granting the GS Mark for "Tested Safety" ("Geprüfte Sicherheit") was voluntary. The de facto mandatory character of the standard was very high though, due to the requirements of the German market. This DIN standard was based on the analysis of an obsolete manufacturing technology and no longer reflected the state of the art. Consumer protection organisations detected and made public the defects of the standard and, as a result, Bicycle Riders Associations and organizers of bicycle races began to oblige their members and participants to demonstrate that their helmets complied with the requirements of US American standards, which were deemed to be much more stringent and relevant.

In reaction, German helmet manufacturers established a technical committee with the German Institute for Standardization (DIN) with the purpose of developing a new national standard for bicycle helmets. Shortly after this, the European Commission launched the proposal for the elaboration of a European harmonisation Directive (a harmonised European technical regulation) on Personal Protective Equipment (PPE). Bicycle helmets were among the products and types of protective equipment to be regulated by the PPE Directive.

As the PPE Directive was intended to become a technical regulation based on the "New Approach", the regulation itself should only include general safety and health requirements. The detailed specifications and parameters for production and testing purposes were to be included in a harmonised European standard. The German technical committee was now converted into a "mirror committee" to the relevant European standardization committee and German experts collaborated with their colleagues from other member states to jointly produce the European standard EN 1078 "Helmets for bicycle riders and users of skateboards and roller skates". The German version DIN EN 1078 entered into force in 1997.

DIN EN 1078:1997 is a voluntary standard. However:

- The indicative reference to this standard in the European Directive
- The publication of this reference in the Official Journal of the European Communities that the official presumption that a product in conformity with the harmonised standard also fulfils the legal requirements of the Directive
- The simplified conformity assessment procedure for products complying with the harmonised standard

guarantee a very high degree of application of the standard. At the same time, the manufacturer's right to choose alternative means for the demonstration of conformity to the general legal requirements remains unaffected.

4. Guiding questions for the preparation of technical regulations

Questions	Remarks
1. What is the problem? Who identified the problem? Do we already have a detailed description of the problem?	
2. Who is responsible for the solution to this problem? Who should be responsible?	
Start of the Regulatory Impact Analysis	
3. Do we need a technical regulation in order to solve the problem? *How urgent is the problem?* *What type of risks are we talking about?* *Do we have any documented results of a risk analysis?* *Is it necessary to carry out our own risk analysis/to direct somebody to carry out a risk analysis?* *Do we already know the most important actors who can contribute to the solution?* *Do we know the most important affected parties?*	Standards? Other voluntary measures by economic actors? Awareness raising? Education, information? Economic and tax incentives?
Yes, we need a technical regulation	
a. 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 accordance with WTO TBT requirements?
4. Can we already make a decision concerning the adequate elaboration procedure for the technical regulation? *To what degree should the procedure be consensus-based?* *Number and frequency of consultations?* *Should we set up an experts group?* *Who will prepare the draft?*	
5. Is there an International Standard or a national adoption of an International Standard on which we could base the technical regulation? *Any research results available yet?* *Are we collaborating with the national standards body?*	WTO TBT Agreement
a. If yes, is the relevant International Standard suitable for application under our specific national conditions? *Geographical/ geological conditions?* *Climate?* *Technical/ technological feasibility?*	WTO TBT Agreement

Questions	Remarks
b. If no, is there a national standard (not identical or equivalent to an International Standard) on which we could base the technical regulation?	
c. Are there any regional standards or foreign national standards on which we could base the technical regulation?	
6. Are there any foreign technical regulations addressing similar problems?	
7. Would it make sense to use the existing standardization infrastructure for the preparation of a new standard?	
a. Should the new standard be prepared as a (sub)regional or a national standard?	
b. Should the standards organisation preparing the standard receive an official mandate for this task?	
c. Should the standards organisation preparing the standard receive financial support for this task?	
8. In exactly what way do we want to use the standard in combination with the technical regulation?	
a. Incorporation of the standard into the regulation?	Copyright!
b. Reference to the standard? *Exclusive reference?* *Indicative reference?* *Dated reference?* *Undated reference?*	Availability of the standards?
9. If we decide to reference the standard in legislation, how will the responsibilities for the revision of the standard and the review of the technical regulation be allocated and organised?	Need to avoid parallel rules (updated voluntary standard versus obsolete "mandatory standard") Cooperation between authorities and standards body

Questions	Remarks
10. If no adequate standards or regulations are available yet, or in case we doubt the adequacy of the existing standards or regulations, do we see the necessity to carry out own studies, examinations, tests, analyses?	
a. If yes, which authority or (scientific) institution could carry out the required studies?	
b. Should these studies also include product and/ or materials testing?	
c. If yes, which laboratories would be competent to carry out the required tests?	
d. Should these laboratories be internationally accredited?	
Compliance with legal requirements	
11. How do we ensure that the legal requirements are complied with?	
12. Which parties will be affected by the regulation and how exactly will they be affected?	
13. How do we ensure that the legal requirements are sufficiently known to and understood by all the affected parties?	
14. How do we create incentives for the affected parties to comply with the legal requirements?	
15. How do we ensure that the affected parties are capable of compliance?	
16. Does compliance to the regulation confront the affected enterprises with problems of a technical or technological nature?	
a. Do we have a sufficient number of national bodies which can offer the required testing, analysis, inspection and calibration services?	
b. Do we see possibilities to support the affected micro, small and medium-sized enterprises in their compliance efforts by means of education and training activities?	

Questions	Remarks
17. Does compliance to the regulation confront the affected enterprises with problems of a financial nature?	
a. Do we see possibilities for financial support to the affected micro, small and medium-sized enterprises?	
Enforcement of the technical regulation	
18. Which conformity assessment procedure(s) will the regulation foresee?	
19. Which bodies will be authorised to carry out the conformity assessment procedure(s)?	
a. What are the criteria for the authorised bodies?	
b. Who assesses and confirms the competence of the authorised bodies?	
c. What is the role of accreditation?	
20. Will a product marking scheme be introduced?	
21. Are there any explicit arrangements for the recognition of foreign test results and certificates?	
22. Are there any explicit arrangements for market surveillance on the basis of the regulation?	
a. Will there be a clear separation between conformity assessment (pre-market) and market surveillance (post-market) activities?	
b. Have the responsibilities for market surveillance been allocated in a clear and unambiguous manner?	
c. Have we planned and can we mobilise adequate human, technical and financial resources for market surveillance?	

5. Regulatory Impact Assessments

A Regulatory Impact Assessment (RIA) is a policy instrument for the determination and assessment of the impact of a proposed regulation, with regard to its cost, benefit and adverse effects.

Worldwide, a rapidly growing number of countries have introduced the obligation to carry out an RIA for different kinds of regulations – especially for proposed technical regulations.

It is important to note, however, that not every planned and proposed technical regulation automatically requires a complete RIA. Such a complete assessment is a complex and extremely costly exercise, which is time-consuming and requires the deployment of various experts. Thus, the compulsory introduction of a full RIA for every proposed technical regulation would significantly slow down the work of the authorities and its own costs would outweigh the benefits. On the contrary, it is recommended to define and describe different types of RIA, varying in stringency and required investment of resources, to be applied in relation to the expected impact of the proposed regulation.

The consultation of 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.

A useful description of the RIA approach applied in the United Kingdom can be found on the website of the Department for Business Enterprise & Regulatory Reform:
http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44477.html

A full RIA should contain at least the following components:

Purpose and intended effect

Risk analysis

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?*

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?*
- *Identify and, wherever possible, quantify costs to the Government, to the specialised authorities involved in the process, to the economic actors, to consumers.*
- *Also identify indirect costs*

- *Identify and quantify (if possible) costs 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 all decisions related to the contents of the technical regulation have been taken and the corresponding provisions have been formulated, a seemingly minor type of examination should not be forgotten:

Editorial examination:
- *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 recognised and agreed both nationally and internationally?*

6. The enforcement of technical regulations by means of effective market surveillance

6.1. Principles

The elaboration 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 authorities may carry out this task either before (conformity assessment) or after (market surveillance) the products are placed on the market. A combination of the two types of inspection is also possible and – as conformity assessment seldom consists of 100 % product tests – even necessary.

As a general principle, testing laboratories, which are authorised to carry out conformity assessment to certain technical regulations, should not be entrusted with market surveillance tasks in the same field. In order to avoid conflicts of interest, conformity assessment and market surveillance tasks should be clearly separated. If testing laboratories and market surveillance authorities report to the same central authority (e.g. the Ministry of Industry) the different areas of responsibility should be organised in such a way that conflicts of interest need not arise.

The primary objective of market surveillance is the protection of all citizens. Beyond this, it is of great significance to the interests of market players, as an instrument against unfair competition practices. Market surveillance is a state task, and the final 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 should dispose of the necessary resources to carry out their tasks in an effective way: monitor the market, initiate corrective action in the case of non-compliance and enforce 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.

In order to guarantee the quality and reliability of their work, the authorised conformity assessment bodies should preferably fulfil the criteria of the relevant international standards – such as for instance ISO/ IEC 17025 on "General requirements for the competence of calibration and testing laboratories".

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 for instance 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.

It is in the nature of things that resources for market surveillance are extremely scarce. The 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 own 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.

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:

- Conduct regular visits to trading, industrial and warehousing premises;
- Where relevant, conduct regular visits to work places and other industrial premises where technical products, plants and installations are put into use;
- Arrange for random checks and on-site inspections;
- Take product samples and submit them to examinations and tests
- Demand economic actors to submit all necessary product-related information

In 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, in order to determine if a detected non-conformity is of a systematic nature. It is also very useful to monitor relatively high-risk products such as machinery at trade fairs and exhibitions, in order to get a good overview of the market and an early opportunity for preventive educational measures.

In the event of the detection of non-conforming products, the authorities must order and enforce 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.

Experience has shown that pure "market policing" by the surveillance authorities seldom 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.

Market surveillance is an element of consumer protection in the wider sense. Surveillance authorities and consumer protection organisations 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 organisations 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.

6.2 Effective market surveillance: Critical factors

Responsibilities and organisation:
- One centralised authority for all sectors?
- One authority for foodstuffs, one for non-food?
- Decentralised market surveillance by the competent authority issuing the technical regulation?

Legal basis for market surveillance:
- Framework legislation on general product safety in place?
- Determination of powers of market surveillance authorities in place?

Coordination and cooperation between national authorities:
- 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, how is market surveillance organised and coordinated in order 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
  - Cooperation with consumer organisations

Strategy development:
- Elaboration of a unified national market surveillance strategy, which can be communicated to all affected circles
- And which serves as the basis for sector strategies

Financial resources:
- Preparation of specific budget plans for market surveillance by the competent authorities, covering especially:
  - 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:
  - 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 relevant data
- Introduction of simple risk assessment procedures and planning tools
- Harmonisation of all procedures and tools for all authorities involved in market surveillance

Information and education campaigns

7. The interplay of framework legislation, regulations and standards in the field of product safety

7.1. Introduction

The effective protection of all citizens against dangerous and potentially noxious products requires – as a starting point for practical measures – a comprehensive and homogeneous system of legal norms and recommendations. Apart from very general legal requirements which establish a kind of "safety net" with regard to all products that are placed on the market, it is also necessary to have regulations containing more specific requirements, which again may be complemented by standards. The interplay of these elements is illustrated by the example of the European system for and approach to product safety.

Note: The European Directives mentioned in the following section have two different fundamental aspects, or in other words, their rationale is twofold: On the one hand, they are harmonization directives, having the purpose of creating uniform provisions for all Member States of the European Union. On the other, they are product safety regulations, aiming at the establishment of a high level of protection for all citizens of the EU. In the following the focus will be more on the product safety aspect.

7.2. Framework laws

7.2.1. Directive on General Product Safety (2001/95 EC)

The main provisions of the Directive

- Only safe products may be placed on the market.
- The responsibility for product safety lies first of all with the manufacturer. Importers and retailers are next in line.
- The Directive is valid for all products that are not covered by specific regulations/ provisions.
- The Directive also covers second-hand products.
- A product is considered safe if it complies with the specific regulations and legal requirements covering the product.
- If a product is not covered by specific regulations, it will be considered safe if it does not, under normal or reasonably foreseeable conditions, present (taking into account its usual or expected life span) any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection of the health and safety of persons, in line with the documented state of the art.
- In the assessment of the safety of a product the following aspects in particular should be taken into account:
  - the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance;
  - the effect on other products, where it is reasonably foreseeable that it will be used with other products,
  - the presentation of the product, the labelling, any instructions for its use and disposal and any other indication or information provided by the producer and by distributors,
  - the categories of consumers at risk when using the product, in particular children and the elderly,
  - the services directly associated with the product supplied, when these services are provided by the producer, in particular the installation and the maintenance of the product.

- The Directive also describes the tasks of the competent authorities for market surveillance as well as the obligations of market actors (manufacturers, importers, wholesalers and retailers) to support the authorities in the fulfilment of their tasks.

7.2.2. Directive on product liability (85/374 EEC amended by 1999/34 EC)

The main provisions of the Directive

Principle of liability without fault:
The Directive establishes the principle of objective liability or liability without fault of the producer in cases of damage caused by a defective product. If more than one person is liable for the same damage, it is joint liability.

In accordance with the Directive of 1985, producer is taken to mean:
- any participant in the production process;
- the importer of the defective product;
- any person putting his name, trade mark or other distinguishing feature on the product;
- any person supplying a product whose producer cannot be identified.

Burden of proof:
The injured person must prove:
- the actual damage;
- the defect in the product;
- the causal relationship between damage and defect.

As the Directive provides for liability without fault, it is not necessary to prove the negligence or fault of the producer or importer.

Exemption of producers from liability:
The producer is freed from all liability if he proves:
- that he did not put the product into circulation;
- that the defect causing the damage came into being after the product was put into circulation by him;
- that the product was not manufactured for profit-making sale;
- that the product was neither manufactured nor distributed in the course of his business;
- that the defect is due to compliance of the product with mandatory regulations issued by the public authorities;
- that the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered. On this point, the Member States are permitted to take measures by way of derogation;
- in the case of a manufacturer of a component of the final product, that the defect is attributable to the design of the product or to the instructions given by the product manufacturer.

7.3 Specific regulations

Since the late 1980s European Directives on the safety of products are – wherever possible – being issued in accordance with the principles of the European Commission's "New Approach to Technical Harmonisation and Standards".

The main elements of this approach are the following:

a) Each Directive will establish essential safety requirements (or other requirements in the general interest such as health and environmental protection) with which the relevant products that are placed on the market must conform. These essential requirements will be formulated in such manner that they can be enforced by the Member States in a uniform way. Furthermore, they must enable the recognised European standards organisations to prepare standards, compliance with which will allow for complete or partial fulfilment of the legal requirements. And finally, they must enable conformity assessment bodies to also certify products as being in conformity directly, in the absence of standards.

b) Manufacturers are free to choose any adequate technical solution that complies with the essential requirements. Products that conform to harmonised standards, whose reference data have been published in the Official Journal of the European Communities, are also deemed to be in compliance with the corresponding essential requirements. Harmonised standards are prepared by the recognised European standards organisations by mandate of the European Commission.

c) Adequate conformity assessment procedures, taking into account the risks inherent to the product in question, will be determined. These procedures may require the involvement of an independent third party, which will be called a Notified Body. Manufacturers shall have different options for conformity assessment, offered by the applicable Directives.

d) Products falling into the scope of New Approach Directives must generally bear the CE Marking, which will signify that the manufacturer declares his product to be in compliance with all applicable essential requirements of all applicable New Approach Directives and confirms that it has been subjected to the relevant conformity assessment procedures.

e) It is the responsibility of Member States to take all required enforcement measures. This includes efficient market surveillance.

The following table shows a list of current European Directives based on the New Approach:

Directive reference	Subject of directive
90/396/EEC	Appliances burning gaseous fuels
00/9/EC	Cableway installations designed to carry persons
89/106/EEC	Construction products
89/336/EEC	Electromagnetic compatibility
94/9/EC	Equipment and protective systems in potentially explosive atmospheres
93/15/EEC	Explosives for civil uses
95/16/EC	Lifts
73/23/EEC	Low voltage equipment
98/37/EC	Machinery safety
2004/22/EEC	Measuring instruments
90/385/EEC	Medical devices: Active implantable
93/42/EEC	Medical devices: General
98/79/EC	Medical devices: In vitro diagnostic
92/42/EEC	New hot-water boilers fired with liquid or gaseous fluids (efficiency requirements)
90/384/EEC	Non-automatic weighing instruments
94/62/EC	Packaging and packaging waste
89/686/EEC	Personal protective equipment
97/23/EC	Pressure equipment
99/5/EC	Radio and telecommunications terminal equipment
94/25/EC	Recreational craft
87/404/EEC	Simple pressure vessels
88/378/EEC	Toys safety

Source: http://www.newapproach.org/Directives/DirectiveList.asp

7.4. Voluntary (harmonised) standards

As mentioned above, Directives based on the New Approach contain only general – but essential – safety and health requirements. These in most cases do allow for uniform enforcement by the Member States' Authorities, but in practice they offer very few clues and information to assist manufacturers in producing their articles in legal conformity. The technical details and proposed solutions needed for this are contained in harmonised standards which the European Commission requests the recognised European standards organisations to prepare.

The reference data of these harmonised standards – whose application remains voluntary at all times – are published in the EC Official Journal. It is only through this publication that the standards receive their official "presumption" effect: if the product complies with the applicable standards, the authorities are **obliged** to presume that it also fulfils the essential requirements of the relevant Directive(s).

Standardization process in the case of a mandate by the European Commission

EU Commission draws up mandate for preparation of harmonised standards in consultation with affected parties

↓

Commission negotiates mandate with one or more of European Standards Organisations (ESO): CEN, CENELEC or ETSI

↓

ESO accepts mandate

↓

ESO prepares work programme

↓

Technical Committee (TC) prepares draft standard

↓

ESO and National Standards Organisations (NSOs) organise public enquiry

↓

TC examines comments

↓

NSOs vote, ESO ratifies

↓

ESO sends reference data of standard to the Commission, including translated title

↓

Commission publishes reference data in Official Journal

↓

NSOs adopt harmonised European Standard (EN) as national standard

8. Some useful sources of information

Good regulatory practice (GRP)
(Subjects: Regulatory management and reform, regulatory performance)
http://www.oecd.org

(Report and presentations of a WTO Workshop on Good Regulatory Practice, 18-19 March 2008)
http://www.wto.org/english/tratop_e/tbt_e/wkshop_march08_e/wkshop_march08_e.htm

(ITC Export Quality Bulletin – Manual of Model Procedures and Guidance Notes for the Implementation of the WTO Agreement on Technical Barriers to Trade
http://www.intracen.org/eqm/?mn=4

Regulatory Impact Assessments (RIA)
http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44477.html
http://www.berr.gov.uk/files/file44544.pdf

New Approach Directives
http://www.newapproach.org

Standards Systems: A Guide for Canadian Regulators
http://www.canadabusiness.ca/ns/holding.cfm?Code=162630&coll=NS_LIB_COLL_E

Standards and regulations
(Contains a document on "Using and referencing ISO and IEC standards for technical regulations")
http://www.standardsinfo.net/info/livelink/fetch/2000/148478/6301438/standards_regulations.html

Technical regulations, GRP and international standards
(Contains UNECE Recommendation "L" on "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")
http://www.unece.org/trade/wp6/major_doc.htm
http://www.unece.org/trade/ctied/wp6/documents/wp6_02/wp6-02-07e.pdf

9. Abbreviations and acronyms

ANSI	American National Standards Institute
ASTM	Formerly the American Society for Testing and Materials, now under the name ASTM International
CE marking	Compulsory product marking in connection with European harmonisation directives on product safety based on the "New Approach"
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CPSD	Consumer Product Safety Commission (USA)
DIN	German Institute for Standardization
EC	European Community
EEC	European Economic Community
EN	European Standard
ESO	European Standards Organisation
ETSI	European Telecommunications Standards Institute
EU	Europe
GRP	Good Regulatory Practice
GS	"Geprüfte Sicherheit" (Tested Safety) – German safety marking scheme
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
NSO	National Standards Organisation
OECD	Organisation for Economic Co-operation and Development
PPE	Personal Protective Equipment
RIA	Regulatory Impact Assessment
SNELL	SNELL Memorial Foundation: Non-profit Organisation for research and development of standards for helmets
TBT	Technical Barriers to Trade
TC	Technical Committee
UNECE	United Nations Economic Commission for Europe
WTO	World Trade Organisation

Annex: Glossary of terms

1. Technical regulation
2. Standard
3. Mandatory standard
4. Conformity assessment procedure
5. Enforcement of technical regulations
6. Placing on the market and putting into service
7. Administrative cooperation (ADCO)
8. Preparation, adoption and application of technical regulations
9. Regulatory cooperation
10. Good regulatory practice (GRP)
11. Regulatory impact assessment (RIA)
12. Harmonisation
13. Legislative harmonisation
14. Technical harmonisation
15. Harmonised standards
16. Equivalence
17. Transparency
18. Legislative approximation
19. Co-regulation
20. Transposition into national law
21. Principle of mutual recognition
22. Recognition agreement (arrangement)
23. Mutual recognition agreement (MRA)
24. Exclusive reference to standards (in legislation)
25. Indicative reference to standards (in legislation)

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.

3.2. COMPILER'S 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. Enforcement of technical regulations

5.1. The enforcement of technical regulations is part of law enforcement in general. Law enforcement is the activity of ensuring observance of and obedience to the law. Market surveillance is an essential tool for the enforcement of technical regulations. The purpose of market surveillance is to ensure that the applicable provisions of technical regulations are complied with throughout the relevant national or regional market and that all citizens benefit from an equivalent level of protection. Market surveillance typically involves two main stages:

- national surveillance authorities monitor that products placed on the market comply with the provisions of applicable national technical regulations
- subsequently, if necessary, they will take action to establish conformity.

For further information on market surveillance in Europe, see chapter 8 of the "Guide to the implementation of directives based on the New Approach and the Global Approach", European Commission, Brussels: 2000.

6. Placing on the market and putting into service

6.1. These terms are of key importance in the context of the application and enforcement of European harmonization directives (= EU technical regulations). Placing on the market is the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community. Making available can be either for payment or free of charge.

6.2. Putting into service takes place at the moment of first use within the Community by the end user. However, the need to ensure, in the framework of market surveillance, that products are in compliance with the provisions of the directives when being put into service is limited.

7. Administrative cooperation (ADCO)

7.1. Administrative cooperation (ADCO) groups were established by the European Commission with the long-term objective of harmonising market surveillance practices – on the basis of New Approach Directives – in the EU and the European Economic Area. Participation in ADCO meetings is restricted to EU and EEA member states' enforcement authorities. Experts and interested NGOs are, however, invited to take part in selected sessions which are open to the public. Typical ADCO issues include

- the exchange of information about structures, procedures and resources for market surveillance and about the practical application of the EU safeguard procedure with respect to non-conforming products
- results of planned and unplanned market surveillance actions
- bilateral or multilateral market surveillance programmes among Member States.

8. Preparation, adoption and application of technical regulations

8.1. Terms used by the WTO Agreement on Technical Barriers to Trade as in Article 2.2 of the Agreement: "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade."

9. Regulatory cooperation

9.1. 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.

9.2. COMPILER'S REMARKS: Regulatory cooperation can be bilateral as between Canada and the United States, regional as among member states of the European Union, or multilateral 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 important, in the regulatory policies, practices, and procedures carried out every day in ongoing compliance and enforcement activities.

10. Good Regulatory Practice (GRP)

10.1. GRP includes all practices that help governments improve regulatory quality. In the wording of the Organisation for Economic Cooperation and Development (OECD) this involves the reform of regulations that raise unnecessary obstacles to competition, innovation and growth, whilst ensuring that regulations efficiently serve important social objectives.

11. Regulatory Impact Assessment (RIA)

11.1. Policy instrument for the determination and assessment of the impact of a proposed regulation, with regard to its cost, benefit and adverse effects.

12. Harmonisation

12.1. The process and/or results of adjusting differences or inconsistencies to bring significant features into agreement.
Source: US Department of Defense.

12.2. The process by which different states adopt the same laws or standards.
Source: Wikipedia.

12.3. Progressing towards equivalence.
Source: SADCSTAN Southern African Development Community – Cooperation in Standardization.

13. Legislative harmonisation

13.1. Harmonisation of legislation in general, including technical regulations.

13.2. Maximum harmonisation and minimum harmonisation are terms used in European Community Law. Maximum harmonisation used in connection with a European harmonisation directive (or occasionally with an EC regulation) means that national law must not exceed the terms of the European legislation. In practice, this is a measure to prevent "gold-plating" of European legislation by national authorities when transposing it into national law.

Minimum harmonisation indicates that the piece of relevant legislation sets a threshold which national legislation must meet. However, national law may exceed the terms of the legislation if desired. It is quite common for a directive or recommendation to consist of a mixture of maximum harmonisation and minimum harmonisation clauses.

14. Technical harmonisation

14.1. Harmonisation of technical regulations, standards and conformity assessment principles and procedures.

15. Harmonised standards

15.1. Equivalent standards. Standards on the same subject approved by different standardizing bodies, that establish interchangeability of products, processes and services, or mutual understanding of test results or information provided according to these standards.
NOTE: Within this definition, harmonized standards might have differences in presentation and even in substance, e.g. in explanatory notes, guidance on how to fulfil the requirements of the standard, preferences for alternatives and varieties.
Source: ISO/IEC Guide 2:2004 Standardization and related activities – General vocabulary.

15.2. SADCSTAN – the Southern African Development Community's Cooperation in Standardization – defines harmonised standards as equivalent standards (In line with the ISO definition presented above). Standards are said to be equivalent if anything that is acceptable under the terms of one standard is also acceptable under the other and vice-versa. The main steps of the approach towards achieving harmonisation are described as follows:

- Interested members of SADCSTAN work towards an agreed text
- The agreed text is made available to SADCSTAN member bodies
- SADCSTAN members publish this text as national standards, or develop equivalent national standards (from scratch or by amending existing standards)

15.3. In the context of the European Union's New Approach to technical harmonisation, harmonised standards are European standards that are adopted by the European standards organisations (CEN, CENELEC and ETSI) following a mandate (= formal request) by the European Commission. Harmonised standards are directly related to New Approach directives and their contents must match the essential requirements for safety and health of the relevant directive. Their aim is to provide guidance to economic operators in complying with the essential requirements of New Approach directives. Their application is voluntary.

After the approval of harmonised standards by the European standards organisations, the European Commission publishes their references (titles, identification numbers) in the Official Journal. This publication is the formal recognition of the link between a directive and a harmonised standard and, with that, the precondition for the mechanism called "presumption of conformity". Member States must implement the harmonised standard at national level. This is done by adopting the harmonised standard in a national standard – without any changes to the contents of the harmonised standard.

15.4. For the ASEAN member countries, harmonisation of standards falls within the competence of the ASEAN Consultative Committee on Standards and Quality (ACCSQ), which is also tackling the establishment of mutual acceptance arrangements in testing, calibration and certification as well as transparency standardization. With regard to harmonisation of standards ACCSQ aims at aligning national standards with international standards. In the situations where national standards in ASEAN do not exist, efforts will be made to cater for ASEAN harmonisation needs through standards development activities within ISO, IEC or other relevant international standards bodies. Where regulated products are involved, ACCSQ will recommend the establishment of minimum essential requirements such as for health, safety and the environment. Harmonisation of standards is carried out through the Technical Working Group 1 (TWG1) Standards and Technical Information.

15.5 Within the Asia-Pacific Economic Community (APEC) the issue of harmonisation of standards is addressed by the Sub-Committee on Standards and Conformance (SCSC) which assists the Committee on Trade and Investment. In the APEC context, the harmonisation agenda first of all includes encouraging greater alignment of APEC Member Economies' standards with international standards. SCSC's main working areas are:

- Alignment with International Standards and active participation in international standardization
- Adoption of good regulatory practices
- Recognition of conformity assessment procedures
- Cooperation in technical infrastructure development
- Recognition of conformity assessment in the voluntary sector
- Recognition of conformity assessment in the regulated sector (e.g. electrical and electronic equipment)
- Standards education
- Food safety cooperation
- Interaction with business community, SMEs, regulatory authorities and the specialised regional bodies on standards related issues.

16. Equivalence

16.1. In the context of the TBT Agreement, equivalence was introduced by negotiators as a complementary approach to harmonization of technical regulations. It is the WTO's conviction that many unnecessary technical barriers to international trade can be eliminated if Members accept that technical regulations different from their own may fulfil the same policy objectives through different means. This approach is contained in Article 2.7 of the TBT Agreement.

16.2. Equivalent standards (See 15: Harmonised standards).

17. Transparency

17.1. International or regional transparency concerning Technical Barriers to Trade (TBT) is ensured through

- Notification: proactive information on all relevant measures and decisions by member states. The information is submitted to an international or regional information management unit, which distributes it further to all members.
- Provision of information in response to inquiries
- Regular, institutionalised meetings between member states' decision makers ("TBT Committee" at WTO level)

18. Legislative approximation

18.1. "To approximate" means "to bring or come near but not exactly to a thing, especially in quality, number etc." Source: Concise Oxford Dictionary.

Thus, legislative approximation is the discipline which brings the laws of a country or region near to those of another country or region, without striving for full harmonisation. Approximation of technical regulations is a route typically chosen by countries or regions which wish to improve their trade and political relationships with another regional community without the wish or the possibility to become a full member of that community. Legislative approximation is sometimes referred to as unilateral regulatory coordination.

19. Co-regulation

19.1. 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 recognised in the field. These parties may include economic operators, social partners, specialised non-governmental organisations and associations.

19.2. In the European Union, co-regulation is one of the key elements of the New Approach to technical harmonisation.

20. Transposition into national law

20.1. In the context of European legislative harmonisation, the transposition of European directives relating to the internal market is fundamental for the smooth operation of the internal market. The Member States have full responsibility for this. They must, in particular, observe two key conditions when transposing directives: the transposition must be correct and carried out within the time limits laid down by the Directives themselves.

21. Principle of mutual recognition

21.1. In the European Union the first step towards the establishment of the free movement of goods and services consisted in the introduction of the principle of mutual recognition. This principle states that no Member State has the right to forbid the sale on its territory of any product that has been lawfully produced or marketed in another Member State, even if that product has been manufactured according to technical regulations and/or standards different from those applied to its own products.
Member States may not waive this principle except under very strict conditions which Involve "mandatory requirements" of general public importance, mainly public health, protection of consumers or the environment. Mutual recognition covers products which are:

- Produced in other Member States
- In free circulation in the Member States
- Produced in the European Economic Area (EEA) States (Norway, Iceland, Liechtenstein).

Mutual recognition does not cover product sectors which are fully harmonised by EC law and products imported from third countries.

22. Recognition agreement (arrangement)

22.1. Agreement that is based on the acceptance by one party, of conformity assessment results presented by another party. Typical examples include testing agreements, inspection agreements and certification agreements. Recognition agreements can be unilateral, bilateral (mutual recognition) or multilateral. They may be established at national, regional or international levels.
Source: Adapted from EN ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles.

23. Mutual recognition agreement (MRA)

23.1. Bilateral recognition agreement - concerning conformity assessment results – between two conformity assessment bodies, based on reciprocity, involving equal rights and obligations for both parties.

23.2. Mutual Recognition Agreements can also be established between states and/or communities of states that have established a common market. In the context of the European Union's external trade relations, Mutual Recognition Agreements (MRAs) have the objective of promoting trade in goods between the European Union and third countries by facilitating market access. They are bilateral agreements, and aim to benefit industry by providing easier access to conformity assessment procedures. MRAs lay down the conditions under which the EU and the third country concerned will accept test reports, certificates and marks of conformity issued by the conformity assessment bodies (CABs) of the other party to the agreement, in conformity with the legislation of the other party.

MRAs include the finalisation of relevant lists of designated laboratories, inspection bodies and conformity assessment bodies in both the EU and the third country. For further information on MRAs between the EU and third countries see chapter 9 of the "Guide to the implementation of directives based on the New Approach and the Global Approach", European Commission, Brussels: 2000.

24. Exclusive reference to standards (in legislation)

24.1. 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.

24.2. COMPILER'S REMARKS: By means of exclusive reference a standard becomes part of the legislation and thus loses its voluntary character.

25. Indicative reference to standards (in legislation)

25.1. Reference to standards that states 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.

25.2. COMPILER'S REMARKS: 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 referred standard for compliance purposes.

Indicative reference to standards is one of the main elements of the European Union's New Approach to technical harmonisation. (See Harmonised standards) Manufacturers using European harmonised standards benefit from a "presumption of conformity" to legislative requirements – and from simplified and much less costly conformity assessment procedures.

German Development Policy