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Conformity to Standards and Technical Regulations

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Introduction

This presentation is about the relationships between technical regulations, standards and conformity assessment. These three subjects are part of a larger complex of relationships that is called a quality infrastructure, which also encompasses the subjects of accreditation, metrology, market surveillance, and quality management and quality awareness. A well functioning quality infrastructure in a country can make a strong contribution to the production of higher quality goods and services and as such to a better export performance. On the other hand, a quality infrastructure forms the basis for the protection of the consumers, because quality goods and services are supposed to take into account health and safety requirements.

The most logical order of presentation is to start with the concept of the technical regulation, because technical regulations make extensive use of standards, and of the procedures and practices of conformity assessment.

Technical Regulation

A definition of a technical regulation can be found in the Agreement on Technical Barriers to Trade of the World Trade Organisation.

A technical regulation is a document, which lays down product characteristics or their related processes and production methods, including administrative provisions, with which compliance is mandatory. It may also cover terminology, symbols, packaging, marking, or labelling requirements as they apply to a product, process or production method.

Therefore, a technical regulation can give specifications how a product should function, how it should operate, what it should not be able to do, how it should be designed, and how it should be made. It is important to notice that the definition does not explicitly specify who issues a technical regulation, but from the context of the Technical Barriers to Trade Agreement it is evident that it is the government (or other designated authorities on behalf of the government). Technical regulations are by their nature part of the body of law in a country and adherence to the regulation can be enforced, just like any other law or decree. Manufacturers and importers should be fully aware which technical regulations are in force in a country and they should ascertain that their products are in line with the requirements; otherwise their product could be banned and/or taken off the market.

Technical regulations have a certain level of similarity with standards. Standards are also documents that lay down product characteristics, and/or design criteria, and/or production methods. The major difference between standards and technical regulations is the fact that standards are voluntary. A producer may choose to follow a standard, or he may opt for another method or solution. Technical regulations are mandatory and leave the producer no other choice than to comply with its requirements.

Reasons for technical regulations

It is a legitimate question to ask why governments issue technical regulations. Of course, there is a whole history of technical regulations and they date back many hundreds or years. There is also a whole body of economic theories about technical regulations and their effect on international trade, on the development and distribution of welfare, and on demand and supply of goods.

Yet, one does not have to go dig into those matters to understand the prime motivation. It is rather quite simple. Ever since the beginning of the Industrial Revolution manufacturers have left a trail of devastation through the supply of inferior products that have killed and harmed people in great numbers. It is, however, not only dangerous products and counterfeited products, but also inadequate production processes and unsafe working conditions that have done grave harm to labourers and very often to people living in the surroundings of factories, as well as to the environment through water and air pollution, and the careless extraction of natural resources. It has always been a sad aspect that in the majority of cases, manufacturers deny responsibility for the obvious failures of their products and production processes.

It is for that reason that governments have started to interfere with the quality of products and the safety of production. In the beginning they started with introducing labour safety regulations and labour laws and rules for dangerous equipment (e.g. steam boiler inspection, lift inspection). However, as economic welfare and education were increasing, consumers developed higher levels of expectation that products and commodities in the market place should be safe and not endanger their health. People also developed the expectation that their health is not endangered by the introduction of pesticides, alien plant material (including genetically modified organisms), plant and animal illnesses, foreign bacteria and the like that may cause serious harm to their health, and to the

indigenous plant and animal species. This development took a very strong turn in the second half of the 20th century with the development of influential consumer organisations in the US and Europe. Protection of consumers from harmful products has now become a standard policy issue in many countries, supported by a wide array of legislation (many in the form of technical regulations) and effective inspection services.

Notwithstanding, the general beneficial effects of technical regulations, there have been many occasions in which governments have used them to restrict the imports from other countries for the protection of domestic industries. Technical regulations become in such situation so-called technical barriers to trade.

Nowadays, it is general accepted that governments may issue technical regulations for a limited number of reasons. The major ones are:

- Safety
- Health
- Environment
- Prevention of deceptive practices
- National security

Elements of a technical regulation

A good technical regulation has to have a number of basic characteristics in order to make it effective.

A precondition is that a government has an idea about what it wants to achieve. In other words, it should have clear opinions about what it wants protect, as well as the conviction that a technical regulation is an effective tool to attain that objective. Ideally, a government should have a national policy and should have transformed (part of) that policy into general and specific legislation to base technical regulations on.

A good technical regulation has the following four elements:

- It has to state clearly and unambiguously the desired specifications of the product or production process;
- It has to identify a regulator, that is the government organisation(s) that will be responsible for the practical implementation of the technical regulator;
- It has to state by what means and processes the conformity of a product to the product specifications will be assessed;
- It has to state which sanctions will apply, if a product fails to meet the requirements.

How to define specifications of a product

The technical specifications of a product or process can be defined basically in two different ways.

The first one is the prescriptive method. The technical regulation prescribes more or less the exact means by which to achieve the desired result. The advantage of this method is that it creates absolute certainty; if a manufacturer follows exactly the given solution his product will automatically be compliant. The downside of this approach is that it gives one single solution and that alternative solutions are not allowed. The other disadvantage is that it puts a limit on the uptake of new technological developments. It takes quite some time before new solutions are more or less generally accepted and the texts of regulations need to be changed from time to time (which by itself may take considerable time). Therefore, change is rather slow.

The second method is a performance oriented approach. The technical regulation gives an objective that has to be achieved, which can sometimes be formulated in very general terms (e.g. 'machines have to be safe'). It is, however, up to the manufacturer to find appropriate technical solutions. The advantage of this method is that it leads to more flexibility, allowing the choice of effective and efficient solutions. Moreover, it supports innovation in technology (without having to rewrite the technical regulations). It goes without saying that in this approach conformity assessment becomes more complicated and more uncertain. Both the regulator and the manufacturer have to make continuously assessments whether the chosen technical solutions lead to the desired objective. This method favours large corporations over small and medium-sized enterprises, because of the differences in available technical resources (R&D departments, design engineers, testing facilities, etc.)

There is no clear preference for the one or the other method. The choice depends very much on the nature of the products, the situation in the relevant branch of industry, and the relative importance of the type of products in the national economy. Within the European Union both methods are applicable and can be identified as "Old Approach" (very effective in e.g. pharmaceutical, chemical and automotive industries) and "New Approach" (very effective for instance in the machine industry and the construction products industries) respectively.

Role of standards

Standards provide useful shorthand to making specifications. Instead of writing detailed lists with requirements, reference is made to (a part of) a standard. Standards are developed by the stakeholders in a certain subject and represent a shared opinion on the state of the art of the technical developments on the subject matter at hand.

Member states of the WTO have the obligation to make as much as possible use of international standards in the formulation of technical regulations. This will help to formulate regulations that are more or less founded on the same technical basis.

However, references to standards in technical regulations require a presumption of conformity, or a deemed-to-comply principle. If a manufacturer applies the standards that are referenced in the technical regulation, it is assumed that his product is compliant with the requirements (until proven otherwise). In technical regulations based on the performance oriented approach, this presumption of conformity places SME's in on a more level base with each other and with the bigger companies, because it reduces their uncertainty in finding technical solutions. As long as a producer follows the standards meticulously he can get it wrong, while bigger companies can still look for alternative solutions outside the prescribed standards. One problem with standards is that they are usually not explicitly written for the purpose of conformity assessment. Therefore, standards contain elements that are not necessary for compliance. Consequently, the use of standards should be done very diligently and only those parts should be referenced that are of relevance for the objectives of the protection of health and safety.

Conformity Assessment

Systems of conformity assessment are not only of interest to technical regulations, but are in principle applicable to any economic transaction. Most of the products produced in the world are not subject to any form of technical regulation. Therefore, we can make a distinction between a regulated and a non-regulated area. However, in both cases the central question is how does one know with certainty that one gets what one has asked for?

In the non-regulated area the answer to this question is up to the buyer and the seller in the economic transaction. It depends in part on the level of trust that they have in each other and in part on the relative bargaining power. The simplest approach is doing nothing, or just accepting the product as it is presented and delivered by the producer/seller. This is very common in almost all consumer transactions (The weak position of the average consumer has been the prime motivation of introducing legislation to protect the economic interests of the consumers).

In many transactions between companies the question is answered by reverting to testing or inspection of the delivered goods in order to ascertain that they comply with the agreed specifications. Testing and inspection can be done by the seller (first party), or by the buyer (second party), or by an independent and competent organisation (third party testing and inspection).

In the regulated area there are basically two types of conformity assessment systems. The first system is pre-market inspection. Products and production process are subject to checks before they are placed on the market. These checks are performed mainly by government inspection services. Typical tools for pre-market inspection are among others design approval, product registrations and licensing, production and product inspections, custom inspection of imported goods.

The second type of systems of conformity assessment is a supplier declaration system in combination with post-production inspections. In these systems, manufactures can offer their product for sale on the market, if they have applied certain measures, such as 'due diligence'. A manufacturer cannot

declare without any justification that his product is compliant. He must have taken precautionary measures to make his claim valid. Making such a declaration has certain legal consequences.

Other measures could be to require the assistance of “competent bodies” in design, product testing, and product and production inspection. Competent bodies can be laboratories, inspection and certification bodies, or technological institutes that have high levels of expertise in certain types of products and can help producers to judge the technical value of safety in their design and products. A more recent trend in this respect is the use of certified quality management systems in the design and production of goods. Supplier declaration systems have to be backed up by random inspections and testing of goods by government operated inspection bodies, in a kind of policing function. This function is called market surveillance.

It is important for countries to have a sufficient number of conformity assessment bodies in areas that are important within the national economy. It is generally easier and cheaper for the domestic industry to use local organisations than to revert to international ones. However, the local organisations do need to have an international compatible level of expertise and competence. It is particularly difficult for developing countries to build up such conformity assessment bodies. It can be rather costly to equip a laboratory, and to recruit, train and maintain the staff of these institutions. Moreover, it is essential to develop the market for such services in order to generate a minimum level of income for laboratories and inspection bodies to become self-sufficient and to recoup the investments. Developing countries may have to depend on donor organisations to make such developments possible.

Not all aspects of technical regulations could be developed during this short presentation. There are other interesting related issues, such as the asymmetrical relationships in free-trade agreements between developed and developing countries, the relationship of technical regulations with current economic theory, regulatory safety nets and market surveillance, and the choice of regulatory measures within policy options, to name a few that merit separate presentations.

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