Global Benchmark Report:

IT Product Safety Regulations and their Impact on the Ease of Doing Business 2017

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Executive Summary

In an effort to assess international regulatory practices impacting information technology (IT) products and recommend positive steps for governments to identify, prevent, and reduce impediments to trade, manufacturing, and supply chain operations, the Information Technology Industry Council (ITI) has published the first of its Global Benchmark Reports, *IT Product Safety Regulations and their Impact on the Ease of Doing Business*. With inspiration from the World Bank's annual Doing Business Report, ITI has scored and ranked 44 countries and the European Union (EU) according to how their product safety regulations for IT equipment impact the ease of doing business for manufacturers seeking to import and sell their products in these markets.

Highlights of the study included the following:

- Within the group of countries that have product safety requirements for a broad range of IT equipment, the median score for ease of doing business was 22 out of a perfect score of 30.

- Based on its Low Voltage Directive (LVD) regulatory model for product safety, the EU received one of the highest scores of 28.

- Most countries with broad requirements, including the United States, Canada, Mexico, Russia, South Korea, and China, were ranked between 20 and 24 out of 30, with Argentina at 17 and South Africa at 15.

- With a total score of 7, India ranked last, due to onerous requirements from its Compulsory Registration Order.

- Within the group of countries that have product safety requirements for a narrow range of IT equipment, the median score for ease of doing business was 26 out of a perfect score of 30.

- Among the remaining countries that imposed safety requirements for a narrow scope of IT equipment (for example, AC adapters), Australia, New Zealand, and Ecuador led with perfect scores of 30 and Colombia was ranked lowest with a score of 19.

ITI concludes that the ease of doing business in most countries could be greatly improved by keeping regulatory intervention to a minimum, following good regulatory practices, and not imposing unjustified impediments on trade, manufacturing and supply chain operations. The report spotlights several countries' product safety regulatory systems, which vary widely. Drawing from the World Trade Organization's (WTO) Agreement on Technical Barriers to Trade (TBT Agreement), which governs the process by which countries enact technical regulations relating to IT equipment and other products, ITI provides industry recommendations for policymakers to improve their rankings. With many countries planning to transition to a new international safety standard for IT equipment in the coming months and years, following these steps may be essential to prevent further growth in non-tariff trade barriers (NTBs) resulting from unnecessarily complex and burdensome requirements.

Introduction

Information technology (IT) companies seeking to do business globally must contend with a complex landscape of technical regulations. Not surprisingly, regulatory compliance poses one of the greatest challenges to the ease of doing business and is a critical factor in whether these companies succeed or fail. This report, *IT Product Safety Regulations* and their Impact on the Ease of Doing Business, is the first in a series of ITI benchmark reports to rank governments based on their technical regulations placed on IT products. It is intended to be a yardstick and a guide for policymakers to better understand the impact of their technical regulatory requirements on the ease of doing business. We also share recommendations based on global norms and best practices to promote the creation of policies that promote, rather than hinder, IT trade and investment.

ITI is the global voice of the tech sector. We advocate for public policies that advance innovation, open markets, and enable the transformational economic, societal, and commercial opportunities our companies are creating. Our membership includes the entire spectrum of technology companies ranging from internet companies to manufacturers of hardware and networking equipment to software developers. In both the United States and in countries around the world, ITI navigates the relationships between policymakers, companies, and non-governmental organizations, providing creative solutions that advance the development and use of technology around the world.

Every year, the World Bank publishes its "*Doing Business Report*" ranking 189 economies according to their ease of doing business.[1] The report provides a helpful snapshot and longer-term benchmark of how "business friendly" these countries are. Policymakers use the report to evaluate whether regulations are meeting their objectives and to determine where policy changes are needed. The ranking is a measure of how their respective countries stack up against others in terms of creating an environment in which entrepreneurial efforts are likely to succeed and where foreign businesses are drawn to trade and investment opportunities.

Similarly, our *IT Product Safety Regulations and their Impact on the Ease of Doing Business* is intended to provide a measurement of where countries stand based on their requirements for IT product safety and to share industry insights to help regulators achieve their public policy objectives while supporting the ease of doing business by keeping regulatory intervention to a minimum, following good regulatory practices, and not imposing unjustified impediments on trade, manufacturing and supply chain operations.

The Importance of Safe and Legal Products

This report focuses on mandatory IT product safety requirements in 44 countries and the EU. Governments seek to protect their citizens from products that could cause injury or property damage (such as electrical shock or fire). As a result, product safety requirements are one of the first types of regulations a government is likely to impose on products, including IT products, and they are the most prevalent of international technical regulations with which IT companies must comply.

When it comes to product safety, a manufacturer's fundamental objective is for its IT products to be safe for their intended use and to be compliant with the applicable government regulations of those countries in which the company markets and sells them. Typically, a company gains assurance that its products are safe

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1   The World Bank scores countries on regulations affecting 11 areas of the life of a business: its establishment, steps required to obtain construction permits and connection to the electrical grid, registering the property, getting credit, protecting minority investors, paying taxes, trading across borders, enforcing contracts and resolving insolvency, and regulations that impact the labor market.

by employing Hazard-Based Safety Engineering techniques or an equivalent evaluation to identify hazardous energy that goes into or is within the product, ensuring safeguards are designed into the product that address the identified hazards, and demonstrating that the applied safeguards mitigate these hazards.

Prior to a product release, a company makes sure that its products are legally compliant by identifying which product standards and regulations apply to a particular product or family of products, by ensuring the performance of all appropriate product regulatory testing and evaluation, and by demonstrating that its products comply with applicable product regulations and regulatory standards in those countries where the company authorizes delivery of the product. A company employs engineers, procures laboratory resources, invests in testing facilities, and bears the costs of product testing and certifications by third-party organizations to carry out this work.

A company that fails in its commitment and delivers products that are unsafe or that do not comply with legal requirements will likely compromise its access to markets, diminish its relationships with government authorities, adversely impact its customers, and potentially face legal action, all of which will damage its brand and reputation. Manufacturers recognize that regulations serve a critical role in protecting consumers from harm and setting baseline requirements to preserve and advance public interests. However, manufacturers also believe that governments' regulatory measures should be consistent with achieving legitimate regulatory objectives, avoid imposing unnecessary burdens on society, and minimize adverse impacts on citizens and business. Companies support product regulations that follow appropriate regulatory practice. Well-designed and implemented product regulations can set a necessary baseline for manufacturers, create a growth-enhancing competitive environment, and establish a level playing field among domestic and foreign companies.

As a rule, companies prefer to manufacture products for the world market instead of "localized" products for a specific country. This provides economies of scale for product design, manufacturing, and delivery. Unfortunately, when governments pursue regulatory requirements that are unique and burdensome in comparison to global norms, companies lose these economies of scale, and struggle to navigate, innovate and adapt. Unique and burdensome regulations are not just an inconvenience – they challenge profitability with new costs and create great uncertainty, driving companies to make radical decisions to mitigate the risks.

For instance, a company may decide to pass on these costs to consumers in the form of higher product prices. Or a company may decide to stop selling certain product models or to reduce local investments because of the high regulatory costs and unwarranted delays due to interrupted shipments or other penalties. This is especially relevant for small and medium sized companies that may not have the resources to address such problems. In turn, consumers and both developed and developing economies are disadvantaged when regulations drive up the cost of IT products and limit access to cutting-edge technology.

The Ranking

Based on their knowledge of and experience with various compliance systems around the world, senior compliance managers from ITI's member companies scored each country's or region's product safety requirements by criteria identified by the WTO Technical Barriers to Trade Committee (TBT Committee) as non-tariff measures that have a critical impact on companies' ability to sell their IT products in the global marketplace.

Among other factors, these criteria include an evaluation of a country's regulatory impact assessment prior to regulating, a determination of whether product safety regulations are based on relevant international standards, and whether the compliance process is predictable for those seeking to import and sell in the market. The full set of criteria and scoring explanation are described in more detail in a following section of the report.

In order to compare IT product safety regulations of a similar type, ITI has divided the ranking into two categories: 1) requirements that impact a broad range of IT products and 2) those that impact a select few IT products.

The following charts present an overview of each country's/region's total score and ranking. For the complete breakdown of scores for countries, see Table 1 and Table 2.

Broad Scope

The following is the ranking of product safety regulations for countries that regulate for a broad scope of IT products.

Rank	Country/Region	Regulation	Score
1	Hong Kong	Electrical Ordinance Law (Home use products)	30
1	Singapore	Consumer PRotection Regulation	30
3	Taiwan	BSMI Safety Requirements	28
3	European Union	Low Voltage Directive	28
5	Uzbekistan	EuroAsian Commission (Customs Union)	26
6	Kazakhstan	EuroAsian Commission (Customs Union)	24
6	Kenya	Pre-shipment Verification of Compliance	24
6	Russia	EuroAsian Commission (Customs Union)	24
6	Mexico	IT Product Safety	24
6	Canada	IT Product Safety	24
11	Nigeria	Pre-shipment Verification Compliance	23
11	Rwanda	Pre-shipment Verification Compliance	23
11	Tanzania	Pre-shipment Verification Compliance	23
11	Uganda	Pre-shipment Verification Compliance	23
11	Zambia	Pre-shipment Verification Compliance	23
16	South Korea	KC Mark	22
16	Belarus	EuroAsian Comission (Customs Union)	22
16	Ukraine	MEDT NAAU	22
19	China	China Compulsory Certification	20

19	United States	OSHA (Workplace safety)	20
21	Argentina	IT Product Safety	17
22	South Africa	NRCS	15
23	India	Compulsory Registraton Order	7

Narrow Scope

The following is the ranking of product safety regulations for countries that only regulate for a narrow scope of products (e.g. only ac adapters or batteries).

Rank	Country/Region	Regulation	Score
1	Austrailia	Electrical Safety Act	30
1	New Zealand		30
1	Ecuador	Regulation for power cords, batteries, ac adaptors/chargers	30
4	Cambodia	Safety Regulation of 2004	28
5	Japan	Den-An Safety Law (ac adapters and batteries)	26
6	Malaysia	Suruhan Jaya	22
7	Thailand	TISI Regulation for rechargable batteries and uninterruptiblre power supplies (UPS)	20
7	Brazil	INMETRO REgulations for power cords, mobile phone batteries and chargers	20
7	Colombia	Regulation for UPS	20

Overview of Findings

All of the ITI member company representatives that contributed to this report agreed that regulatory uncertainty poses some of the greatest challenges to their companies' ability to succeed in markets around the world, in addition to hindering global economic growth. To address this issue, they encouraged the development and adoption of globally aligned, internationally recognized standards and regulatory best practices to help prevent an ever-growing patchwork of localized rules and regulations companies must navigate.

Within global supply chains, adding complexity translates into additional time and cost to bring cutting edge products to the marketplace and for consumers this means a lack of access to critical technologies that bring economic and social benefits. With many countries currently planning to transition to a new model of product safety standards for IT equipment, participants in this work also agreed that the complexity of regulations will only continue to grow over the next few years.[2]

Some highlights:

- Within the group of countries that have product safety requirements for a broad range of IT equipment, the median score for ease of doing business was 22 out of 30 (with 30 being the top score).

- Based on its LVD regulatory model for product safety, the EU received one of the highest scores of 28.

- With a total score of 7, India ranked last due to onerous requirements of its Compulsory Registration Order.

- Most countries with broad requirements, including the United States, Canada, Mexico, Russia, South Korea, and China, scored between 20 and 24 out of 30, with Argentina at 17 and South Africa at 15.

- Among the remaining countries that imposed safety requirements for a narrow scope of IT equipment (e.g. AC adapters), Australia, New Zealand, and Ecuador led with perfect scores of 30 and Colombia was ranked lowest with a score of 19.

- The median for countries with narrow requirements was 26.

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2   Many countries are now considering moving to IT product safety regulations based on second or third editions of the international standard, ISO/IEC 62368, a hazard based approach to product safety.

A Closer Look

To better understand the ranking and the wide range of scores for each criterion, we now take a closer look at some examples of product safety regulations in several countries and in the EU. We briefly describe what each country does to regulate, highlighting best practices as well as pointing out where there is room for improvement. As regulatory systems continue to evolve, we note some recent changes to these programs and expectations for the future.

Global Ranking of ICT Product Safety Regulations - Overview
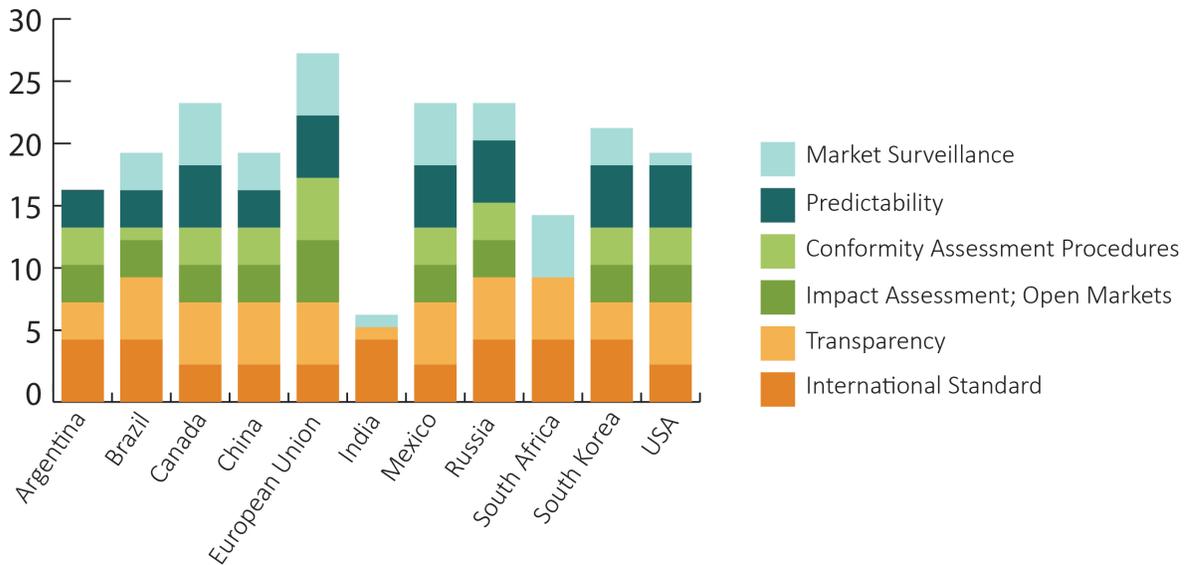
European Union (Overall Score: 28)

The EU's LVD for product safety received a top ranking. The 28 EU Member States have put in place a single product safety framework that greatly facilitates the ease in doing business. LVD requirements are based on European safety standards that are mostly aligned with commonly accepted international safety standards. The areas that are not aligned have caused problems for companies and is reflected in the EU's scoring on its use of international standards. The EU's LVD program scored high on all other categories. The region's transparency ranking was very good, as there is ample time for a company to learn and prepare for changes to the requirements. Manufacturers can use a competent lab (including their own) anywhere in the world to test their products, and they can issue a Supplier's Declaration, where manufacturers test and provide documentation to regulators as proof. Third-party testing and certification, which is performed by an independent lab, are optional and at the discretion of the company. The EU Member States also participate in market surveillance, using the Rapid Exchange of Information (EU RAPEX System) to exchange their audit findings. To provide clear direction and help companies understand the rules and requirements, the EU provides readily available information such as "The Blue Guide".[3] Overall, the EU scores best by having a clear, simple product safety regulation that has been effective in ensuring safe products for its citizens and in supporting companies that can operate in an open, transparent market.

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3   See: http://ec.europa.eu/DocsRoom/documents/18027/

Japan (Overall Score: 26)

Currently, Japan's product safety requirements for IT equipment are narrow in scope. Japan only includes AC adapters and batteries and are based on internationally accepted standards. Japan scores high for regulatory predictability and accepts international test reports. In 2020, Japan is expected to publish significant updates to its Den-an Law that governs product safety for IT. These changes will include a broad expansion of products that must meet safety requirements, with inspections on all finished products. As it considers updates to its Den-An law, the government of Japan's consultation process has been largely transparent, with international stakeholder participation and the publication of regular updates. However, as of today there are many unknown details such as which products will be in scope and which will be exempt from the requirements. In addition, there are industry concerns with early reports that manufacturers will have to retain at least three years' worth of product safety records and have them available for Japan's regulatory authorities.

United States (Overall Score: 20)

The United States doesn't have a mandatory safety regulation for IT products marketed or sold. Instead, the U.S. Occupational Safety and Health Administration (OSHA) regulates IT products used in the workplace. OSHA regulation is based on a U.S. safety standard which has some significant differences from the most commonly accepted international safety standard. As a result, the U.S. scored lower in this category. OSHA's policymaking is very transparent, with a public commenting process strictly followed through notices in the Federal Register. ITI members report that OSHA performs a limited, obligatory regulatory impact assessment. Most importantly, OSHA's Nationally Recognized Testing Laboratory (NRTL) program is unique to the U.S. preventing manufacturers from leveraging third-party test reports and certifications already obtained outside of the NRTL program. Even with these shortcomings, respondents rated OSHA high for predictability; if the company follows the rules in this unique U.S. regulatory program, then companies have high confidence that the products can be tested and certified on time. However, OSHA scored very low on market surveillance, as OSHA requires two or more third party factory audits of products per year.

Argentina (Overall Score: 17)

Argentina requires electric and electronic products to be safety certified to the Argentina standard or to the international standard. This regulation covers a broad range of IT products. Under the rules, a company is required to have its products tested by a test lab in Argentina and undergo annual factory inspections. Argentina rated low on its market surveillance program because it is excessive to have a sample product tested each year by a lab in Argentina to verify its compliance. In 2015, Argentina issued a resolution that tightened existing requirements, adding new requirements on labeling, and removing exemptions of some products. Companies participated in a public comment process and raised serious concerns. The new government of Argentina held further dialogue with stakeholders and issued another resolution to repeal many of the requirements from 2015. Looking ahead, ITI expects Argentina's ease of doing business will improve, as the government appears to be open to review its regulations, to streamline and align with international practices, and to follow good regulatory practices.

India (Overall Score: 7)

Since its implementation in 2012, India's Compulsory Registration Order (CRO) has created major obstacles to doing business in this rapidly growing market. Among the IT companies surveyed for this report, all believe that the CRO has created a unique, overly burdensome and unnecessarily complex regulatory environment for product safety. The Indian safety standard referenced by the CRO is based on the internationally accepted equivalent standard to which IT products are already tested. Despite this, manufacturers must still submit

products from each factory for testing and registration by government approved labs located in India, rather than accepting international test reports from respected labs located in other parts of the world. Limited capacity and technical expertise of the Indian labs have also led to bottlenecks and manufacturers have been forced to switch labs quickly following various lab suspensions. Without first addressing existing issues with the CRO, Indian authorities have instead expanded the scope of the requirements once and are currently looking to expand it a second time.

Unfortunately, India has not taken a risk-based approach to regulating product safety, as evidenced by the inclusion of professional products such as servers and storage equipment in the CRO. As a result, manufacturers are struggling to comply and they have repeatedly asked the Indian regulatory authority to align its conformity assessment requirements with international norms, to exempt or reduce the burden on low-risk products, and to focus on improving the safety of products that pose the greatest risk to the Indian public. However, the Indian government has not made any such fundamental changes. Compounding the challenge, modifications to the CRO are often communicated via updates to an online list of frequently asked questions (FAQs), resulting in a lack of predictability. In addition, an insufficiently open and transparent decision-making process has contributed to confusion and disruptions in complex, global IT supply chains, impacting the ability of the tech industry to meet the needs of customers in India.

As this report goes to press, authorities in India have been canceling registrations for non-safety related reasons, affecting the import of hundreds of product lines.

Table 1. Ease of Doing Business Ranking for Broad IT Product Safety Requirements

Country/ Region	International Standards	Transparency	RIA and avoiding obstacles to trade	Portability of conformity assessment	Predictability	Market Surveillance	Score
Hong Kong	5	5	5	5	5	5	30
Singapore	5	5	5	5	5	5	30
Taiwan	5	5	5	3	5	5	28
European Union	3	5	5	5	5	5	28
Uzbekistan	5	5	5	3	3	5	26
Kazakhstan	5	5	3	3	5	3	24
Kenya	5	5	3	1	5	5	24
Russia	5	5	3	3	5	3	24
Mexico	3	5	3	3	5	5	24
Canada	3	5	5	5	5	1	24
Nigeria	5	5	3	0	5	5	23
Rwanda	5	5	3	0	5	5	23

Country/Region							Score
Tanzania	5	5	3	0	5	5	23
Uganda	5	5	3	0	5	5	23
Zambia	5	5	3	0	5	5	23
South Korea	5	3	3	3	5	3	22
Belarus	5	5	3	3	3	3	22
Ukraine	5	5	3	3	3	3	22
China	3	5	3	3	3	3	20
United States	3	5	3	3	5	1	20
Argentina	5	3	3	3	3	0	17
South Africa	5	5	0	0	0	5	15
India	5	1	0	0	0	1	7

Table 2. Ease of Doing Business Ranking for Narrow IT Product Safety Requirements

Country/Region	International Standards	Transparency	RIA and avoiding obstacles to trade	Portability of conformity assessment	Predictability	Market Surveillance	Score
Australia	5	5	5	5	5	5	30
New Zealand	5	5	5	5	5	5	30
Ecuador	5	5	5	5	5	5	30
Cambodia	5	3	5	5	5	5	28
Japan	5	5	3	5	5	3	26
Malaysia	5	3	3	3	5	3	22
Thailand	3	3	3	3	5	3	20
Brazil	5	5	3	1	3	3	20
Colombia	3	3	5	3	5	1	20

Criteria and scoring

Since its implementation in 1995 with the establishment of the WTO, the TBT Agreement[4] has been an essential tool to help prevent and address the use of technical requirements as unnecessary barriers to trade. The TBT Agreement establishes rules and procedures regarding the development, adoption, and application of voluntary product standards, mandatory technical regulations, and conformity assessment procedures (such as testing or certification) used to determine whether a particular product meets such standards or regulations. TBT Agreement requires WTO members develop and apply standards, technical regulations, and conformity assessment procedures on a nondiscriminatory, transparent basis, using relevant international standards and guidelines, when appropriate.[5]

The TBT Agreement provides a solid model for good regulatory practice, and because of this, we have used it as the basis for scoring countries on their ease of doing business. Below, we describe each criterion and how the TBT Agreement asks WTO members to apply it. We also provide a metric by which it has been scored for this report.

1.   Use of international standards with minimal national deviations

The TBT Agreement calls on WTO members to use relevant international standards, or the relevant parts of them, as a basis for their technical regulations and to use relevant international recommendations and guides, or relevant portions of them, as the basis for their conformity assessment procedures. The TBT Agreement, however, does not require the use of relevant international standards, guides and recommendations if they would be ineffective or inappropriate to fulfill the WTO member's "legitimate objectives" (Arts. 2.4 and 5.4).

In addition, WTO members should participate "within the limits of their resources" in the preparation by international standardization bodies, of international standards for products for which they either have adopted, or expect to adopt, technical regulation, and in the elaboration of international guides and recommendations for conformity assessment procedures." (Art.2.6 and 5.5).

Score Criteria:
   0   National requirements not aligned with relevant international standards.
   1   National requirements harmonized with relevant international standards with additional National Deviations or Group Differences having a significant impact.
   3   National requirements harmonized with relevant international standards with additional National Deviations or Group Differences having a minimal impact.
   5   National requirements fully harmonized with relevant international standards without any National Deviations or Group Differences.

2.   Transparency

To help ensure transparency, the Agreement requires Members to publish a notice at an early stage and notify To help ensure transparency, the TBT Agreement requires WTO members to publish a notice at an early stage and notify other members through the WTO Secretariat when it proposes to adopt a technical regulation or conformity assessment procedure and to include in the notification a brief indication of the purpose of the proposed measure. These obligations apply whenever a relevant international standard, guide, or recommendation does not exist or the technical content of a proposed technical regulation or conformity

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4   See: https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm
5   See: https://ustr.gov/trade-agreements/wto-multilateral-affairs/wto-issues/technical-barriers-trade

assessment procedure is not in accordance with the technical content of relevant international standards, guides, or recommendations. In such circumstances, members must allow "reasonable time" for other members to comment on proposed technical regulations and conformity assessment procedures, which the TBT Committee has recommended to be "at least 60 days" (G/TBT/26), and take comments it receives from other members into account (Art. 2.9 and 5.6).

The TBT Agreement establishes a Code of Good Practice that is applicable to voluntary standards and obligates WTO members and standardizing bodies that have accepted it to publish a work program every six months containing the standards it is currently preparing and to give interested parties at least 60 days to comment on a draft standard; once the standard is adopted it must be promptly published (Annex 3).

The TBT Agreement also requires that all technical regulations and conformity assessment procedures be promptly published (Art. 2.11 and 5.8).

In addition, the TBT Agreement requires each WTO member to establish an inquiry point to answer all reasonable questions from other members and interested parties and to provide documents relating to technical regulations, standards, and conformity assessment procedures adopted or proposed within its territory (Art. 10.1).

Score Criteria:
   0 No application
   1 Some application but inconsistent or incomplete
   3 Adequate application
   5 Broad, comprehensive application

3.   Regulatory impact assessments and avoiding unnecessary obstacles to trade

When preparing or applying a technical regulation, a WTO member must ensure that the regulation is not more trade-restrictive than necessary to fulfill the member's legitimate objective (Art. 2.2).

The obligation to avoid unnecessary obstacles to trade applies also to conformity assessment procedures. Conformity assessment procedures should not be prepared, adopted or applied with a view to – or with the effect of – creating unnecessary obstacles to international trade; they must not be stricter than necessary to provide adequate confidence that products conform with applicable requirements (Art. 5.1.2).

WTO members are obligated to confirm the need for government intervention and set policy objectives accordingly (Art. 2.2 and Art. 5.1.2). They must identify alternatives to regulation, consider the option of not regulating, and consider the option of improving existing regulations rather than introducing new ones.

Assessing regulatory impact and avoiding unnecessary obstacles to trade also entails using relevant international standards as a basis for regulatory measures; recognizing the equivalence of other WTO members' technical regulations; recognizing the results of conformity assessment in other members; defining available technical infrastructure; and using international and regional systems for conformity assessment. This process should also ensure any proposed measures are non-discriminatory (Art. 2.1, 2.2, 5.1, 5.2).

Performing a regulatory impact assessment requires the use of data (e.g. quantitative and/or qualitative) to identify impacts of alternatives; conducting cost-benefit analysis of alternatives (taking account of both direct and indirect impacts); assessing trade restrictiveness of alternatives; and assessing whether alternatives impose different requirements (including with respect to conformity assessment procedures) on foreign manufacturers (Art. 2.1, 2.2, 5.1, 5.2).

Score Criteria:
> 0 No application
> 1 Some application but inconsistent or incomplete
> 3 Adequate application
> 5 Broad, comprehensive application

4. Portability of conformity assessment results

The ease of doing business internationally depends on a company's ability to leverage economies of scale, including those for testing and certification; there is great benefit from testing or certifying a product once and using these results to meet requirements in multiple markets, without the need for duplicating this work. In order to promote the portability of conformity assessment results, the TBT Agreement requires WTO members shall:

- Whenever practicable, formulate and adopt international systems for conformity assessment and become members thereof or participate therein (Art.2.6 and 5.5).

- Give positive consideration to accepting as equivalent technical regulations of other members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations (Art. 2.7).

- Ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures, in cases where relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent (Art. 5.4).

- Play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of guides and recommendations for conformity assessment procedures, with a view to harmonizing conformity assessment procedures on as wide a basis as possible (Art. 5.5).

- Recognize "whenever possible" the results of conformity assessment procedures (e.g. test results or certifications), provided the member is satisfied that those procedures offer an assurance of conformity that is equivalent as its own. (Art. 6.1 – without such recognition, products might have to be tested twice, first by the exporting country and then by the importing country.) The agreement recognizes that members may need to consult in advance to arrive at a "mutually satisfactory understanding" regarding the competences of their respective conformity assessment bodies (Art. 6.1).

The TBT Agreement also encourages WTO members to enter into negotiations to conclude agreements providing for the mutual recognition of each other's conformity assessment results (i.e., mutual recognition agreements or MRAs) (Art. 6.3).

Score Criteria:
> 0 No application
> 1 Some application but inconsistent or incomplete
> 3 Adequate application
> 5 Broad, comprehensive application

5. Predictability of outcome

The TBT Agreement requires consistency over time and between affected parties in applying the rules by the

authority and by the test labs. Completion of conformity assessment services, such as testing, on time and at agreed costs.

Score Criteria:
- 0 Unpredictable. Companies regularly must escalate issues to address surprises.
- 1 Mostly unpredictable. Companies are often unsure of outcomes.
- 3 Mostly predictable. The application of rules and completion of conformity assessment services are generally as expected.
- 5 Predictable. There are very few unexpected outcomes.

6. Market Surveillance Program

The WTO member government authority may have a market surveillance program to check on the compliance of production units after granting initial approval or certification of a product. The kinds of requirements under a market surveillance program include marketplace sample verification, visual verification, product test verification, factory audits and renewal of approvals/certifications.

Score Criteria:
- 0 Annual or bi-annual product retesting by a laboratory in-country (Argentina Model).
- 1 Two or more per year third-party factory audit of products (North American Model).
- 3 Annual third-party Factory Audit based on quality management (EU Model).
- 5 Market/Customer sampling or Complaint Driven surveillance (Global, EU Model).

7. Other considerations

Fees: In this scoring, ITI has not included information about fees directly related to the product safety approval process. For example, fees associated with certificate or license issuance typically range from about $1,000 to $4,000. In addition, there may be fees associated with renewal of third party certificates or licenses, factory surveillance, or provision of product samples for unit verification testing. These fees are also exacerbated when there are requirements for in-country testing of equipment. While such fees may have a cumulative impact, they are generally far less than the indirect costs associated with delays in getting products to market and costs resulting from greater regulatory uncertainty.

Product labeling: Regulatory requirements that include mandatory product labeling can also have a significant impact on the ease of doing business. Rules that require special types of labels such as holograms or those that force manufacturers to obtain labels with serial numbers that must be applied in a specific order to a large number of products are extremely burdensome. Additionally, products may have to be redesigned in order to meet labeling provisions. This often occurs with very small products with limited surface area that must accommodate a wide range of international regulatory marks and information.

This impact can be reduced when labels are allowed to be on the product, on the packaging, or in accompanying materials such as user manuals, when the products are below a minimum size. Rules that do not include special printing instructions and those that permit manufacturers to mass produce the labels without prior communications with the regulating authority are also beneficial. Optimally, regulations may allow for the use of electronic labeling (e-labeling), where labeling information can be displayed on a device's screen or through the use of a machine-readable code (e.g. QR code), or web link on the product or packaging. There is currently a standard for e-labeling in development in the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). Once adopted, this standard will help in the effort to have countries align their e-labeling requirements globally.

Recommendations

When considering a new regulation, a government should set multiple objectives. Foremost, the government should have a clear goal that can best be achieved through regulation. Additionally, the government should assess and seek to minimize the impact of the regulatory measure on manufacturers and importers, including how the regulation will affect market access. It should also encourage investment and the creation of an open environment for innovative and new technologies, and foster competition among the players in the sector, all of which have the desired effect to improve consumer choice and lower costs.

A government should conduct an impact assessment of relevant alternatives on the basis of a balanced consideration of benefits and costs before it drafts regulatory measures. The relevant alternatives should include the assessment of non-regulatory options where feasible and applicable, including a "do nothing" option. This impact assessment should be evidence-based using the best available data, and all factors (both qualitative and quantitative) should be considered, including potential economic, environmental, public health and safety, social, and distributive impacts, as well as the degree and nature of the risks involved.

When the impact assessment demonstrates regulatory measures are necessary, a government has the option to set requirements to local, national, or international standards. As a general rule, a regulation that references international standards for its technical requirements helps the ease of doing business by harmonizing product requirements across borders.

A government has a range of options in setting Conformity Assessment (CA) procedures. If the government employs an approach to CA procedures that is not sufficiently rigorous, it may not adequately ensure compliance. On the other hand, a government that employs an overly rigorous approach adds too much cost and unnecessary burdens on companies. Ideally, a government should set a conformity assessment approach which minimizes the burden and aims for simplicity to achieve a sufficient level of confidence.

Where relevant, feasible, and consistent with regulatory objectives, the government should consider each of the various IT product categories and its associated safety risks (e.g., the likelihood of occurrence, the degree of injury, etc.).

For example, a wireless mouse operated by two AAA batteries poses a different level of risk than a notebook and its AC adapter, which is different still to a data server under the control of – and operated by – engineering professionals. The government should not require these vastly different IT product categories to undergo the same CA procedures. The government should instead consider exemptions of very low risk product categories from regulatory measures. Also, the government should recognize that Type Approval CA procedures are not always necessary as some products are low risk and companies can issue a Supplier's Declaration of its products' conformance to the requirements.

In setting up its product regulation, a government's choices will either support an open market or hinder trade and competition. Regulatory measures should be designed to avoid unnecessarily divergent or duplicative requirements with other countries, when possible. The government should participate in mutual recognition agreements with other governments, or recognize the testing results and approvals of third-party labs participating in private-sector mutual recognition agreements.

The government should choose to be open and transparent when drafting new or changing existing product regulations and support participation by citizens, industry and other stakeholders with adequate time, opportunity, and tools (including the internet) for stakeholder input and public comment at appropriate stages

of the policymaking process in advance of their final adoption. Doing so allows companies to prepare for new or changing requirements, provides an opportunity to provide constructive feedback and voice concerns, and creates certainty of continuous supply chain flow (e.g. no product holds, on-time changes in design, components, manuals, and labels).

By keeping the CA procedures simple, the government can reduce the headcount of those overseeing and administering its CA program, and assign more resources to run a solid market surveillance program. The deployment of a good market surveillance program is a key means of controlling product compliance in the market. The market surveillance program should include random sampling of products in the marketplace. A visual inspection of the product can be conducted to see if the requisite labels and markings are in place. If the authority has doubts, it can require a market sample unit undergo a selective testing or contact the company with questions. The government should prioritize its effort on those companies that pose serious risks and on those who are most likely to fail to comply. Greater scrutiny should be placed on repeat offenders. The benefit is two-fold, as a deterrent for bad actors and an incentive for good actors.

When a product is alleged to pose a hazard and/or not conform to the requirements, the company should be allowed to respond, to provide additional supporting information, or to request further investigation.

If the alleged incident is confirmed to be true, the government should impose the appropriate intervention actions. Examples of intervention actions include, but are not limited to, formal warnings with a remediation plan, product hold, product recall, discontinuation of sales, and criminal fines and penalties. The regulatory authority should follow the principle of proportionality in considering the right intervention action. For a non-compliance event which does not result in a safety hazard (such as a minor administrative non-compliance or mislabeling) a warning with remediation plan may be appropriate. For a non-compliance event which directly poses a safety hazard, the intervention action should be to quickly remove unsafe products from the market (e.g., by lot numbers or range of date codes) and to deter future unsafe products from being released into the marketplace. In the case where the company is purposely circumventing requirements, criminal fines and penalties may be appropriate.

The government should monitor and evaluate the effectiveness of existing regulatory measures on a periodic basis through a transparent procedure. Companies and stakeholders should be allowed to provide input into these evaluations. And the government should modify, expand, simplify, or repeal its regulatory measures in light of what has been learned in the evaluation, with the aim to minimize burden in achieving its regulatory objectives.

Conclusion

According to the WTO, non-tariff measures by governments have almost twice the impact on the ease of doing business as tariffs. Many of these non-tariff measures are the result of their countries' unique requirements that, together, have created a global patchwork of standards and conformity assessment requirements, including those for IT product safety. Without regulatory certainty and predictability, costs increase for manufacturers that must navigate complex rules as well as for the imposing governments that must expend more resources to manage them. Perhaps the biggest cost is the reduced access for consumers to technologies that enable fundamental social and economic benefits.

IT companies rarely manufacture products for a single country; they make products for the global market. Accordingly, to reap the full benefits of trade and investment in IT innovations, countries must choose to forego unique approaches to product safety, keep regulatory intervention to a minimum, follow good

regulatory practices, and not impose unjustified impediments on trade, manufacturing and supply chain operations. In this way, improving the ease of doing business in their home country supports a stable, global regulatory environment that benefits all stakeholders while creating new societal and economic growth opportunities for their citizens by adopting and leveraging the innovations being created by the tech sector.

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