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ARTIGO

Regulatory research

Pesquisa regulatória

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ABSTRACT

We present in this paper the concept, importance, and scope of research into the regulatory framework of regulation and legislation, with a particular focus on legislation related to legal metrology. This study also describes a comparative analysis of the various forms of regulation and the associated regulatory research, with the ultimate goal of better defining the concept and to validate the need to have research groups within a country's regulatory bodies.

Based on this work, we conclude that regulatory research is a key factor in the success of any regulatory body's activities. Such research helps to avoid the creation of absurd or impractical regulatory barriers to a country's technological development, or worse, to permit "orphans," that is, technologies that are outside regulatory control, as is currently the case. Indeed, for a country to have a robust technological infrastructure, especially if it is still a developing country, strong and competent regulatory control is essential. However, this must be balanced by an atmosphere that fosters continuous and consistent technological innovation, and such development must also be self-sustainable from economic, social, and environmental viewpoints.

KEYWORDS: regulation; regulamentation; normatization; regulatory research; Brazilian regulatory agencies

RESUMO

Apresenta-se neste trabalho o conceito, a importância e a abrangência da pesquisa regulatória no âmbito da regulação e da regulamentação, com foco particular na regulamentação relacionada à metrologia legal. Faz-se também uma análise comparativa entre as várias formas de regular e regulamentar, e as suas pesquisas regulatórias afins, tendo como meta principal situar melhor o conceito e validar a necessidade de se fazer pesquisa nos órgãos e agências regulatórias do país. Com base neste trabalho, concluímos que a pesquisa regulatória é um fator chave para o sucesso de qualquer plano de ação de regulação para os agentes regulatórios do país. Ela ajuda a evitar a criação barreiras regulatórias absurdas, ou não práticas, para o desenvolvimento tecnológico do país, e evitar também a circulação no território nacional de tecnologias órfãs do controle regulatório, como se vê ainda hoje. De fato, esta infra-estrutura tecnológica robusta, que ainda precisa ser urgentemente desenvolvida na sua plenitude, deve ser um processo contínuo e consistente de inovação tecnológica, e necessariamente auto-sustentável do ponto de vista econômico, social, e também ambiental.

PALAVRAS-CHAVE: Palavras-chave: regulação; regulamentação; normatização; pesquisa regulatória; agências regulatórias brasileiras

Introduction

The word "research" is widely used by various segments of society, but its interpretation is diverse and depends heavily on the sector or area in which it is used. In fact, it is used both to describe a scientific method used to arrive at an expected (or unexpected!) result, and also in the sense of seeking to obtain general information with/without aggregate value, often to gain useful information for a certain specific purpose (often termed the gray or white literature). The essence of the concept of science with its methods and methodologies is still not well "thermalized" in academia, and it is even less assimilated into society in general[1,2,3,4].

There is in fact a precise definition and knowledge of the concept of "research," but it is limited to a few specialties. Dissemination of an accurate concept of research and its implications into the public consciousness has been relatively slow and its reach is relatively narrow; therefore, it has often been misrepresented. This is particularly true in government regulatory sectors and among regulators who participate in the regulatory dynamic of a country. Regulators have often mistakenly believed that proper regulation, control, and enforcement are possible without the need for strong regulatory research. Some may even believe that it is only necessary for regulators to have good technical training and to be good bureaucrats, meaning that they should be familiar with the various laws and the established standards in related technical manuals[4,5,6,7,8,9]. However, we consider that regulators should be more than mere bureaucratic technicians – they must think exponentially.

To exemplify the need for regulatory research, consider the "wine barrel problem" posed by the German mathematician and astronomer Johannes Kepler (1571–1630)[10]. The problem involved working out a method to determine the correct volume of a wine barrel and identify the proportions that would optimize the volume of such a barrel. It is noteworthy that Kepler was one of the first scientists, if not the first, to apply robust formal regulatory research to this problem, and this was as early as the 16th century. The problem involved aspects of legal metrology, which we define precisely below. Going further in time to 1901-02, we can also mention that the Wright Brothers (Wilbur and Orville), who competed with Santos Dumont on who had invented the airplane, in their aviation´s research faced a problem of legal metrology, and the consequent regulatory research, due to their need for standards measurement of wind pressure, they then invented their own instryument for a more accurate study of the wind[11,12].

Modern society has a large number of technological products that are in common use but whose possible effects on health and the environment are still not completely understood. With new products regularly entering the market, new licenses and certifications will be required, and the need for these raises a number of questions. What are these new products likely to be, and will they have an effect on the country's gross domestic product (GDP)? Are these technologies more dangerous than those currently subject to regulation? Are the regulatory bodies regulating some products that no longer require regulation? What are the safety items required for industrial equipment and products that make use of nanoparticles and nanomaterial? How can we assess the risks associated with nanobiology? What are the possible effects of such technology on human general health and the environment? What advice can the regulatory research provide in such scenarios? Do the principles of ALARA (as low as reasonably achievable) and precaution still apply[5,6]?

It is therefore essential that research be performed in regulatory environments to assist the relevant regulatory body to clarify its stated function in an optimal and proactive manner as opposed to a reactive manner. In this paper, we define regulatory research as scientific research that can be developed by the public sector (first sector; state/government), the private sector (second sector; productive sector), or nongovernmental organizations (NGOs, the third sector), and that adds scientific value to legislation issued by the regulatory agencies, which are affected by this research. Such research is also a useful tool to produce methods for monitoring scientific and technological innovations, with concrete potential for public dissemination in the short, medium, and long terms, and with significant potential impacts on health, safety, and the environment. What is the potential usefulness and validity of such regulatory research to the regulatory bodies? This research will primarily permit the regulatory bodies to prepare studies to justify the exemption from or graded reduction of regulatory control of products, equipment, and services, which might have this prerogative. A case in point is that of the regulation of research nuclear reactors, for which a graded approach is recommended instead of the much greater regulation used for power reactors. Regulatory research is also important to support the revision of regulatory documents already in use or the creation of new ones. Finally, regulatory research is also the scientific and technical anchor for normative documents and regulations and for the enforcement of such regulations when and where it is necessary to for the regulatory body to intervene[7,8].

Owing to the inherent risks of using new technologies or technologically innovative goods that are released for public use without legal control ("orphan" technologies), it is essential that all the regulatory control to be achieved by normative documents should be based on the requirements that need to be taken into consideration, especially in terms of health, safety, and protection of the environment. It should also be noted that some technologies have multiple regulatory paternities, that is, they are controlled by more than one regulatory body (for example, power nuclear reactors, nuclear submarines, or medical technologies, such as positron emission tomography), as this can cause major economic barriers for countries; thus, all regulatory bodies should be part of an integrated regulatory management system. Creation of economic barriers based on defective regulatory technical documents (that is, those

not supported by robust scientific research), which, in many cases, create standards incompatible with national export interests, can also be avoided with proper robust regulatory research. This is an important issue that needs to be addressed afresh by regulatory agencies as these barriers can easily arise, and are amplified by globalization, mundialization, and planetarization. Changes introduced by defective regulatory documents, without strong scientific justification, are ratified by a lack of strong local regulatory research[9].

Methodology

It may be useful to define the terms used above. Globalization generally refers to consumption and culture, and is more related to finance and production. By contrast, planetarization is related to the formation of blocks.

Regulatory research can be developed for the short, medium, and long terms. It is focused entirely on how to model and formalize regulatory documents to regulate goods, services, and equipment that are released by the industrial sectors for use or consumption without regulatory control but that can affect the health, safety, and security of the population, as well as the environment, including food, water, and air. This type of research also aims to maintain regulatory monitoring to track the results obtained by science and technology in the short, medium, and long terms. In fact, control of technological goods is the final part of the regulatory process that begins with correct monitoring of pure research achievements and extends up to the moment when the goods or services affected by this research are delivered to that market. It is, of course, expected that these goods should be safe, and that they should be traceable "from the cradle to the grave".

"Within ten years we'll be using 20% of goods and services which, today, has not yet been invented." (Jacques P. Brochard)

"...the next ten years will bring much technological changes throughout the twentieth century, so that the governments will be unable to accompany them." (Hart - Rudman)

"One has to understand the present to predict a possible future." (Waldimir Pirró e Longo)[6].

There are several promising areas of present and possible future research that are likely to introduce new regulatory issues and overwhelming challenges to the regulatory bodies. For instance, important issues may arise from third-sector activities, such as advertising, architecture, arts and antiques, crafts, design, fashion, film, interactive entertainment software, music, performing arts, editorials and graphics, controlled software, general software, radio, and television. What are the regulatory researches that inspired the legislators in these areas? And what to say of more diffuse and complicated legal control supervening, considering the use of natural resources, such as water, air, and forests?

Results

Some fundamental principles governing the scientific monitoring of regulatory research results can be defined.

All regulatory research should be evaluated in light of the protection of human health, using when necessary the principles of precaution, ALARA, or the optimization principle, and/or ALATA (as low as technologically achievable).

All regulatory research should be evaluated in light of the full protection of the environment.

All regulatory research needs to address fundamental technologies and sustainable technological development.

Any scientific regulatory research should have as an important goal the minimization of waste generation, by optimizing the physical, chemical, and biological processes. There should be application of the fundamental concept of environmental management and responsibility, with technology assets controlled from cradle to grave.

All scientific and technological regulatory research should be aligned with a proper regulatory system so that research, regulation, and guidelines are in line with the sustainable technological development of the country. It is also necessary to consider the dynamics of globalization and the internationalization of science and technological development. Decisions should also take into account aspects or conflict of consumer protection and economic decisions.

Discussion

It should be emphasized that regulatory research differs from pure and applied non-regulatory research in that the partial or final products from such research (namely research reports (pre-prints), technical or legal documents, books, or scientific articles) is targeted at assisting the regulatory body or agency to perform tasks such as making changes to poorly designed or outdated regulations, guidelines, and technical and regulatory documents; developing regulations and standards where none exist based on the requirements at issue and ensuring these are consistent and have due technical and academic robustness; developing regulatory positions on topics of immediate importance; making changes to regulatory positions as required; preparing normative acts relevant to the regulatory body or agency to ensure the basic rights of the population; and making changes in legislative acts relevant to the regulatory body or agency to ensure the basic rights of the population.

The products derived from regulatory research must be concrete from the regulatory standpoint, tangible, and with a high level of added social value. For instance, legal metrology is, in essence, an exclusive function of the State. It consists of a set of technical procedures and legal and administrative acts established by legal provisions and made by the public authorities that aim to ensure the quality of measurements taken in commercial operations, as well as those that affect consumer health and the environment, among others[13,14].

Conclusions

In the specific case of regulatory research in legal metrology, it should be grounded in a special regulatory "eye"

and a critical regulatory oversight. Such research should be part of an integrated and interdependent system, taking into account the following variables.

Technical. This implies strong scientific monitoring and technological knowledge.

Administrative. All the relevant technical knowledge for the regulation must have a legal framework, as well as an efficient administrative infrastructure for its implementation. This implies the development of an integrated regulatory management system so that the regulatory body can win the respect of those being regulated, not simply because of its enforcement power but because of its regulatory scientific and technical competence.

Legal. Alone, technical and administrative frameworks are not sufficient for proper regulation and enforcement. It is also necessary and essential to have a legal framework in order for the enforcement to work as intended and to provide adequate legal grounds for the regulators. Even enforcement procedures that have a reasonable scientific and technical background and strong regulatory management can fail if there is lack of legal robustness[15,16].

Systematization and creation of efficient methodologies for the development of research within the regulatory body demands reflection on various aspects of regulation, and several issues need to be addressed to ensure that institutional success is achieved. In order to implement or advance regulatory research in any regulatory agency, several considerations need to be taken into account.

At the beginning of the process, it is vital that there is accurate assessment of the multiple forms of the institutional cognitive model (history, values, strengths, weaknesses, level of "layers," and institutional "resistance/viscosity," that is, resistance to change by sectors/layers). In short, it is necessary to understand the cognitive dynamics of the institutions before any attempt is made at internal changes. However, whatever the cognitive model of the institutions, the process will only work if it is conducted with rather than dictated to the institution.

The intellectual capital of an institution is a vital asset/input and an important driver of the success of any enterprise management or institutional re-engineering action.

Identifying the institutional and intellectual capital to build the matrix of skills required (areas of need versus resources allocated) is the starting point of the process.

An additional important point is to map the people involved by title and experience in order to get an idea of the depth of work that they are capable of performing. Such mapping should take into account the entire spectrum of knowledge within the staff (technical, undergraduate, or postgraduate), along with their respective specialties and backgrounds. After this study, these skills should be matched with the institutional needs to identify the intersections and gaps, thus generating the institutional matrix of skills and tasks, and thereby determining the real institutional needs and possibilities.

A country's demand for regulation and regulamentation may be natural or induced, after prospecting the local industrial power and import pattern. In order to regulate a particular technology, an in-depth risk analysis and impact assessment (considering health, safety, and environmental protection) is required. The same is true for services where the impact may be more subjective in nature and may require more broad-based regulatory research, possibly involving psychosocial knowledge, in order to avoid harmful subjective effects on the population. In such situations, the effects are often more psychological in nature, such as those seen after nuclear/radiological accidents, as occurred in Brazil (Goiania) and the Ukraine (Chernobyl). After assessing the impact and risk analysis for each technology, the regulatory body can categorize the demands by area of knowledge to perform the necessary regulatory research and subsequent regulation/regulamentation, and of course the standards of production necessary for effective and practical regulatory-based actions.

Consequently, we conclude that regulatory research is a key factor in the success of any regulatory body action plan. It helps to avoid the creation of absurd or impractical regulatory barriers to technological development in the country and enables the development of a technology infrastructure by means of continuous, consistent, and self-sustaining technological innovation. In order to reduce the increasing number of technological goods that are orphaned from regulatory control and released to the global world market for general public use, it is essential that all countries have effective regulatory research in place in order to face these global safety- and security-based technological challenges. In short, without a strong regulatory research program, it is not possible for any country to have real and sustainable technological development. The low number of international patents deposited by Latin American countries compared with developed countries is closely related to the lack of strong correlation between pure, applied, and technological research in such countries, a problem that could be mitigated by a strong metrological (legal, scientific, and industrial) research base fueled by robust, relevant regulatory research[1,2,3,4,5,17,18,19,20,21].

Final considerations

There are also several important regulatory issues in the area of health-management systems to take into consideration, and the advent of globalization will make it even more difficult for the regulatory bodies to address this problem. Consider, for instance, the recent case of contamination of beef products with horsemeat in Europe, which made international news. The meat itself was not harmful to human health, and in most cases did not adversely affect the taste of the product, but the possible presence of antibiotics that could be harmful to human health made a great difference in the approach taken by the regulators toward this novel regulatory issue. Of course, the matter of business ethics also had to be considered, but this subject is much more difficult to quantify and is even more difficult without the existence of a body of specific regulatory

research, which is likely to involve crossover into areas such as anthropology, sociology, psychology, and ethics.

There are many other examples of health-related regulatory issues that were not properly addressed by the regulatory bodies around the world due to a lack of effective regulatory research. For instance, in Brazil, there was the recent case of breast prostheses filled with non-medically approved silicone. In that case, regulatory research and collaboration between INMETRO and ANVISA, which had already been developing a research project in that area, apparently solved the problem.

There was a similar issue with titanium dental implants that resulted in a series of health problems in some patients, including rejection and infections. ANVISA, in collaboration with INMETRO and the stakeholders, was able to take appropriate action and set proper regulatory controls on the use of this technology. However, this only occurred after the implants had already damaged the public health; thus, it was more reaction than action. It is possible that with proper regulatory research, this problem would have been identified and addressed at an earlier stage.

Another very important regulatory issue that requires very strong regulatory research is the metrological control of the pharmaceutical sector concerning the medicines that are produced and released for public use. Such regulatory research should mainly consist of creating metrological protocols to determine if the information accompanying such medicines for public use indeed corresponds to the true amount of active substance necessary to create the expected positive effect of the drug. This is also true for the legal metrological control of ionizing-radiation technologies used, for example, in radiotherapy and nuclear medicine. Equipment sold in Brazil to measure emissions of ionizing (and non-ionizing) radiation does not have proper legal metrological control, as it does not need to be formally submitted to the legal metrological formality of model approval ("aprovação de modelo"). This is a very important regulatory issue that should be addressed as soon as possible because of its clear potential impact on public health and the environment.

There have also been many cases where good regulatory practice resulted in benefits to the health and welfare of society. Bad regulation, on the other hand, can have numerous adverse effects on society, including increased bureaucracy, reduced or even halted economic development, and negative views of national regulatory bodies, which is detrimental both to them and to the country as a whole. In such a battle, there are no winners, only losers.

Finally, we would like to quote from an interesting editorial published in *Science* on the effective regulatory oversight of new technologies, namely regulatory research.

Science and The population

Editorial - Science, 2001; 292: 1021

How best to conduct the dialogue in a way that fosters trust?

Science and The population

Robert M. May

"Scientific understanding has probably expanded more in the past 50 years than in all previous history. Its applications have made our lives better. As one example, global average life expectancy at birth 50 years ago was around 46 years and today is 64 years; over this interval, the average difference between developed and developing worlds has shrunk from 26 to a still shameful 12 years. Increasingly, however, we recognize unintended adverse consequences of our well intentioned activities: Witness climate change and the loss of biological diversity. More regionally, we worry about the ethics of, a risk from, possible applications of advances in bioscience, such as stem cell cloning, genetically modified crops, and xenotransplants.

In the United Kingdom, and in Europe more generally, every week seems to bring a new committee, report, or debate on science and the population. And a good thing too. I believe we need to do a better job of deliberately asking what kind of world we want subject to the opportunities offered by scientific advances and the constraints that science clarifies rather than just letting things happen. A recent poll shows that 84% of the Britains think that scientists and engineers make a valuable contribution to the population and 68% think that scientists want to make life better for the average person. But the real issue, as the same poll showed, is that roughly 50% thought that the pace of current scientific advance was too fast for government to keep up with through effective oversight and regulation. So how best to conduct the dialogue, as old as democracy itself, between government policymakers and the public in complex scientific areas, in a way that fosters trust?"

Sir Robert May is president of The Royal The population of London.

Supplementary references are available on Science Online at www.sciencemag.org/cgi/content/fulV292/SS19/l021/DCl

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