

# **The Brazilian Guide on Good Regulatory Practices**

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## 1. INTRODUCTION

The regulatory activity and, particularly, technical regulations, have been adopted intensely and become increasingly sophisticated in the past few years. New approaches have been adopted to ensure its transparency, its impact assessment– which a few studies estimate at around 2% to 3% of the Gross Domestic Product (GDP), in Brazil –, and to potentialize its efficacious implementation.

Good regulations, implemented in a flexible, consistent, coherent manner, one that is proportional to the intended legitimate objectives, is an important tool to promote the development and the progress of the society as a whole. In this regard, the adoption of good regulation practices allows benefits on its implementation, so as the Government efficaciousness and efficiency in fulfilling its legitimate objectives. In addition promotes the citizenship, economical progress and minimizing the technical regulation effects on environmental, social and economical field. Therefore, several international bodies have been undertaking studies on good regulatory practices. Besides, multilateral and bilateral agreements have been affecting the way technical regulations are established.

In Brazil, as a signatory country of several of these agreements, the regulatory authorities have their own technical regulation cultures and traditions, which competence to prepare such regulations is established by specific legislation. Therefore, a multiplicity of approaches and manners of establishing the Brazilian technical regulation suggests the need to adopt guidance and recommendations, promoting the aligning and systematizing their development, adoption, and implementation process, consolidating these agencies' experience and incorporate to this activity the recent developments occurred in the domestic and international scenarios.

This is of the utmost importance, considering the global scenario, the economical blocks and external market penetration, which already postulates, inexorably, industrial and foreign trade policies worldwide, the recognition of conformity assessment processes, including the competence certification of services, processes, and personnel involved, whose consecution is supported by the regulation applied to them. Therefore, it is indispensable to consolidate international economic insertion to trade players. In effect, the developed markets do not recognize the quality of a product unless the services, processes, and personnel involved are certified and also comply with prescriptions of conformity to a standard or regulation. Therefore, it is indispensable for the Brazilian industrial and foreign trade development policy that regulations applied to products, services, processes and personnel are align with international practices, facilitating their recognition and acceptance in different markets.

In this regard, the Conmetro – the National Metrology, Standardization, and Industrial Quality Council –, decided to publish the Brazilian Guide on Good Regulatory Practices, which was prepared by the CBR – the Brazilian Regulatory Committee, the Council's advisory body, composed by several central regulatory authorities and other State bodies, in addition to the ABNT – the Brazilian Technical Standards Association.

The Guide, which provides guidance for the process of preparing, adopting, and implementing technical regulations, seeks to potentialize, these benefits:

- a) To facilitate the implementation of international, multilateral, regional and bilateral agreements, considering the Brazilian signatory position, aligning with the international regulatory practices;
- b) To contribute on the promotion of a major integration among Brazilian regulatory authorities;
- c) To contribute to harmonization, consistency and coherence in regulatory practices adopted by Brazilian authorities;
- d) To contribute to improvement and incentive of technical standards adoption in the elaboration process of technical regulations;
- e) To contribute to the international recognition of conformity assessment practices adopted in Brazil; and
- f) To act as an effective instrument for Brazilian industrial and foreign trade polices, promoting the innovation, the social, economical and technological development of Brazil, therefore, facilitating the its international insertion.

Likewise, this Guide's content is expected to offer subsidies to the Brazilian central and local legislation development, particularly with regard to its unfolding into technical regulations.

## 2. SCOPE

This Guide provides advice and recommendations for technical regulation elaboration, adoption, and implementation seeking to contribute to the improvement of the Brazilian regulation practices. It is addressed to Brazilian authorities who are in charge of elaborating, adopting, and implementing technical regulations applied to products, services, goods, processes or personnel.

### NOTES

1. The expression "regulation" or "technical regulation" (view item 3) is used here to designate any and all regulation, observing the global trend, even when a definition established by some other agency indicates its application is limited to a product's technical characteristics.
2. This Guide's Annexes are merely informative in nature.
3. The explanatory or informative notes, when pertinent to this Guide, are written, such as these, with format that differs from the rest of the text.

## 3. TERMS, DEFINITIONS, AND ACRONYMS

There are several definitions for the main terms used in the technical regulation context. Several of these definitions are included in agreements Brazil is a signatory member, such as, for example, the World Trade Organization's Technical Barriers to Trade Agreement, or agreements in the Mercosur sphere,. The concepts associated to these terms have been evolving in time, however, not all definitions that appear in the mentioned agreements have been revised. Therefore, according to consulted source, several definitions may be found for identical terms. With this in mind, only the main definitions required to understand this Guide's content appear herein, and, at no prejudice to their best understanding, it may be complemented with the concepts that appear in the mentioned agreements and in the international guides and standards.

### 3.1 Regulation

The adoption of normative acts through which governmental agencies establish requirements that must be complied with by economical agents and/or citizens (Annex A).

**NOTE:** Normative acts are the laws, decrees, resolutions, ordinances, regulations, normative instructions and other mandatory acts issued by public entities that are competent to publish them.

### 3.2 Technical regulation

The document that enunciates the product characteristics, processes and related methods, including the applicable administrative provisions and the mandatory compliance. It may deal, partially or exclusively, with terminology, symbols and packaging requirements, marking or labeling that apply to a product, service, good, and personnel, process, or production method.

**NOTE:** A technical regulation can be complemented by technical guidelines establishing a few means to achieve conformity with the regulation's requirements, i.e., a prescription that is considered satisfactory to achieve conformity.

### 3.3 Technical standard

Document established by consensus and issued by an recognized agency which provides, for common and repeated use, rules, guidelines or characteristics for products, services, goods, personnel, processes or production methods. Its compliance is not mandatory. It may also deal with terminology, symbols, and packaging, marking or labeling requirements that are applicable to a product.

#### NOTES:

- 1: Technical standards must be based on consolidated results, whether scientific, technological or derived from experience, seeking to optimize the benefits for the society.
- 2: Technical standards related to consumption relationships must meet the hypotheses foreseen by the Consumer Defense Code (Law 8078/90) and the understandings set forth by the National Consumer Defense System.

### 3.4 Conformity Assessment

Any activity aimed at determining the compliance, directly or indirectly, with the pertinent requirements established by technical regulations or standards. .

**NOTE:** Conformity Assessment include, among others, procedures such as: sampling, testing and inspections, evaluations, verification (or checking) and conformity guarantees; registration, accreditation, and approval, as well as their combinations. They also cover the specific

terminologies used in a few segments, such as homologation, model approval, and metrological verification.

### **3.5. Acronyms Used**

ABNT – Brazilian Technical Standards Association

Anvisa – National Health Surveillance Agency

CBR – Brazilian Regulatory Committee

Conmetro – National Council for Metrology, Standardization, and Industrial Quality

EU – European Union

GATS –General Agreement on Trade and Services

GDP – Gross Domestic Product

IPPC – International Plant Protection Convention

ICS – International Classification of Standards

IEC – International Electrotechnical Commission

Inmetro – National Institute for Metrology, Standardization, and Industrial Quality

ISO – International Organization for Standardization

MAPA – Ministry of Agriculture

Mercosur – Southern Common Market

NBR – Brazilian standard

OCDE (or OECD) – Organization for Economic Cooperation and Development

OIE – World Organization for Animal Health

OIML – International Organization of Legal Metrology

RIA – Regulatory Impact Assessment

SBAC – Brazilian Conformity Assessment System

Sinmetro – National System for Metrology, Standardization and Industrial Quality

SPS – Agreement on the Application of Sanitary and Phytosanitary Measures

TBT – Agreement on Technical Barriers to Trade

TRIPS – Agreement on Trade-Related Aspects of Intellectual Property Rights

WTO – World Trade Organization

WTO/DSB - Dispute Settlement Body

## **4. REFERENCES**

The following documents were consulted and possibly used to develop this Guide.

- Conmetro, Resolution No. 02/2005.
- EU. Mandelkern Group on Better Regulation: Final Report. Nov. 2001.
- EU. Impact Assessment Guidelines. SEC(2005)791. Jun. 2005.
- GATS
- GTZ. Guideline for Implementation of a Regulatory Impact Assessment (RIA) Process. Vietnam. Mai. 2005.
- MC. A Guide to Preparing Regulatory Impact Statements. Ministry of Commerce. New Zealand. Mar. 1999.
- OECD. The OECD Reference Checklist for Regulatory Decision-Making. 1995.
- OMB. Circular A-4: Regulatory Analysis. Office of Management and Budget – White House. Washington – DC. Sep. 2003.
- SPS
- UK. Office Cabinet, Better policy making: a guide to regulatory impact assessment
- TBT
- TRIPS

## 5. GENERAL PRINCIPLES ON GOOD REGULATORY PRACTICES

Technical regulations, as regulatory tool (view Annex A) – measure or intervention implemented under Government authority – is compulsory, i.e., it must be complied with by the entire society. To be legitimate, effective and efficacious, it must have a few attributes, as organized in this Guide, pursuant to the principles established by Article 37 of the Brazilian Constitution: “public management, to be excellent, must be Legal, Impartial, Moral, Public, and Efficient.”

### 5.1. Effectiveness

A regulation must have legal, political, economical, and social robustness to be effective, i.e., it must be accepted and applied by the entire society, achieving the objectives that guided its publication. A regulation’s effectiveness is shielded by the following attributes:

5.1.1. Legality – Strict compliance with the law, i.e., no normative act may have its excellence recognized if it isn’t in line with the Law;

5.1.2. Social Impact – Distribution of its effects on the society, keeping economical, social, and environmental aspects in mind;

5.1.3. Adequacy – Consistency with other regulations and policies, particularly those addressed to economical and social development;

5.1.4. Rationality – Requirements based on the available science and technological resources and proportional to the intended objectives, in the strict limits to meet the society’s needs;

5.1.5. Subsidiarity – Evaluation if the best option is a central or local initiative in such a manner the decisions taken attend to the closest level possible to the citizen.

### 5.2. Impersonality

A regulation, not only concerning its mandate, but, also, with regard to the participation in its elaboration, must observe strict equality in treatment in order to not establish a distinction among those who must fulfill it as well as, equally, consider the needs of the society as a whole, observing:

5.2.1. Impartiality – The regulation must be adopted for the collective benefit and interest and the regulatory agency must maintain neutrality in its implementation process.

5.2.2. Clarity and Simplicity – The requisites must be expressed clearly, in a language that is accessible to all of those who must comply with; as simple as possible, with no prejudice to the objectives to be achieved, and detailed strictly as necessary to be well understood.

5.2.3. Fairness – The obligations and sanctions must be treated in such a manner its application is impartial and consistent. Similar situations must be treated equally.

### 5.3. Morality

The regulation must be guided by publicly accepted moral principles, respecting the society’s cravings, the Government commitments, and the bilateral and multilateral agreements signed. In this regard, the regulation must serve legitimate and clearly identified objectives, observing:

5.3.1. Ethical Commitment – Respecting principles of competition, fair trade, and investment facilitation in the domestic and international spheres;

5.3.2. Responsibility – Appropriate consideration must be given to its applicability. The authority in charge of the policy and of the resultant regulations must be identified clearly and be easily accessible by the interested parties. When appropriate, they must review and improve the regulatory prescriptions to solve difficulties encountered in applying them.

5.3.3. International Compatibility – Respect to the Brazilian Government international obligations, particularly in standardizing regulations with the appropriate international references.

**NOTE:** International agreements Brazil has signed have provisions on the obligations and principles to be observed in the regulation process. Particularly, the agreements established in

the multilateral trade system's scope are emphasized, such as the World Trade Organization (WTO) Agreements, such as the Agreement on Technical Barriers to Trade (TBT). The regulatory authority must also observe the international agreements that apply to their field of activity, e.g., the Agreement on the Application of Sanitary and Phytosanitary Measures, and Brazil's adherence to the International Organization of Legal Metrology (OIML). Annex B presents information on this issue.

#### 5.4. Publicity

Wide-ranging divulging of information regarding technical regulations and conformity assessment procedures while in elaboration phase, in such a manner to let stakeholders and the society to follow up all the process onset, including other countries, particularly the TBT's country members, with the following guidelines in mind:

5.4.1. Transparency – Stakeholders participation and consultation must be ensured ever since the initial regulation elaboration phase. This participation and consultation must be organized to allow the widest-ranging participation as well as fair access to the process. The participation rules must be public.

5.4.2. Openness – Intensive availability and accessibility of the regulation to all of those who must fulfill it. Access must be ensured to everyone, particularly for the clarification of those who may face difficulties to get to know and exercise their rights.

#### 5.5. Efficiency and Efficacy

Technical regulations seek to solve problems that have been identified clearly and must be created to achieve the result of the policy in effect, promoting benefits to justify the costs entailed in its adopting.

5.5.1. Proportionality – Reaching objectives efficaciously, with minimum impact on free competition, not imposing more restrictions than necessary;

5.5.2. Need – Certainty it will be the best instrument to reach the intended ends;

5.5.3. Economicity – Minimize the costs involved in adopting and implementing it, whether for those who must comply with or for those who must make sure it is complied with.

5.5.4. Reasonability – Minimize market costs and distortions, with a cost/benefit analysis and risk assessment, considering the alternatives for the regulation;

5.5.5. Flexibility – Encourage innovation via the approach per objective, i.e., statutory prescriptions of the results one hopes to achieve and the expected performance, avoiding making specific technical solutions explicit.

### 6. TECHNICAL REGULATION: STRUCTURE AND CONTENT

Given the diversity in manners and purpose of regulations, it is less practical to establish a standardized structure. However, for simplicity, clarity and easy understanding, this Guide presents a generic structure, below, in distinct chapters that may be followed in most cases.

**6.1. Objective**, describing, briefly and directly, the technical regulation's purpose.

**6.2. Application**, describing to whom, and under what conditions, the technical regulation applies to.

**6.3. Terms & definitions**, establishing the main terms required to understand and to implement the regulation; when necessary, this chapter is used to explain possible acronyms.

**6.4. General, Technical, and Administrative Requirements**, explaining the regulation's prescriptions and mandates and composing the body of the document. It is usually advisable to have the requirements in one or more items to ensure text simplicity, logic, and fluidity. The items are organized per subject or process, or in some other manner, and the prescriptions are established in a clear and objective manner, avoiding overly extensive paragraphs.

The regulatory prescriptions are established observing the recommendations made by several international agreements Brazil is a signatory member and, also, in consonance with the international trends, whenever possible a more generic approach must be used, the so-called performance requirement, one that specifies the intended objective and allows the

stakeholders to determine how to best meet it, instead of limiting this mandate's consecution to restricted means or procedures, the so-called prescriptive requirements, which can inhibit technological innovation and development. In this regard, referring the fulfillment of a prescription to complying with technical standards, optionally, is a good and recommended practice.

**6.5. Conformity Assessment Procedures**, in which the conformity assessment procedures are defined to show compliance with the regulation established.

**NOTE:** This does not involve detailing the procedural standards for a specific testing, rather determining which conformity assessment procedure should be used and, if necessary, establish a specific aspect related to conformity assessment.

The conformity assessment program association to a technical regulation, which is under the power and the option of the authority in charge, is an effective way to provide certainty that the prescriptions it contains are being met. The choice of the conformity assessment procedure to be applied must be made carefully, particularly keeping technical and economical viability studies in mind, i.e., the adoption of a certification mechanism that ensures the highest level of confidence with the lowest possible governmental intervention and at the lowest possible cost for regulators and regulatees. The regulator authority may, if it believes this is the most appropriate measure, request the Inmetro, as the Sinmetro's central executive agency, the decision for the most indicated conformity assessment program to be used for a regulation purpose.

Annex B deals with this issue with a more detailed guiding approach.

**6.6. General & Transitory Provisions** describes other provisions required for perfect regulation application and those that will be adopted in a period of transition until the regulation's full implementation, when this is foreseen.

The deadline for a regulation's full implementation is a critical issue and is related to several factors that influence the actual operationalization of the prescriptions it contains. As such, it must be carefully discussed and agreed to by the several stakeholders involved, whether industrial or commercial, in order to change their processes or flow their stocks; whether it be agencies that will apply the conformity assessment procedures, for possible adjustments to be made to the required technological structure; whether the agencies that will inspect its fulfillment, to qualify the required structure.

### **6.7. Other optional chapters**

**6.7.1. References**, to describe the use of technical standards or other normative references, domestic or international, when they are used as a base for the technical regulation. Annex B deals with conceptual and practical issues involved in using technical standards to prepare technical regulations.

**NOTE:**

International standards are those issued by International Organizations, i.e., those open for all countries to participate in.

**6.7.2. Justification**, presenting the main justifications used to adopt technical regulations.

**NOTE:** The "considerations" preamble, appearing in the normative act that adopts the regulation, when any, renders the "justification" chapter innocuous.

**6.8. Annexes**, for a specific prescription, complementing a regulatory requirement or to provide additional information for the regulation. The initials are mandatory and are used to establish the testing report format, or the testing procedure to evaluate a prescription. Informative Annexes must appear after the mandatory ones. Among the latter may be included a specific Annex to present the bibliography adopted.



## 7. TECHNICAL REGULATION: ELABORATION PHASE

Elaborating a technical regulation must be a systematized process, involving several stages to orientate its best conception. This Guide, which adopts a practice that is widely used in international venues, presents recommendations to develop a technical regulation, accordingly to stages outlined in this chapter. A few stages may be fulfilled in several manners. It will be up to each authority, based on its competence, specificities, traditional procedures, magnitude, on the sensitivity and complexity of the matter to be regulated, to make the choices it believes to be the most convenient and appropriate. Special attention must be given to the *participation of stakeholders and productive sectors involved*, including them in the discussions since the process' initial stages, whether to obtain their effective contribution in elaborating the regulation, to consolidate support, or to its legitimate adoption. In this regard, identifying and seeking participation of specialists and key persons opinions from other governmental agencies and from the academic sector; from corporate and professional associations; consumer, worker and environmental organizations; from finance entities and agencies; as well as from other entities of social interest, is a measure of the utmost importance for the successful adoption of a technical regulation.

It must also be kept in mind that in order to obtain an effective and efficacious regulation, there must be appropriate answers to these questions:

- Has the problem been clearly identified?
- Have all options to solve the problem been taken into account?
- Has the conception and implementation of the technical regulation proposal been considered?
- Has preparing performance-based technical regulations or standards been considered?
- Have international obligations, standards and guidelines been taken into account?
- Have the mechanisms to demonstrate conformity compliance been considered?
- Have measures to review and monitor regulation implementation been considered?
- Have the stakeholders been consulted?
- Is the regulation clear, consistent, wide-ranging and accessible to the users?
- Have the social, economic, environmental and political impacts the regulation causes been taken into account?
- Has it been defined how the products, services, goods, processes or personnel regulated will be followed-up on?
- Has the collection of existing standards been considered? If so, were standards that may serve as a base for the regulation been selected?
- Was a critical analysis of the selected standards been made to decide if it is appropriate to add or remove requisites?

Generically, the following guide is used to prepare a technical regulation:

- Establishment of the goals to achieve;
- Evaluation of the regulation's impact;
- Evaluation of the relationship with existing legislation, including international, multilateral or bilateral agreements the country is a signatory member;
- Basic project to elaborate the regulation;
- Notification, consultation, and public hearings.

### 7.1 Goals

It is important that goals to achieve with the regulation be clearly defined, in such a manner to monitor the process used to elaborate it and to evaluate its implementation's efficacy and efficiency. Therefore, the problem to be solved must be described carefully and precisely to have its nature and magnitude clear and to orientate the proper identification of these goals. To do so, one must try to answer these questions:

- Has the problem been defined correctly?
- Which sectors will be affected by the problem? How?
- What are the core issues and aspects involved in the problem for the public and for the specific stakeholders?
- What caused the problem? What events or behaviors contribute to it?
- Is the Governmental intervention required?

- Is the regulation the Government best alternative?
- Is there a legal base for the regulation?
- What Government level is appropriate for this action?
- Do the regulation's benefits justify its costs?
- Is the regulation's effects and consequences in the society transparent?

The purpose of adopting a regulation must be stated in a simple, direct, objective, and unambiguous manner. It is desirable to quantify at least part of them in order to set efficacy indicators in the implementation stage.

It is important to have the description of the problem and of the goals to be reached with the regulation available for stakeholders, and especially those involved in their elaboration process.

Special attention must be given to involving other Government agencies that may have stakes in or be affected by the technical regulation's proposal with regard to the problem to solve and the goals to achieve.

## **7.2. Regulatory Impact Assessment**

It is recommendable to evaluate the impact the regulation will have on the economical, social, and environmental dimensions to provide the society a good regulation. It is expected from the responsible regulatory authority the confirmation of a critical analysis undertake concerning the impact such a regulation will have and the assurance the positive impacts surpass the negative ones, whether economical, environmental or social, derived from the regulation implementation.

This Guide focuses on studying the technical regulation's impact, i.e., after the decision to regulate has been made. If this study indicates there are disproportionate or unacceptable costs, whether economical, environmental, or social ones, involved, the decision to regulate must be reevaluated under the light of the several regulation alternatives available.

There are several approaches and techniques that can be used to evaluate the regulation's impact, such as the cost/benefit and cost/efficacy analyses, or risk analyses. Annex C has further considerations on evaluating the regulation's impact, while Annex D, presents an example of a risk analysis method.

It must be emphasized that one of the possible Regulation Impact Assessment conclusions may be the recommendation to not regulate based on the analyzed proposal and of conceiving a new technical regulation proposal that will be acceptable from the analysis viewpoint.

## **7.3. Analysis of the relationship between the national legislation and international agreements**

One of the frequent difficulties faced to implement new technical regulations is the possibility of a conflict existence with the legislation in effect. Therefore, since the beginning of the regulation elaboration process, one must undertake a wide-ranging survey of the existing legislation that applies to the matter and to how it can affect implementation and application. This survey must be made on central and local levels and include international, bilateral, or multilateral agreements.

It is also important to clearly identify the instance and most appropriate level of Government intervention to solve the problem and achieve the intended results as to minimize the effects on the market and on the regulatory framework.

Another issue to be addressed is the need to have a clear authority to establish the regulation and possible or potential superimpositions or interferences by regulatory competencies, in addition to measures to eliminate such superimpositions or interferences, under the penalty of compromising its implementation's efficacy. Among the possible measures to eliminate possible superimpositions or interferences are agreements among regulatory authorities, publishing a joint normative act, reviewing the regulatory frame and also the pertinent legislation or of the objective, field of application, and range of the regulation under development.

Many times the application of a regulation involves methods, processes, or measurement instruments which only Conmetro and/or Inmetro are competent to regulate, according to the legislation. In such cases, the regulatory authority must use these entities to adopt prescriptions, when none exist yet, or the appropriate process or measurement instrument to achieve your regulation's prescriptions.

#### 7.4. Basic project of regulation elaboration

It is desirable to systematize a technical regulation's writing and discussion process to give it more consistency and facilitate opportune goals achievement. An organized process includes:

- Elaborating a base text to reflect the regulatory authority's initial intention;
  - ➔ The authority in charge of publishing the regulation's first project, which may include international and national standards and other documents on the issue, hiring specialists, etc. Therefore, the first measure must be surveying the international, regional, and national standards and other normative documents available on the matter, both already published and those that are being prepared for publication and that are the most appropriate for the goals to achieve.
- Structure a workgroup or commission involving the several segments of the society and specialists involved in the matter;
  - ➔ Stakeholders participation, since the beginning of the process, is an essential condition for the proposed regulation's effectiveness. The commission or workgroup must be coordinated by one of the participants, formally assigned for this purpose, who will be in charge of leading the work and of taking care for the several necessary actions to be carried out within the agreed terms;
- Establishing the operating rules for the workgroup or commission, including the deliberations and decision-making process;
  - ➔ It is important to keep records of work development, including minutes or equivalent documents;
  - ➔ The advisory nature of this group or commission must be clear from the onset, and, also, that the regulatory authority always has final responsibility for regulation approval;
- Setting an action plan and meeting timeline to guide work development;
  - ➔ Comments and suggestions made for the base text, analyzing and incorporating, or not, the suggestions, the deliberation meetings, and other actions, must be in compliance with the deadlines the workgroup or commission agrees to.

One of the major challenges faced to elaborate technical regulations is the observation on clear and precise prescriptions and, thus, understandable by the public and economical agents involved. Technical regulations traditionally use, to a certain degree, a legislative language, at times excessively technical and hard to understand. If it is impossible to always use daily language, since it must ensure a specific level of foresee ability and safety, the regulation must be as clear and concise as possible.

A few official documents set guidelines out that help improve technical regulation writing, as follows:

- Complementary Law # 95, dated February 26 1998;
- Complementary Law # 107, dated April 26 2001;
- Decree # 4.176, dated March 28 2002;
- The Presidency of the Republic's Writing Guide.

#### 7.5. Notifications, Consultations, and Hearings

Observing the principles of the good regulatory practice principles, particularly transparency guidelines, ethical commitment, and wide-ranging participation of the stakeholders, involves formal, essential mechanisms, including the fulfillment demonstration of the international agreements commitments, notably the WTO/ TBT.

The most appropriate measure is combined use of several distinct means, maximizing the consultation process' reach and minimizing the corresponding costs. It is fundamental, though, for the regulatory authority to make sure the stakeholders have had a clear and evident opportunity to participate in the process and that the several viewpoints were taken into account and understood.

Three mechanisms, to demonstrate the regulatory authority's pro-active attitude, are usually used:

##### 7.5.1. Notification

Under the terms of the TBT, a country is required to communicate to other signatory members information related to the elaboration of a technical regulation, especially when it may have an impact on international trade or when its prescriptions are not in line with an international standard.

An enquiry point for such Agreement is assigned and established in the member's territory to implement the Notification process. Therefore, every technical regulation or conformity assessment procedure proposal, as well as technical standards planned, shall be notified to WTO/TBT, which will then forward the information to all WTO country members. The enquiry point is also the place to where comments, suggestions and even criticisms shall be addressed on the notified regulation.

NOTE: There may be more than one enquiry point in the Country member, based on the specific activity areas, or by adherence to the distinct international organizations. In Brazil, Inmetro is the TBT's enquiry point, while ANVISA and the MAPA are the enquiry points for the SPS.

A typical notification usually informs:

- The country that present the notification;
- If applicable, the name of the local government involved;
- Agency in charge;
- Name and address (including the telephone and fax numbers, e-mail, and Website, if available) of the agency or authority assigned to deal with the comments on the notification, if different from the above;
- Notification on the agreement's corresponding article;
- Products covered (normally the classification of the product used in the scope of the agreement or in the classification's title is the international tariff classification code. The code, according to the ICS classification, may also be provided, when applicable);
- Notified document title, number of pages, and language;
- Content description;
- Objective and justification, including the nature of the urgent problems, when applicable;
- Pertinent documents;
- Date proposed for adoption;
- Date proposed to entry into force;
- Final date for comments;
- The place where the text is available (whether at the enquiry point or if available at some other organization).

It is recommendable simultaneous communication on the proposal for the stakeholders, whether domestic or foreign. Therefore, the Notification and the National Public Consultation must occur simultaneously.

#### 7.5.2. Public consultation

Public consultation is one of the formal mechanisms used to inform and include the society in the regulatory process, conferring it, therefore, legitimacy that guarantees to the authority the acceptance and applicability of the regulation. It is imperative for the regulatory process' transparency and quality, particularly in a democratic society such as Brazil.

Among other benefits, public consultation allows one to:

- Make the technical regulation elaboration process legitimate;
- Divulge the regulation's idea as early as possible;
- Provide a reasonable period for the affected parties to make the required adjustments;
- Make sure the technical requirements proposed meet the intended objectives and the stakeholders' needs;
- Prevent and identify other consequences and effects, out of the technical regulation scope;
- Ensure the technical regulation' applicability;
- Give the stakeholders an opportunity to manifest themselves and to interfere in the technical regulation's content;
- Improve the technical regulation's content;
- Make sure the new technical regulation is coherent with the legislation in effect;
- Evaluate if the outcome of its application is effective to its greatest possible extent;

- Validate the technical regulation;
- Establish a commitment, among the stakeholders, on the technical regulation;
- Facilitate the implementation process.

The public consultation is processed via a formal act, published in the Official Gazette (DOU), announcing:

- The object of the consultation;
- If it is not provided together with the full text of the proposed regulation, where it can be found;

NOTE: The regulation's full text may be published in the DOU or in an informative act of its placement in public consultation that informs it is available at an Internet site belonging to the authority in charge of publishing it.

- The deadline for comments, suggestions or complaints to be presented;
- How these comments and suggestions are presented;
- How comments and suggestions will be treated; and
- Since there will be a decision-making process with regard to the public consultation, especially information about the hearings, if foreseen.

Comments and suggestions that are received will be identified, whether to ensure the process' transparency or to the recommended interaction with its authors, who get a technical justification regarding the acceptance, or not, of each comments and suggestions received. These formal meetings are normally held in the form of hearings, as the following description.

### 7.5.3. Hearings

One of the ways to collect comments and suggestions is by holding hearings. In this case, one or more formal meetings, that complement the process of receiving comments and suggestions, are held. hearings are commonly announced in advance, using means that allow stakeholders to be aware of them. In the announcement, it is also convenient to briefly inform the purpose of the hearings, its location, date, and the time it will be held, the form(s) of participation and where to get more information on it.

It is a good practice to make an explanatory document available about the regulation to be discussed, including a preliminary impact evaluation, if one has been performed. Likewise, it is important to have a clear explanation on how the hearings will occur and how its outcome will be treated.

Those who sent comments and suggestions must be invited to participate, and be given a chance to present their viewpoints. The invitation must be made in advance in order for interested people be able to participate (at least 15 days in advance).

It is a good practice to make a bulletin available, in advance, presenting a list of the comments or suggestions, their authors, prescription it refers to and a recommendation to be forwarded to the commission or workgroup.

If it is necessary to hold more than one hearing to analyze and discuss the comments and suggestions, it is convenient to clearly inform how the partial results will be consolidated and taken into account.

It is important to give careful consideration to the place where the hearings will be held, or provide remote communication mechanisms to maximize participation and minimize the session's costs.

## **8. TECHNICAL REGULATION ADOPTION**

### **8.1. Approval & publication**

Once the final draft are ready, after the stakeholders' contributions and suggestions are considered, the technical regulation goes on to final approval.

The authority's specific procedure must be followed via the appropriate mechanism (ordinance, normative act, etc.).

It is important, to ensure the process's transparency and that it complies with the commitments taken on internationally, that the regulation, as soon as approved, is published immediately, i.e., that the entire society be made aware of it.

Regulations are normally published in the Official Gazette. However, it may be convenient, to divulge and disseminate it also by publishing in other media, such as, for example, in the regulatory authority's website.

### **8.2. Proceedings in urgent situations**

Urgent situations may occur, and perhaps some stages will not be fulfilled. Situations related to national security, to preventing abusive practices, to protect human or animal health or safety, plant or environment sanity, due to new facts or particular supervening circumstances at times imposing the technical regulation's urgent adoption. In such cases, it may be necessary to abbreviate or simplify stakeholder consultation. Nonetheless, it will be necessary to meet the commitments Brazil has signed.

To adopt technical regulations in urgent situations, the stakeholder consultation term is usually shorter (e.g., to 30 or less days) and the regulation's impact evaluation done in an expeditious manner.

A possibility to be considered is temporary adoption of regulatory measures to control the situation while more detailed studies are done following all stages recommended for the technical regulation. Clearly announcing this strategy will be adopted is a key factor for the initiative's success as to keep those who must fulfill the regulation from getting confused about what they must actually do.

## **9. TECHNICAL REGULATION IMPLEMENTATION**

### **9.1. Preliminary cares**

Once the technical regulation has been approved and published, it is necessary to implement it. The implementation involves adopting a series of measures, planned as early as possible, preferably while the technical regulation is discussed and developed, including:

- Establishing the period for its full implementation;
- The need to divulge the regulation's going into effect;
- The measures to make it accessible to the stakeholders, explain it and fulfill and have it fulfilled, particularly in the case of micro and small companies, to which it is necessary to facilitate access to the regulation and to the resources required to adopt it;
- Adopting the instruments to monitor its fulfillment and to perform a critical analysis of its implementation;
- Preparing inspection mechanisms, including qualifying the authorities in charge of executing it, when the legislation allows and the regulatory authority decides to delegate it; and
- Holding conformity assessment procedures, which may require the development of competent technical structures to hold them (lab, inspection or certification agency accreditation, for example), or possible adoption of transitory procedures, such as assigning specific agencies to perform the conformity assessment procedures until the appropriate technological infrastructure is available.

### **9.2. Implementation period**

A critical issue is the period it takes to implement it, i.e., when it will start being required and, possibly, the establishment of a phase of transition.

When the regulation goes into effect immediately after being published, it is important that the measures required to be fully operational have been planned, developed, and implemented while the regulation was under development.

However, a deadline is often set for the technical regulation to go into effect. In this period, the measures required to implement it, such as qualifying the agencies that will be in charge of inspecting the agencies involved with the required conformity assessment procedures; regulation dissemination among those that must apply it; establishment of the mechanisms needed to divulge and support its adoption; and, when appropriate, due to requirements imposed by international, regional, multilateral or bilateral agreements, adopting an adaptation term.

It is recommendable to plan the implementation term appropriately in order for the needed conditions to in fact be available to avoid or mitigate unnecessary or unintended market impacts, such as, for example, the need to discard non-conforming products stocks. Another conditioning factor to establish the implementation term is the need, by those who must comply with the technical regulation, especially micro and small companies, to make changes to their productive processes or to make other types of adaptations that demand time and resources, including financial ones, to deal with the requirements. The need for the companies to deplete their stocks, in the case of products, must also be kept in mind. It is recommendable to allow shorter adjustment terms to the productive sectors than to the retailers sectors.

Naturally, the term will be a compromise solution between the needs of those who must comply with the regulation and the goals that led to the regulation being adopted avoiding, therefore, implementation date delays that could affect the initiative's credibility and hinder the commitment to the regulation's actual adoption.

### **9.3. Assisted implementation**

Experience has shown that it is appropriate to set actions to promote and facilitate implementation, i.e., "assisted implementation." This is a process that is planned to implement the regulation that includes proactive articulation by the regulatory authority with the stakeholders. Such articulation includes providing divulging measures; covering the several government agencies involved, as well as other actors, particularly corporate entities, foment agencies, and non-governmental organizations with a relevant role in the area.

It would be convenient for the process of divulging the issue to the stakeholders at the earliest stage as possible. In particular, for micro and small companies, it is important to

remember it is not easy to have information reaching them. It is necessary to help them process the information in such a manner to let them be adjusted to the regulation's requirements. It is necessary to keep the micro and small companies from being surprised by the regulation when "inspection knocks on their doors."

Through this process, it is possible to encourage and articulate support actions for regulation implementation by those who must comply with it, with special attention paid to micro and small companies. Support measures and mechanisms may be established to qualify companies and their staffs, technical assistance mechanisms, qualification and capacity building support for the agencies involved in the conformity assessment procedures, consumer sensitization and awareness actions, among others.

The assisted implementation process must also include implementation process monitoring and surveillance measures. Such measures may go as far as covering ad-hoc committee creations, with stakeholder representatives, to follow-up on the process.

It is recommendable to undertake reasonable efforts to divulge the regulation and its implementation process. The public consultation process usually only involves the stakeholders. Thus, once adopted, it is convenient to divulge the new regulation to a wider-ranging target public.

Regulation divulging and availability may be considered a public service. The goal is to reach the biggest possible number of people. Therefore, it is recommended the texts be, when possible, self-explanatory, especially to the segments of the population that is further from accessing the law. The Internet, without ignoring the printed or spoken word, and even other means of communication, may be an appropriate means for this divulging.

It may be convenient to have explanatory texts regarding the regulation and its requirements. Other entities or authors may become involved in developing and divulging the explanatory material on the regulation. This may be the case of corporations or finance agencies. Folders, instruction leaflets, and other means may help divulge the technical regulation.

#### **9.4. Common technological base (the required infrastructure)**

The technical regulation's implementation requires the existence of an appropriate technological infrastructure, both for conformity assessment procedure application and for market surveillance activities and even to provide support and technological assistance to the companies. This technological infrastructure, composed by testing labs, metrological standards, calibration labs, inspection, certification and accreditation agencies, and by inspectors and auditors, whose construction, qualification and maintenance is expensive, both in terms of resources and in terms of time, often face barriers such as personnel with low qualification levels, lack of funds, and, at times, limitations in the decision-making power by those in charge of the implementation.

It is important however, to seek to establish common bases for the technological infrastructure, particularly with regard to adopting, whenever possible, common references and methods in line with international references. Having a common technical and technological base is an important factor for competitiveness and for the quality of the services rendered to the society.

It is recommended the regulatory authorities monitor and systematically critically evaluate adjusting the technological infrastructure that is used and identify possible new needs or improvement opportunities.

In general, there are limited resources available, and since the applicable technical requisites are increasingly demanding and sophisticated, regulatory authorities should carefully examine the need to establish new structures and evaluate the opportunity to use the technological base that is already installed in Brazil. Therefore, for example, it may be more convenient, efficacious, and efficient to use the accreditation services provided by well established agencies with renowned competence, or accredited labs, such as those of the Brazilian Conformity Assessment System (SBAC), instead of putting a new accreditation structure together or of installing a lab for a specific purpose, always respecting the specificities and limitations of the legislation that applies to each case, particularly with regard to the non-transferable nature of the policy's power. The regulatory authority must decide on the best solution from the technical, managerial, and administrative viewpoint, but one must consider the possibility of avoiding double efforts and, also, that the technical regulation has prospective purposes as well and it is an important tool to develop or induce improvements in the Brazilian technological infrastructure.



## 9.5. Inspection

Inspection is an activity that is essential for effective technical regulation implementation. Thus, it must already be considered as of the earliest stage of the regulation's preparation, and it must be appropriately planned.

Generally, inspections aim at determining whether or not the regulation is actually implemented in order to keep products, services, goods, processes or personnel that do not comply with the requisites that have been established from being put in the market or used, something that could put the safety of the citizens and fair competition among manufacturers at risk.

When the legislation allows, the authorities involved in the inspections may not be exactly the same as those that prepared and published the technical regulation. In this case, institutional arrangements among the regulators and those involved in inspection actions must turn the delegation viable, and the delegated agency must be a public entity. Inspection may even be delegated to other entities at some other level of power in the scope of the states or provinces. It is important, particularly in this case, that the regulatory authority prepares and standardize specific procedures to guide inspection execution, as well as, to ensure its efficiency and efficacy, qualifying and licensing inspectors responsible. Annex E shows an advisory approach on inspection and other market surveillance practices.

## 9.6 Market Surveillance Practices

The surveillance actions in the market are predominantly aimed at identifying non-conformities in order to establish improvements, whether in the technical regulation, or in the procedures used to evaluate conformity. These actions are not the inspection activity and must be distinguished from it.

By undertaking surveillance procedures in the market, it is possible to detect non-conformities that may originate from deficiencies in the technical regulation or in the technical standards it refers to, in the metrological standards, in deficient performance of accredited or assigned agencies or labs, in deficient manufacturer performance, among others, or, which is more common, in the quality tools established in the conformity assessment procedure (audits, type testing, sampling, manufacturer quality management system, etc.). The conformity assessment procedure or program manager must then analyze the non-conformities, identify their origin, and set applicable improvement actions.

A regulatory agency is usually in charge of surveillance, in the market, on the products, services, goods, processes, or personnel that are the object of the regulation, but this may also be done, when for the purpose of improving the technical regulation or the conformity assessment procedures as a whole, by other public and private consumer or competition defense entities. Through them, the regulatory authority evaluates the fulfillment of the established regulations.

Market Surveillance is an activity that complements the inspection work and may be expensive and laborious. However, it allows for important results, both to keep non-conforming products, services, goods, processes or personnel from reaching the market and for its greatly important educational role, allowing for an opportunity to evaluate the regulation's implementation efficacy.

When conceiving the regulation's implementation process, it is important to foresee market surveillance, planning this activity, establishing appropriate methods, the responsibility, and the authority of the entities involved.

As with inspection, agencies in charge of market surveillance may not be the regulatory authority. However, such authority must determine who will have this role, an attribution which is usually assigned to the organization that is in charge of managing the conformity assessment process the regulation calls for.

The market surveillance process should make its results available and divulge them in a wide-ranging manner in order for those involved or for those affected by the regulation to be informed.

Annex E has an advisory approach on the inspection and on other market surveillance practices.

## **10. FINAL CONSIDERATIONS**

### **10.1. Stakeholders participation**

Stakeholder participation follows the entire technical regulation preparation process and it is essential and very important, including to build support for its adoption and to ensure its effective implementation.

This participation harmonizes the parts' interests better, as long as focus on the requisites required to reach the technical regulation's goals.

That way, in addition to the stakeholders' participation in the public consultation, one should consider involving them in the entire process of elaborating, adopting, and implementing the regulation.

To do so, the regulatory authority should plan stakeholder involvement as to ensure their participation and undertake all reasonable efforts to achieve it. The regulatory authority must seek to clearly identify them. Stakeholders usually include other government and regulatory agencies, corporate entities, consumer and environmental organizations, worker and social interest organizations, professional associations, finance entities and agencies, key persons opinions, academics, among others. As such, it is convenient to try to identify specialists, corporate representatives, and representatives of relevant groups of society, all of whom should be heard during the elaboration process.

The need for opportunities to undertake separate consultations with representatives from specific interest groups may be identified, depending on the nature of the theme that is object of the regulation. Stakeholder participation planning must reflect both the need for information and to build support for the intended regulation.

It is common to face hurdles with the participation of consumers and other stakeholders, such as environmental or social organizations. Because of the theme to be regulated, it may be recommendable for the regulatory authority to take the initiative of actively facilitating these representatives in the work, including supporting part of such participation's costs.

On the other hand, it may be that a few of the stakeholders' representatives need to check and build positions among their members, demanding the time needed to allow their effective participation. Therefore, the deadlines set forth for comments or to allow stakeholder participation should take this aspect into account.

The means for stakeholder participation may include forming groups, committees or commissions to prepare the text or to supervise the technical regulation's development, to hold meetings with the identified segment's representatives (these meetings' degree of formalism may vary according to the public that is present, to the type of public, and to the use of other means for stakeholder participation), stimulated consultations, and interviews with opinion-formers, among others, as well as the availability of information in Internet pages.

The most appropriate measure is usually combined use of several distinct means, maximizing the consultation process' reach and minimizing the corresponding costs. What is fundamental is that the regulatory authority can make sure the several viewpoints were understood and taken into account and, also, that the stakeholders have had a clear chance to participate in the process, and as early as possible. Likewise, it is important to ensure equal opportunities to the several stakeholders.

In any event, several means of participating in the process should be considered and the regulatory authorities should have a proactive attitude regarding stakeholder consultation and participation, encouraging their participation, seeking to accept suggestions, opinions, and regulation elaboration views.

Communication with stakeholders must be simple and direct in order for the language and the means to not become an obstacle against participation.

Stakeholder participation is a key to the regulation's successful implementation and, since it facilitates their needs being taken into account, it contributes to generalized support for the technical regulation.

### **10.2. Regulation and compilations availability**

One of the difficulties commonly mentioned when one studies technical regulation use and application in Brazil is obtaining them in a quick, unequivocal manner. It is often not possible to immediately identify which regulatory authority is in charge of a given theme and subject. The bigger the regulatory authority's responsibility range, the bigger the complexity and the greater the difficulties.

It is recommendable to have databases with the regulation in effect available, as well as possible previous versions. This compilation focuses on allowing those who must comply with the technical regulation to consult it. It is handy, in addition to having articulation among the several databases, to have simple, direct, immediately and easy access to them.

#### 10.2.1. Facilitating access

It is important to develop practical, simple, accessible and efficacious mechanisms for the stakeholders to get information on the regulation in effect, on the regulation that is being implemented, and on the one that is expected to be reviewed. This allows the transparency required for the regulatory activity to be achieved and potentializes and facilitates regulation adoption by those who must comply with it.

The information on the regulations in effect should be organized per subject or product, in databases available in the regulatory authority's website, and access to these databases take place without the need to cover an excessive number of steps. Access to databases must be as friendly as possible and must not require specialized knowledge, whether regarding computer use or about the regulation's theme.

It may be efficacious to attribute codes or other references similar to regulations for control purposes. These codes should be as simple as possible and their use intensively disseminated to avoid more confusion derived from the multiple use of several codes.

The easiest possible access to the compilations and databases of the regulations in effect is a decisive factor for successful regulation implementation.

#### 10.2.2. Control and compilation

With the proper identification and use of technical regulations in mind, it is suggested, especially in the stages used to identify the regulation and its possible versions, that the control of these versions, including the differences among them, and their registration and availability, be clearly described in the technical regulation.

The compilation of the regulation in effect, i.e., its collection and organization, must be available in several media, such as in the regulatory authority website in the Internet, on hardcopy, and in other electronic media. When making the regulation's compilations, it is important to be careful in order to be updated and complete, since the users will normally use them as references to survey the regulations in effect.

One of the advantages of the compilations is that they bring together the technical regulations themselves in a single place, in addition to the other complementary legal acts and possible changes, corrections, etc.

The regulatory authorities must control the technical regulations in effect in order to be easy and simple to identify, obtain, get to know and implement the regulation, especially by those who must comply with it.

Likewise, other information required for regulation implementation, such as other applicable technical regulations, the list of accredited competent labs to undertake testing that may be required, the agencies involved with the conformity assessment procedures foreseen in the regulation, or other technical information, must be available in a simple, easy manner.

### **10.3. Critical analysis**

It is imperative the technical regulation be analyzed critically, to ensure its efficacy, that its objectives are met, and to prevent market distortions or unforeseen or unintended effects.

Actions should be developed to identify the required and pertinent information. Sources for this information could include manifestations made by the users, consumers or by the regulated sector, impact result analyses after the implementation, market surveillance results, and inspection activity information.

## Annex A

**LEGISLATION X REGULATION X STANDARDIZATION****A.1. Technical regulation as part of the regulatory activity**

Regulation can be described as a measure or intervention implemented under the State's authority, the purpose of which is to discipline the behavior of the intervenient agents that are covered by such authority. Regulations include legislation and other instruments applied by authorities with legal competency for this.

Regulations are an important tool to preserve and encourage the public's interest in complying with the State's legitimate objectives, which are related to aspects involving health, safety, fair competition, and consumer, asset, and environmental protection, among others.

Regulations are, therefore, an intervention of the State in the way the society or the economy operates and they are needed when the lack of intervention may result in loss or damage or might compromise the reach of legitimate goals. Therefore, regulations have a defined goal, which is a problem to avoid or correct.

To achieve the intended objective, the State can employ several actions, among which setting technical regulations. Others are, for example, contractual policy encouragement and accountability mechanisms, mutual acknowledgement agreements or mechanisms, or undertaking educational campaigns.

The nature of the problem to be solved or avoided and the magnitude of the economic, political, and social impacts derived from applying each of the options, condition the strategy and, consequently, the instrument (or set of instruments) to be adopted. Therefore, the authorities should evaluate the alternatives they have in advance to check whether the technical regulation is in fact the most indicated instrument to solve or prevent the problem.

Another aspect to be considered is the regulation initiative that may come from the legislative, from the judiciary and even from the popular initiative.

Technical regulations are mandatory documents issued by an authority that has a mandate to do so. They establish requisites for products, services, goods, processes, personal competencies or their results. They may include prescriptions on the production methods and processes, provision or rendering or even aspects related to products, services, processes, goods or personal competencies, such as terminology, labeling, procedures to check or demonstrate conformity, etc.

For their very nature, technical regulations have direct impact on the types of products, services, goods, and processes that can be provided in a given market.

Technical regulations may be the only efficacious way to reach the intended objectives. This is particularly true when significant risks to the health, safety, and to the environment are at stake. Thus, a well-conceived and updated technical regulation can become a powerful instrument to reach economic and social well being, without compromising innovation and creating unnecessary obstacles to trade, to attract investments, and to economic efficiency. As such, technical regulations must not be more restrictive than necessary to achieve the intended objectives and they must undertake all efforts for it to be efficient and efficacious while achieving these objectives.

**A.2. Technical regulation and technical standardization**

Technical regulations can establish, in detail, the technical characteristics required for the products, testing methods and other technical requisites needed to apply the regulation or resort to technical standards for that purpose.

The regulator agency must decide whether or not to use technical standards.

When considering whether or not to use technical standards as one of the bases for the regulation, it is important to undertake a critical analysis of its content in order to make sure it has appropriate solutions to meet the technical regulation's purposes.

Because of the circumstances of the problem one hopes to solve with the regulation, the requisites set by the technical standards may not be the most appropriate ones, whether because they are technologically outdated or for other reasons, such as differences resulting from geological or weather characteristics, or even other ones. In this case, the regulator agency may have to prepare an adjustment document ("tailoring") for an existing standard or develop the technical requisites itself.

It must also be added that technical regulations may use one or more technical standards as a base for their requisites, or part of them, and establish other ones directly that are not

covered by the technical standards or that for other reasons recommend they be established.

It is also important to note, since standards and technical regulations are made with common technical and scientific bases, it is possible a few requisites in both documents match, and this does not mean any reference is made to the standard or that the standardization agency's author's rights are breached.

When using technical standards as a base for technical regulations, this should be done in the simplest possible manner to avoid confusion and technological outdatedness, considering the technical standards are subject to periodical reviews.

By and large, technical standards are not free and must be purchased by the users. This can hinder their use in the technical regulation. Several measures have been made to overcome this difficulty, one of which is the regulatory authority making an agreement with the standardization agency that holds the rights for the standard to make it available free of charge.

Due to the authority's responsibilities with regard to the object of the regulation, there is the concern to make sure the established technical requirements are appropriate to make sure the results intended by the technical regulation are achieved.

Considering the regulator agencies have no control over the standardization process, the requisites the standards establish may not be appropriate for the technical regulation. This is one of the reasons why it is important for the regulatory authority to become actively involved in the process of elaborating and maintaining these standards. Note that the regulatory authorities' involvement in the standardization process is recommendable when the standards are used as one of the ways to provide the technical base to meet the technical regulation. The authority can always make it clear that if the technical standard does not meet its needs, it will not use it as one of the bases for the technical regulation. Similarly, even if it does not participate actively, it is highly recommendable the regulatory authority follow-up on standard development.

#### **A.2.1. International, regional, national and foreign technical standards**

As mentioned, the recommendation technical regulations use the international guidelines and standards as reference is in international, regional, multilateral or bilateral agreements Brazil is a signatory country.

However, for several reasons, it may not be appropriate to use them as reference. In this case, it is also possible to use technical standards as one of the bases for the regulations, using regional or national standards (foreign standards and the NBR standards, published by the ABNT), or even technical standards developed by associations.

The order of preference for technical standard use in the regulation, if international standards are not followed, is to prioritize regional standard use (belonging to agencies Brazil is part of), followed by Brazilian Standards, foreign standards and, finally, standards belonging to foreign associations. It is clear that, when selecting the technical standards to use, it is fundamental to make sure the selected standards provide the appropriate technical base considered necessary by the regulatory authority.

The Brazilian Standards are published by the ABNT (Brazilian Technical Standards Association), which is the National Standardization Body, formally acknowledged as such by the State via Conmetro Resolution 07/1992.

Technical standards elaborated with stakeholders participation are also submitted to critical analyses and reviewed periodically. The revision (or confirmation) of the Brazilian Standards is a systematic process that may be requested whenever this is considered necessary.

Whenever possible, it is recommended international standards be adopted as the national ones. The ABNT is in charge of this initiative, but it is recommendable regulatory authorities contribute to and support the decision to adopt them. In particular, when a technical regulation is supported to some extent by international or regional technical standards, these standards should be adopted as Brazilian Standards in order for their content to be readily accessible by users in Brazil. To achieve this, the regulatory authority should articulate such adoption with the ABNT. However, there may be situations, resulting from specific technical issues, in which national standards differ from the international or regional ones.

Sometimes, foreign standards, or even standards developed by technical associations from other countries, may meet the regulatory authority's needs and be used to support a technical regulation. However, one should be aware of the fact that the capacity to participate in, and, thus, interfere with the foreign standards' content is rather limited or even inexistent. Therefore, one should carefully consider the decision to refer to foreign

standards in the technical regulation. A possible solution is using them transitorily until one can count on equivalent Brazilian Standards.

### **A.3 On the Country's international commitments**

Several international, regional, multilateral and bilateral agreements Brazil is a signatory of may affect technical regulation activities, since they include provisions about the obligations and principles to be observed in such activities.

Technical regulation adoption must not hinder the terms of the agreements, under the penalty of their being questioned by the other signatories members and even of making the Country susceptible to questioning in the pertinent international venues such as, for example, the WTO's Dispute Settlement Body (DSB).

In particular, emphasis is placed on the agreements established in the ambit of the multilateral trade system, such as the WTO's Agreement on Technical Barriers to Trade (TBT), and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which have direct impact on the technical regulation.

#### **A.3.1. On the TBT Agreement (Agreement Technical Barriers to Trade)**

This is a multilateral agreement in the ambit of the WTO. It is aimed at making sure technical regulations, technical standards and conformity assessment procedures do not become unnecessary barriers to international trade while acknowledging the Country Members right to set regulatory measures to achieve their legitimate goals.

The TBT applies to good trade, i.e., industrial or agricultural goods as well as to the processes related to them, excluding the aspects that regard sanitary and phytosanitary measures, which are the object of a specific agreement.

Three principles are the reference for the TBT's provisions with regard to technical regulations:

- Non-discrimination, based on which the treatment given to goods originating in another WTO's Country Member must not be less favorable than that given to goods produced locally or in any other country;
- Not create unnecessary barriers to international trade and, thus, technical regulations must not be prepared, adopted or applied aiming at becoming such unnecessary barriers to international trade;
- Harmonization, described as the adoption, by several countries, of common regulations and standards for the same issues.

##### **A.3.1.1. Technical regulations and the TBT**

The several agreement provisions result from this set of principles, Particularly, with regard to the technical regulation (as appearing in article 2 of the agreement):

- Technical regulations must not be prepared, adopted or applied aiming at becoming unnecessary barriers to international trade;
- Among others, defending national security, preventing abusive practices, protecting human and animal health, plant sanity or protecting the environment are considered legitimate technical regulation objectives;
- Technical regulations must not be maintained if the conditions that gave rise to them no longer exist;
- Technical regulations must not be more restrictive than necessary to fulfill the legitimate objectives, considering the risks not complying with them would bring about;
- When it is necessary to establish technical regulations and there are pertinent international standard (or their issuing is imminent), members must use them, as a whole or in pertinent parts, as a base for these technical regulations, except when adopting them is inefficacious or inappropriate such as, for example, due to climatic, geographical or technological factors;
- A member must justify the preparation, adoption or application of technical regulations that have significant impact on trade with other members, when this is requested by any of the members;
- When appropriate, members must specify the technical regulations based on performance requisites instead of on the product's descriptive or design characteristics;
- When a technical regulation is in agreement with the pertinent international standards, it must be presumed it does not create an unnecessary barrier to international trade.

#### A.3.1.2. Transparency and the notification mechanism

One of the key points for an agreement of this sort to work is the need for transparency while its members adopt and implement the technical regulation. To ensure this, the agreement sets forth a few measures related to divulging and to the possibility of advanced knowledge regarding the intention to establish technical regulations, as well as to the possibility of offering comments on technical regulations under preparation.

The notification mechanism seeks to ensure transparency in agreement application and in the regulation process itself by its members. Thus, each member country sets an enquiry point, which is an organization that is in charge of being the communication channel with the WTO and the other WTO Country Members on the technical regulations that have been adopted or that are being adopted by the country, and to forward comments submitted to the technical regulation proposals in the other countries. In Brazil, Inmetro is the enquiry point for the TBT.

Through the notification mechanism, each time a country intends to adopt a technical regulation that differs from the international technical standards and that might affect international trade, such country must formally notify the other WTO Country Members of its intentions. This must be done in advance in order for other Country Members are able to manifest themselves and offer comments that must be considered and which must be answered appropriately.

#### **A.3.2. On the SPS Agreement (Sanitary and Phytosanitary Measures)**

With its central focus on sanitary and phytosanitary measures, the SPS Agreement, similarly to the TBT, sets prescriptions to make sure such measures do not become obstacles to international trade development, among which:

- The need to use methods that define the desired protection level based, whenever possible, on a risk analysis based on scientific evidence;
- Use of pertinent international technical standards, guidelines or recommendations, issued by the World Organization for Animal Health (OIE) Codex Alimentarius or in the International Phytosanitary Protection Convention (IPPC), when they exist, as a base to adopt the sanitary and phytosanitary measures;
- Encourage harmonization and equivalency of these measures; and
- Make it mandatory to notify the technical regulation initiatives whenever there are no pertinent standards, guidelines or international recommendations arising from the OIE's Codex Alimentarius or from the IPPC, or if the content of a sanitary regulation proposal is not substantially the same as the pertinent international standards, guidelines or recommendations arising from these organizations, and if the regulation has a substantial effect on trade with other WTO members.

## Annex B

### Choosing the Appropriate Regulatory Response

#### B.1. Conformity Assessment Procedure

The expression Conformity Assessment is used generically here to encompass all certification processes, according to a technical regulation, a product, process or service, whether, for example, a product's homologation by the health or agriculture area's authority, or legal control of measurement instruments by the legal metrology authority.

There is no doubt the association with a conformity assessment procedure is the most effective way to fulfill a regulation, i.e., to provide an appropriate level of confidence that the regulation's requisites are being met. Another factor to be considered is that the requirement to place visual conformity identification on the regulated product greatly facilitates inspection, since if one does not exist this may mean the product is on the market irregularly.

When the regulation is associated to a conformity assessment procedure whose assessment bodies are accredited by Inmetro, the regulatory authority must define whether it wants to assign or accredit such bodies to follow-up on and evaluate their performances, including the possibility for penalty impositions. In this case, an appropriate legal instrument must be established.

The regulatory authority can also require products be registered as a condition to be marketed. Such registration may be an outcome of a regulation requirement or perhaps of a decision made by the authority to guide the regulation's application better or to improve the inspection or surveillance and supervision of products that are on the market. The demand for registration may include requiring the product's conformity with the technical regulation be demonstrated previously via a conformity assessment procedure. On the other hand, the regulatory authority may supervise registration maintenance via inspection actions that may include conformity assessment procedures.

#### B.2. The choice of Conformity Assessment Procedures

The SBAC, Brazilian Conformity Assessment System, uses, in isolation or combined, several mechanisms to check and attest to a product or service's conformity to the prescriptions of a standard or of a technical regulation. The main ones are: *certification, manufacturer declaration, inspection, labeling, and testing*. Choosing one of them, or an appropriate combination of them, takes legal, technical, social, political, and economic and financial aspects into account.

The central idea is to adopt the conformity assessment procedure that ensures the highest degree of conformity with the least possible amount of government intervention and with the lowest costs for regulators and regulatees.

Although the manufacturer's statement is nearly always the least expensive conformity attestation mechanism, particularly for the regulated sector, it is not always recommended it be adopted, especially when a high degree of safety is required that only products in conformity be available in the market. On the other hand, its use may be indicated when the presence of a non-conforming product is not grave and the costs associated to other alternatives are disproportionately high.

In this regard, the cost/benefit and risk analyses are indispensable tools to guide the applicable choice of conformity assessment procedures.

By and large, the following issues may influence the choice:

- Lowest possible cost for an appropriate degree of confidence and compatibility with the problem the technical regulation will solve;
- Product characteristics, and background, if any, of production failure frequency;
- Risk associated to a possible consumption accident;
- Level of confidence in the procedure that is used relative to the risk involved in having a non-conforming product in the market;

NOTE: When increasing the degree of confidence in product conformity, the conformity assessment procedure's costs also increase. This increase in confidence grows to a certain point at which the increase in confidence is small compared to the corresponding cost rise.

- Technical and laboratorial infrastructure to undertake possible prescribed testing;
- The sector's technological improvement rate;
- Impact on the product's competitiveness;



- Follow-up difficulties in the market;
- Compatibility with international references and practices to facilitate its acknowledgement by other markets;

### **B.3. Other aspects to consider**

In addition to the care taken in the conformity assessment procedure selection, it may be desirable for the manufacturers to also have appropriate management systems to ensure the supply of products or services that comply with the technical regulation. Note, however, that certified management systems, although necessary, are not, in and of themselves, sufficient to ensure the confidence that the product or service is in conformance with the technical regulation.

It is also important to keep the impact conformity assessment procedure requirements have on small and midsize companies and on their employees. In this particular case, with regard to the possible demands for certifications of the competency of the people involved in providing a product or service.

It is also important to make sure equal treatment is given to domestic and foreign products, without discrimination, observing the applicable international agreements.

Using the technological infrastructure available in Brazil to provide confidence to the conformity assessment procedures should be considered, such as that allowed by Sinmetro, in order to avoid effort redundancy and expensive investments.

Confidence in all conformity assessment process links is a critical factor for the technical regulation implementation's efficacy, and this confidence is allowed by a series of elements that are related to the technical competency, credibility, and efficacy of the adopted solutions. Thus, it is recommendable the conformity assessment procedures the regulation calls for are those that are strictly necessary to ensure compliance with the technical regulation.

When it is necessary to foresee more than one conformity assessment procedure in the technical regulation, to deal with the different possibilities in product or service provision (e.g., to foresee possible imported product shipment or lot inspections), the degree of freedom of choice among the recommended procedures should be clearly indicated and one must make sure the alternatives that are considered result in a same degree of confidence for the products or services, in order for them to not inadvertently create discriminatory conditions.

On the other hand, it is often necessary for the conformity assessment procedures the technical regulation calls for to be described in more detail in other complementary documents. These documents are usually developed within the established conformity assessment program to prove compliance with the referred regulation.

## Annex C

**IMPACT ASSESSMENT: CONSIDERATIONS AND EXAMPLES****C.1 The Importance of Regulatory Impact Assessment**

In recent years, mechanisms have been developed and disseminated to assess technical regulation impacts. These mechanisms, generically called Regulatory Impact Assessment (RIA), are aimed at providing information to the regulatory authorities to allow them to foresee the consequences of implementing the technical regulation and support the decision-making process from its conception to its adoption. As such, Regulatory Impact Assessment is a fundamental tool to elaborate good technical regulations that meet the intended objectives with the least possible impact.

Technical regulation impact assessment is a process that, as such, follows-up on the regulation's entire elaboration, from the decision to elaborate it through its formal adoption, concentrating on the probable impacts derived from adopting a change to the practiced policies and on the set of possibilities to implement the change. The RIA is typically developed in several stages:

- An initial RIA is prepared when a regulation proposal first considered, in order to decide on proceeding to proposal elaboration;
- A partial RIA is prepared immediately before the formal stakeholder consultation procedure on the regulation proposal. It is highly recommendable for the RIA to be made available and included in the documentation in an analysis on the regulation's proposal, i.e., that the RIA be available with the proposal's text;
- A complete RIA, made at the end of the regulation elaboration process that will include a more detailed analysis and that reflects the stakeholder consultation process results regarding the regulation's proposal.

The RIA is an important instrument to ensure the process of adopting a regulation is transparent, as it allows all those involved to have information on the consequences that are expected from adopting the regulation in an informed, conscientious manner.

**C.2 Typical Regulatory Impact Assessment Content**

Typical content in a RIA includes:

- Introduction
- Purpose and nature of the regulatory change proposal
- Consultation process
- Analysis and review of the options to solve the problem
- Benefits and costs of the proposed change
- Conformity, implementation, and monitoring
- Summary and recommendations

**C.3 Questions to be considered in the Regulatory Impact Assessment**

The following is an example list of the issues to be covered in a RIA:

- Nature of the problem (what is the problem that is being approached?);
- The regulation's foreseeable effects (can one expect the regulation to have results that are better than the market's action? Or may it have worse results?);
- Alternative solutions (what are the alternative approaches to deal with the problem, including non-regulatory actions?);
- Regulation benefits (What are the likely benefits brought-on by the proposed options? Which groups will benefit from them? How may the benefits be shared by the several stakeholders?);
- Regulation costs (what are the likely costs of the proposed options? Which groups will bear these costs? Who may these costs be shared among the several stakeholders?);
- Stakeholder consultation (what are the public and the stakeholders' views and perceptions on the proposed options?);
- Support to the regulation (what support can be identified among the stakeholders for the proposed options?);
- Impact on competition (what are the likely impacts on competition?).

Getting the appropriate answer to these issues is no easy task. However, there is increasing use of the RIA by the regulatory authorities because this tool makes an effective contribution to the implementation of a good regulation. When well conducted, a RIA provides valuable information to the decision, including with regard to considering and assessing the proposed regulation's global impact; to its consistency with the public policies and other regulatory instruments used by other authorities; to the benefits and costs of implementing the regulation; to identifying unintended impacts that affect groups that had not been considered; the determination regarding whether specific groups may be disproportionately affected, among others.

The RIA must also, in and of itself, count on a wide-ranging stakeholder consultation process throughout its development, a key part to assess the regulation's impact and the quality of its results. It must, therefore, be planned and implemented appropriately to ensure its coverage and efficacy.

Often times, the results, negative or positive, or adopting one of the technical regulation options are not distributed uniformly among the stakeholders. Therefore, it is important for the analysis of these options to cover sectors and groups that are affected by each alternative based on such positive and negative impacts. It must be kept in mind that it is unlikely one will achieve, in most cases, 100% conformity with regard to the technical regulation. It might also be worthwhile to measure the cost/benefit of additional efforts to increase conformity with the established requisites.

At times, it will not be possible to present the options' costs and effects in monetary terms, and it would be good to detail the data that are available and their relevance on the regulation's potential impacts.

One of the main difficulties faced while undertaking these analyses is data availability and reliability. The required data and information are determined by the nature of the problem, by the approach that was used and by the available resources to undertake the Regulatory Impact Assessment. The quality of the data must be a constant concern throughout the assessment. During the stakeholder consultation phase, new data may be collected and the quality of the existing data checked. The person in charge of preparing the technical regulation's impact assessment must be attentive to the need to have appropriate data and to obtain such data. When the information or the data (or the results of an analysis) are not as precise as required, it is preferable to mention the value ranges (e.g., R\$ 1-2 million) than to make an estimate that might be misleading.

It is usually necessary to establish contour conditions and specific conditions which, if assessment results are affected, must be made clearly explicit. It is also recommendable to assess the impact the estimates related to these conditions will have on the studied costs and benefits. Given the importance of these conditioners on the Regulatory Impact Assessment's outcome, it is important to detail the following information:

- The main predefined conditions and contour conditions;
- The information and data sources;
- Deficiencies in the information that was used;
- The purpose of the analysis;
- Possible estimate distortions;
- The main intangible costs and benefits; and
- Any other information considered as necessary to assess the analysis' objectivity.

#### **C.4 Analytic Tools used in Regulatory Impact Assessment**

Several analytical tools are usually used to assess the regulatory impacts, among which cost/benefit analysis, cost/efficacy analysis, and risk analysis, described below, are the ones used the most.

##### **C.4.1 Cost-Benefit Analysis**

The benefits derived from the options that were studied for the regulation and its implementation are quantified monetarily, and the net result of the cost/benefit ratio assessed. In this method, since the costs and the benefits are calculated in monetary terms, they are directly comparable and are estimated in terms of the economy as a whole, and not individually. However, a limitation of this method is that not all costs or benefits can be expressed directly in monetary terms. On the other hand, it allows the costs and benefits to be determined in time, including in the mid- and long-term. Using this technique, the stricter positive and negative scenarios of the several options to solve a problem are assessed using an approach that allows the objective comparison of the advantages and disadvantages of any number of alternative actions used to solve the problem. However, this analysis demands significant technical and analytical capacity and data and information

availability, and it is not appropriate to treat the themes that involve fairness, although it may be adopted for this purpose. Another difficulty derives from the fact it is not possible to determine costs and benefits when there are no applicable market prices (e.g., what is the price of saving a life?). In such cases, other assessment tools should be used, such as the cost/efficacy analysis.

#### **C.4.2 Cost/Efficacy Analysis**

This technique may be used to compare the costs of different options that have the same or equivalent results. The cost-efficacy analysis is particularly useful to assess proposals for which it is easier to quantify benefits (stating them in physical units such as, for example, lives saved, tons of particulate material emitted, etc.) than estimate them in monetary terms. This is the case, for example, of issues involving environmental protection, health preservation, and educational measures.

A limitation it faces is that it can only be applied to the costs of different options that could be used to reach the same results, and it does not allow one to know the gains the society could achieve by adopting some proposal other than the lowest cost one. On the other hand, it discards higher cost proposals used to achieve similar benefits.

#### **C.4.3 Risk Analysis**

The purpose is to assess risks, which are understood as the combination of probability with the consequence or damage caused by an event, resulting from the several options analyzed and of regulation implementation. Using this method is especially important when issues such as health, safety and the environment are at stake. When applying this approach, establishing the acceptable limits and surveying the risks, it is possible to identify the ones that are critical, study measures to treat them and check whether they are acceptable after treatment is applied. Annex D shows an example of a risk analysis method.

It is important to acknowledge that any method has its own limitations and is not entirely satisfactory, since they were in fact developed to deal with specific problems. The analysis must take this into account. Likewise, the availability of appropriate data to make the assessment is a common difficulty that must be considered and overcome. The benefits are often involuntarily overestimated due to excessive regulation proponent optimism. Therefore, attention must be focused on achieving effective assessment results and on avoiding wasting scarce analytical resources with unnecessarily complex methodologies. This is particularly true in the Brazilian situation, where the Regulatory Impact Assessment habit is being introduced.

#### **C.5 RIA Approach - example**

Technical regulation impact assessment is a dynamic process throughout the entire regulation preparation and adoption process.

The structure and content shown herein are adaptations made of the approach adopted in the United Kingdom, one of the several approaches in use to assess technical regulation impacts. Thus, the considerations and the structure and content example shown in this Annex are merely illustrative and are intended to assist in the understanding of the use of this tool and of its implications and should not be considered as the only recommended methodology.

Three regulation impact assessments are usually prepared: a preliminary regulation assessment, when the intention of developing an "initial" technical regulation is announced to support the decision of developing the regulation; another "partial" one to provide the relevant information, and a study of the impacts and consequences of supporting the stakeholder consultation process; and a third, often referred to as "complete," to clarify the decisions that were made and to assist in the implementation process when the regulation is approved.

Typical RIA content includes:

- a. Full title
- b. Purpose and intended results
  - Objectives, to detail what the proposal hopes to achieve and how fast.
  - Antecedents, to describe the current situation and the measures to treat it.
  - Justification, to describe how the current situation would be had the State not intervened or the impact on the current situation if such intervention were ceased.
- c. Consultation

- In the ambit of the State, to list the several State bodies that were consulted (ministries, regulatory agencies, other bodies)
- To the stakeholders, to register the consulted stakeholders, the consultation mechanisms that were used, consultation results, and their impact on the decision that was made.

d. Options

Identify all options considered and each one's potential to reach the intended objectives. The option of "doing nothing" must be included, not only because the implication of not acting must be clearly established, but also because they represent the base for comparison to the other options. Indicating the risks associated to each option (note the risk is the combination of consequence and the respective probability and, as such, it is important to refer to the consequences and to the probabilities) and the ways through which these risks can be mitigated or controlled. The process of implementing each option must be described.

e. Costs and benefits

- Affected sectors and groups, to list the sectors and groups the proposal may affect. These may be groups of individuals or private or public organizations. Consider the fact that some of these groups or sectors may be impacted disproportionately by the regulation. When this is the case, this must be clearly indicated. At times, it may be difficult to predict the exact costs and benefits. In this case, a value range, clarifying the extreme and the most likely limits, must be presented.

- Benefits

The technical regulation's benefits must be identified and quantified.

- Costs

The cost analysis must even consider administrative costs. The cost survey should include an estimation of those that are inherent to inversions made by those who should fulfill the regulatory prescriptions when implemented.

f. Assess the impact on small companies

Consider each option's impacts on micro, small and midsize companies and record their results.

g. Assess the impact on competition

Set an assessment of the impact on the competition for each option.

h. Application and implementation, sanctions and monitoring

How the proposal will be applied and implemented, under which authority it is established, the sanctions for those who do not comply, and the monitoring measures.

i. Implementation

Include, as an Annex to the RIA, a regulation implementation plan showing who is responsible for it, the measures taken, and a timeline.

j. Post-implementation review

Indicate how and when the proposed regulation's efficacy will be measured. It is recommended the regulation be critically reviewed 3 to 5 years before being implemented.

l. Summary and recommendation

What option is being recommended and why. Refer to the analysis made to reach the solution. Show in a table (example below) the information brought up for each option.

Initial and partial analyses usually use topics "a" to "h"; partial analyses usually also have a description of how stakeholder consultation is planned to occur, which is essential to undertake the RIA and for its results' quality.

Cost & benefit summary table

Option	Total benefit, per year: economic, environmental, social	Total cost per year: - economic, environmental, social - political & administrative
1		
2		

3		
4		

Another possible way to present option assessment results, a little more complex than the previous one, is shown below.

Problem/Regulation objective	Options studied	Impact foreseen due to the proposed changes			
		Intended benefits	Costs	Impact distribution	Summary of the critical points brought up in the public consultation

## Annex D

**RISK ANALYSIS – Method Example**

The main purpose of Risk Analysis is to support the regulator agent's decision regarding defining the regulation instrument to be used. The central idea is collecting and classifying information, analyzing such information based on predefined criteria and determine the degree of risk involved in the situation under analysis and, thus, improve the decision-making process regarding the form of regulation and the type of treatment to be implemented for the identified risks.

Using a risk assessment method has these advantages:

- Define, with a greater degree of confidence, the requisites the regulation demands;
- Boost confidence in the results of the analysis of the situations that need regulation;
- Support decisions made, as appropriate for each situation;
- Support the definition of the appropriate protection level for each situation;
- Allow future verification of the data used in the risk assessment for possible adjustments and corrections;
- Assist in registering the information that was used to allow information traceability.

The proposed method involves these steps (figure C.1 presents a scheme for the risk assessment process):

- a. Determination of the activities performed for the situation under analysis (context determination);
- b. Determination of the existing hazards (causes), i.e., undesired events for the identified activities;
- c. Determination of the damage each hazard could have;
- d. Determination of the likelihood each existing hazard may occur;
- e. Determination of the consequences the damage may have;
- f. Risk assessment criteria definition. Defining these criteria involves the classification of the consequences, (Table C.1), of the probabilities (Table C.2), and of the resulting risks themselves (Table C.3);
- g. Risk determination by crossing the results obtained in steps "a" to "e;"
- h. Comparison of the risks found with the criteria defined in step "f". An example of risk classification is provided in Table C.3. Figure C.2 shows this stage schematically;
- i. Set priorities for the classified risks (compared to the criteria) as risks that must be treated or unacceptable risks;
- j. Define the controls that are required to treat each of the risks considered as unacceptable.

The methodology used to identify hazards and assess risks should:

- Emphasize a preventive approach;
- Ensure risk classification and identify those that should be eliminated or controlled via treatment measures;
- Be consistent with operating experience, proven good practices, and with the capacity of the risk control measures that are used;
- Provide subsidies to determine the measures to be taken;
- Ensure required action monitoring to ensure their efficacy and implementation term.

Hazard (cause) and risk identification must be undertaken in a structure systematic process and must include all of the hazards and risks that may be identified, whether or not under control.

A wide-ranging list of the events that result in hazards must be prepared. The list of events must be considered in detail in order to identify what might happen. The causes and possible scenarios for each event in the list must be considered.

The tools and techniques used to identify the hazards and risks are, among other:

- Checklists;
- Judgments based on observations, experience, and records;
- Flowcharts;
- Brainstorming techniques;
- System analyses;

- Scenario analyses.

A preliminary analysis should be made to exclude similar or low-impact risks from a more detailed study. Whenever possible, excluded risks must be listed to show risk assessment consistency.

The possibility an event will occur and its associated consequences must be analyzed in the context of the existing controls, as must the magnitude of such consequences, using statistical analyses and calculations. If previous data are unavailable, estimates may be made to reflect the organization's degree of expectation regarding the occurrence of a certain event or result. To reduce the inherent subjectivity of the estimation processes, the best sources of information and techniques available should be used, such as:

Sources	Techniques
<ul style="list-style-type: none"> <li>▪ Previous records;</li> <li>▪ Pertinent experiences;</li> <li>▪ Sector practice and experience;</li> <li>▪ Pertinent publications;</li> <li>▪ Experiments and prototypes;</li> <li>▪ Opinions of specialists and experts.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Structured interviews with specialists;</li> <li>▪ Use of groups of multidisciplinary specialists;</li> <li>▪ Individual assessments using questionnaires;</li> <li>▪ Use of failure and event trees.</li> </ul>

Risk assessment may be carried out at several degrees of refinement, depending on the available information and data. The analyses may be qualitative, semi-quantitative, quantitative, or a combination of them.

The quantitative analyses are more expensive and complex. In practice, qualitative analyses are used initially to obtain a general indication of the level of risk.

When using quantitative analyses, the sensitivity analyses must be used to test the effect of hypothesis and data changes.

There are several mechanisms and approaches that can be used to assess probabilities and consequences. One of the efficacious ways to assess probabilities and consequences is by classifying them, such as in the examples provided in the following tables. Therefore, the combination of the probability and consequence classifications results in an understandable, easy-to-use risk classification. Naturally, each level of risk must be associated to specific intervention levels.

## Tables

**Table C.1 - Qualitative consequence measures**

Level	Description	Description example
1	Insignificant	No lesions, minor financial loss
2	Minor	Treatment with first aid, medium financial loss.
3	Moderate	Medical treatment required, high financial loss.
4	Major	Severe lesions, activity continuation compromised, major financial loss.
5	Catastrophic	Death, activity interruption, enormous financial loss.

Note – The measures that are used must reflect the organization's needs and nature and the activity being studied.



**Table C.2 – Qualitative probability measures**

Level	Description	Description example
A	Nearly certain	Expected to occur most times
B	Probable	Likely to occur most times
C	Possible	Likely to occur sometime
D	Unlikely	Might occur sometime
E	Rare	Might occur only under extraordinary circumstances

Note: These tables must be adapted to meet a given organization’s needs.

**Table C.3 – Probability and consequence classification example  
Qualitative risk analysis matrix – risk level**

Probabilities	Consequences				
	Insignificant	Minor	Moderate	Major	Catastrophic
A (nearly certain)	H	H	E	E	E
B (probable)	M	H	H	E	E
C (possible)	L	M	H	E	E
D (unlikely)	L	L	M	H	E
E (rare)	L	L	M	H	H

Legend:

- E:** extreme risk, required for immediate action
- H:** high risk, required for management attention
- M:** moderate risk, the management’s responsibility must be specified
- L:** low risk, managed by routine procedures

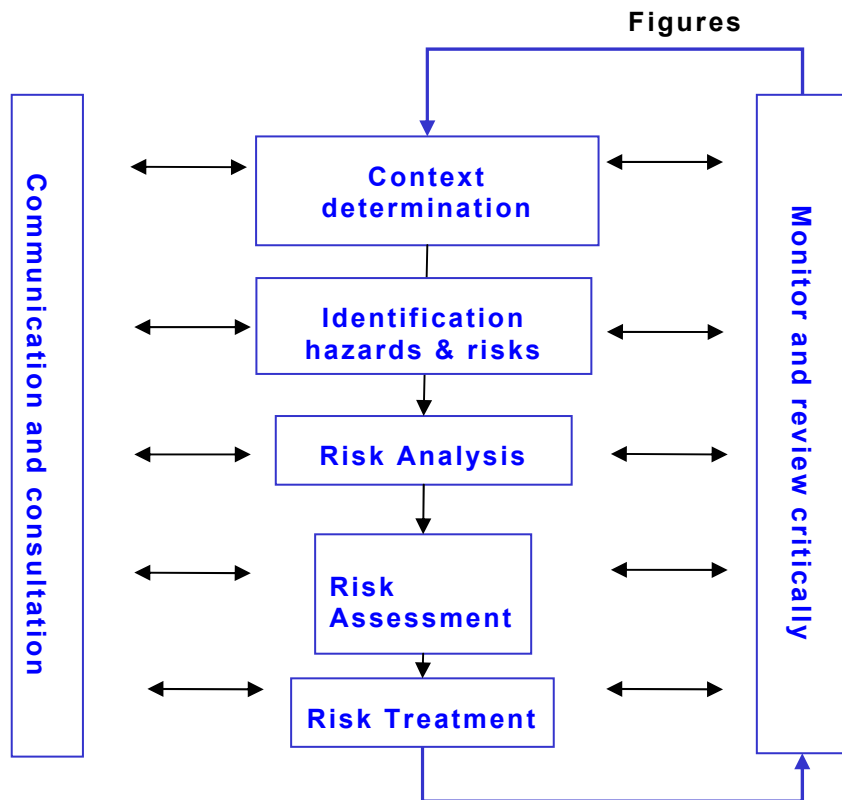


Figure C.1 – Risk assessment process scheme

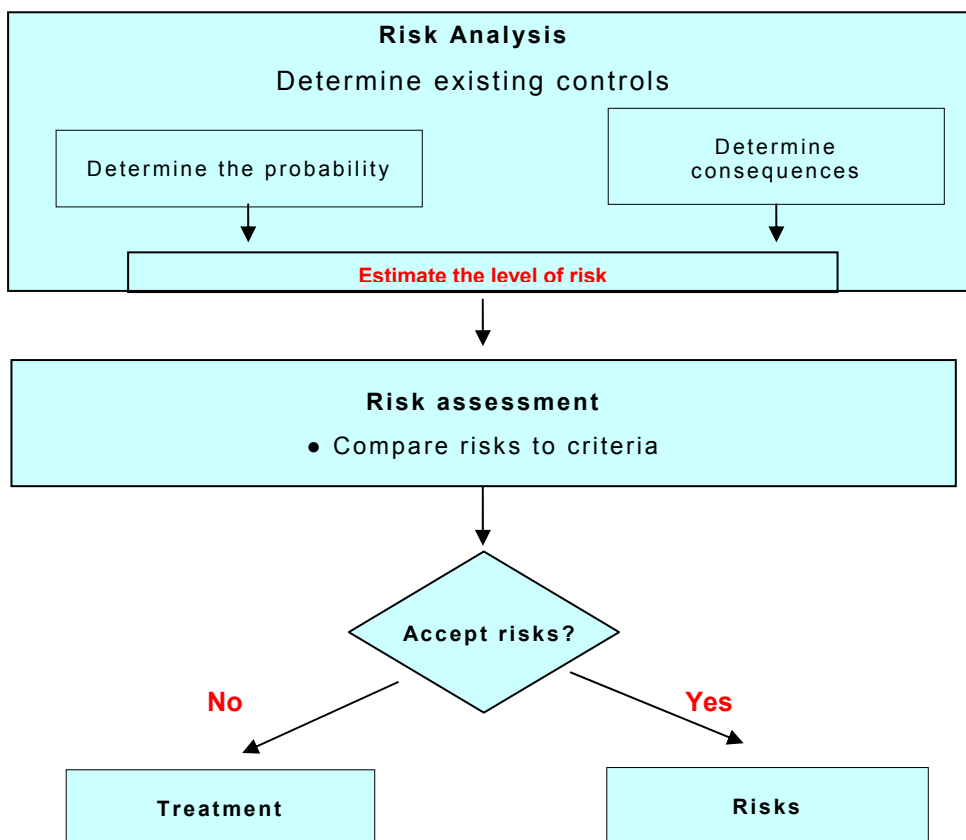


Figure C.2 – Schematic flow to compare risks to criteria

## Annex E

### **INSPECTION AND OTHER MARKET SURVEILLANCE PRACTICES**

#### **E.1. Inspection Practices**

Inspection is the most renowned way to follow-up on regulated products, processes, and services in the market. It focuses on preventing the presence of irregular products in the market, i.e., that do not meet the regulation's requirements. This is typically the practice of administrative police seeking to prevent the presence of irregular products in the market, i.e., those that do not meet regulation requisites.

The administrative police power confers public entities the right to apply the sanctions legislation prepared specifically for this purpose defines, on those in breach of the regulation: interdiction, apprehension, destruction, pecuniary fines, etc.

Inspection may be carried out in different manners, a few of which simple, others more complex, among which:

- Verification of the presence of visual identification of the record or of the conformity attestation;
- Product visual inspection;
- Undertaking of expeditious testing at place where the product is used or displayed for sale;
- Collection for lab testing or inspections with the assistance of more sophisticated techniques;

#### **E.2. Other Market Surveillance Practices**

Other market surveillance mechanisms may be carried out, whether related to the administrative police power exercise, whether to support analyses regarding the need to improve the regulations. Examples include:

##### a) Registration

Although this is not an act that is typically done to surveillance the market, registration may be a very useful tool to materialize it. It is also an administrative police action required for it to exercise its legal investiture. In general, it is inherent to the regulatory authority.

Registration works as a pre-condition in order for the product to have access to the market. It can be done simply based on information submitted by the manufacturer, information that is compatible with the regulation's requisites, and even for conformity attestation, after the product has gone through a conformity assessment process. Another registration practice is being carried out by the regulatees themselves.

##### b) Deletion and Complaint set analysis

The regulatory authorities have different communication channels with the citizen, such as the ombudsman's office, toll-free phone numbers and Internet websites to better receive and treat deletions, complaints and requests for information. A global analysis of these demand's statistics signals important opportunities to improve regulations or at least to undertake divulging campaigns and to provide clarifications on the regulations.

##### c) Accident Database

Regulatory authorities in Brazil that have or are developing such databases are still rare. Knowing how much accidents cost and their causes allow for clarification campaigns, regulation improvements, and even data provision in order for manufacturers to develop better products.

##### d) Conformity Verification

Conformity verification may be done for products whose regulations are associated to conformity assessment requirements, as is the case of the Brazilian Conformity Assessment System (SBAC).

This involves removing products that are regular in the market, i.e., with proof of conformity, to, after testing are performed in labs, check whether they reach the points of sale preserving the characteristics based on which they had their conformity assessed and attested to.

If non-conformities are identified, the cause of this is analyzed and may be lab or conformity assessment body failures or, more importantly, failures in the regulation itself. Many regulation improvements are achieved through this practice.

Conformity verification emphasizes prevention but, when irregularities are identified, they may lead to penalty actions.

In a few countries, conformity is checked by the competition. When the competition performs this activity, this boosts the regulatory authority's capability to surveillance the market. This practice has been being introduced in Brazil in the ambit of the Brazilian Conformity Assessment System.

e) Internet Pages

Following-up on the information available in Internet pages belonging to regulatory entities in other countries may also support regulation improvements. Considering the existence of the so-called globalized products, the timely identification, for example, of consumption accidents in other countries may lead to proactive regulation improvement measures that may keep such accidents from occurring in Brazil.

f) Following-up on news published by the press

Several media outlets, whether in print, spoken and televised, currently have spaces that are aimed at consumption relations issues. These spaces showcase frequent consumer complaints, denunciations and even requests for information regarding regulated products. Monitoring these spaces and analyzing the collections of facts that are reported on regarding a certain product may also lead to regulation improvement opportunities.

## Annex F

**PRACTICAL AND EDITORIAL ASPECTS****F.1 Regulation Text**

A Technical Regulation, due to its mandatory character, requires the prescriptions to be easy, clear, and understood unequivocally by those it is aimed at and, also, by the society as a whole.

Prescriptions must be structured directly, in a simple, concise style, preferably written in current use terms without requiring the use of a dictionary.

Using fancy expressions, technical terms and excessively long paragraphs must be avoided. Technical jargon and other specific terms, when needed, must be defined in the body of the regulation, in a chapter used for this purpose.

**Notes:**

1. In the regulation's body, only the essential terms to give more clarity to a more technical prescription. What is meant must always be explained after the text, in highlight.
2. Footnotes should be avoided.

**F.1.1 Terminology & Definitions**

Terms that are not self-explanatory, of general knowledge, or that have more than one meaning, must be defined based on the meaning they have in the text.

The terms should be used, preferably, in their basic grammatical form, i.e., nouns in the singular and verbs in the imperative.

The definitions must be limited to presenting strictly the required and sufficient amount of information in order for the concept to be perfectly understood. Avoid ambiguous and unclear terms, the concept of which should be clarified in a different concept's definition body. Using drawings or figures to clarify a definition's content, is a plausible resource, but only when indispensable for the concept to be understood better.

The preferred structure for a definition is: the term to define followed by the concept one wants to give it. Example: **Technical regulation:** document that enunciates the characteristics...

**F.1.2 Abbreviations**

Acronyms, abbreviations and symbols must be avoided throughout the text, opting for making the required mentions unabbreviated.

When they must be used, their meaning must be explained in the "Definitions" chapter, after them.

**F.1.3 Verbal forms**

A regulation usually closes the mandatory prescriptions and might contain a few recommendations or detail permissions and prohibitions. The choice of the verbal form to translate each of these situations must be careful and not lead to any ambiguity or prejudice to the actual prescriptive intention, as follows:

- To express a **requirement**, use the verb in the imperative or in the infinitive preceded by "must."

Example:

*Pay the fee...*, or

The interested party *must pay* the fee...

**Note:** Never use "*may*" instead of "*must*" to mean an obligation.

- To express a **prohibition**, use the action verb preceded by the negative prefixes, or "cannot", "is not allowed" or, even, "is forbidden."

Example:

*Do not pay* any values to the agent..., or

Paying any values *is not allowed*..., or

No values *can be paid*..., or

*It is prohibited to pay* any values...

**Note:** Never use "*should not*" instead of "*cannot*" to express a prohibition.

- The following verbal forms are common when a prescription closes a **recommendation**:

*May*..., or

*Should not...*, or

*It is recommendable...*

- A **permission** is usually expressed as follows:

*May...*, or

*Is allowed...*, or

*Is not necessary...*

## **F.2 Other Editorial Details**

### **F.2.1 Writing numbers**

Writing numbers must comply with the following instructions.

**Note:** These prescriptions do not apply to numbers that do not represent amount, for example, numbering elements in sequence, identification codes, dates, telephone numbers, etc.

F.2.1.1 A comma is always used to separate the integer from the decimal of a number; when the number's absolute value is less than 1, a 0 is placed to the left of the comma.

F.2.1.2 Numbers that represent amounts of money or of products, goods or services in tax, legal and/or commercial documents must be written with the numerals separated in groups of three, beginning from the comma to the left and to the right, with stops separating these groups from one another.

F.2.1.3 The space between a number and the unit's symbol must meet each case's needs, for example:

a) in running phrases or texts, the space usually corresponds to one or half of a letter, but no space must be allowed if there is any possibility for fraud;

b) in table columns, using spaces between the numbers and the corresponding unit symbols is optional.

### **F.2.2 Measurement Units**

In technical regulations, only use measurement units that are legal in Brazil.

Measurement units, their multiples and submultiples, must be written in full or using symbols that are used to represent them. These symbols, as such cannot be flexed to indicate plurals or have abbreviation stops.

It is wrong, for example, to write M, or mts., or ms, to mean meter or meters, the proper symbol for which is "m".

Likewise, "kg" is the International Unit System's symbol for kilogram; K, KG, Kg, or Kgs., do not represent this mass unit multiple.

The General Legal Unit Chart in Brazil is the object of Conmetro Resolution No. 12/1988.

### **F.2.3 Numbering Items (Itemization)**

Identifying the several prescriptions is an important condition to facilitate consultation and the corresponding clarifications to the interested party and, specifically, to typify possible breaches.

Sections or chapters are identified by numerals (1, 2, 3, ...) and items and sub items by combined numerals, in increasing order (1.1, 1.2, 1.2.1, 1.2.2, 1.2.1.2, ... 9.3.4.2).

Annexes are identified by letters (Annex A, Annex B, ...)

### **F.2.4 Tables and Figures**

Tables and figures are used to present information, or a prescription, or for a regulatory requirement to be easier to understand.

They must be numbered independently of the clause they make reference to, in a sequence that is particular to each one of them, according to their order in the text. Example: Table 1, Table 2, Table M; and Figure 1, Figure 2, Figure N.

A table's title must head it, for example:

Table 1 – Dimensions.

The figure's title is centered below it, for example:

Figure 1 - Forms

Notes regarding a table or figure must be treated independently of the footnotes or of the notes that are integrated to the text. They must be the last line in a table's grid or appear after a figure's title.

When a table takes-up more than one page, mention this as indicated in the examples:

Table 1 (continuation)

Table 1 (conclusion)

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