# Global Benchmark Report

ITE Electromagnetic
Compatibility (EMC) Regulations
and their Impact on the Ease of
Doing Business

2021



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About ITI. ITI advocates for public policies that promote innovation, open markets, and enable the transformational economic, societal, and commercial opportunities that our companies are creating worldwide. Our members represent the entire spectrum of technology: from internet companies, to hardware and networking equipment manufacturers, to software developers. ITI's diverse membership and expert staff provide a broad perspective and intelligent insight in confronting the implications and opportunities of policy activities around the world. Visit <a href="http://www.itic.org/">http://www.itic.org/</a> to learn more. Follow us on <a href="mailto:Twitter">Twitter</a> for the latest ITI news.

# **Executive Summary**

The Information Technology Industry Council (ITI) has published the 2021 Global Benchmark Report, *ITE EMC Regulations and their Impact on the Ease of Doing Business* to assess the impact of international electromagnetic compatibility (EMC) regulatory practices that affect information technology equipment (ITE). This report focuses on programs worldwide that address non-wireless, non-telecom regulatory requirements for EMC. This report recommends positive steps for governments to identify, prevent, and reduce impediments to trade, manufacturing, and supply chain operations. With inspiration from the World Bank's annual Doing Business Report, ITI has scored 15 countries and the European Union (EU), Eurasian Economic Union (EAEU), and the Gulf Cooperation Council (GCC) according to how their EMC regulations for ITE impact the ability to do business for manufacturers seeking to import and sell their products in these markets.

The World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement has been an essential tool to raise awareness of and address barriers to trade resulting from technical regulations aimed at ensuring ITE electromagnetic compatibility. The TBT Agreement provides an appropriate baseline framework for good regulatory practices and we have used it to form the basis for scoring countries on their ease of doing business. Based on their knowledge of and experience with various compliance systems around the world, senior compliance managers from ITI's member companies have scored each country's or region's EMC requirements using criteria established through key provisions in the TBT Agreement, including those governing international standards, conformity assessment, and notification and transparency that have a critical impact on companies' abilities to sell their ITE products in the global marketplace. Based on ITI's scoring methodology, we found that:

- Four countries scored a perfect 30 points: Australia, Japan, Morocco, and New Zealand. The EMC programs in these countries feature aspects that are essential for ease of doing business, such as incorporating international standards by reference, including ample transition times, accepting supplier's declaration of conformity (SDoC), and providing high levels of transparency and predictability.
- The United States' 24-point score was impacted by its inclusion of a unique emissions test standard for EMC testing, ANSI C63.4, whereas most countries in the world allow testing to international CISPR 22 and/or CISPR 32 requirements.
- The EU scored only 22 of 30 points. Although the EMC Directive allows the use of SDoC, EU scores in avoiding obstacles, international standards, and predictability are significantly hampered by systemic concerns around reliance on regional standards, backlogs in the publication of standards granted a presumption of conformity, and regional deviation from widely accepted international standards, including as a result of interventions by Harmonised Standards (HAS) consultants. We encourage the European Commission to review its current policies to ensure that the review of harmonized standards by HAS consultants does not unduly delay their development and

<sup>&</sup>lt;sup>1</sup> With the exception of Belarus (EAEU), all countries assessed either individually or as part of a governing regional entity in this report are members of the WTO and are parties to the WTO TBT Agreement and obligated by the commitments therein.

- publication or create divergences with international standards that could lead to market access barriers.
- Canada's EMC scheme scored only 20 points, mainly due to the recent change in their EMC standard that has led to unique limits not aligned with any international standard and an unwillingness to allow continued compliance with the previous issue of the standard that satisfied Canada's legislation on interference causing equipment.
- The lowest scored countries are Vietnam and South Africa, both of which accrued only 18 of a
  possible 30 points. Vietnam's score was significantly impacted by their introduction of new
  requirements without ample transition times and promulgation of standards that require incountry testing without sufficient lab capacity in place. South Africa's score is diminished because
  of a lack of clarity around EMC certificate requirements and the convoluted nature of their
  certification process.

ITI concludes that the ease of doing business in most countries could be greatly improved by following good regulatory practices, including early and transparent notifications, incorporation of international standards and acceptance of international test reports, adequate transition times, risk-based approaches to regulation and conformity assessment, and avoidance of unjustified impediments that impact trade, manufacturing, and supply chain operations. Drawing from the WTO TBT Agreement, which establishes baseline commitments under which countries enact technical regulations without imposing unnecessary restrictions on trade in goods, ITI provides industry recommendations for national policymakers to improve their scores while still achieving their public policy and EMC objectives. When considering a new regulation, we recommend that a government consider multiple objectives:

- Foremost, establish a clear and objective EMC goal and determine whether that goal can best be achieved through regulation or whether other governance approaches may be sufficient.
- Where regulation is deemed necessary, assess and seek to minimize the impact of the regulatory
  measure on both market access and on the manufacturers and importers that are subject to the
  regulation.
- Pursue regulation in a manner that facilitates trade, 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 of improving consumer choice and lowering costs.
- For new equipment approvals, ensure systems allow for adoption of the latest editions of international standards with appropriate transition periods (at least one year in most cases).

To reap the full benefits of trade and investment in IT innovations, countries should choose to forego unique approaches to product EMC, 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 a country supports a stable, global regulatory environment that benefits all stakeholders while creating new societal and economic growth opportunities for their citizens who adopt and leverage the innovations created by the tech sector.

# Introduction

Information technology equipment (ITE) 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 companies succeed or fail. Designing and manufacturing ITE to avoid the interference problems that electromagnetic compatibility (EMC)-related regulations intend to prevent is often the easy part, and difficulties enter in as companies seek to satisfy the conformity assessment elements of regulations.

This report, ITE EMC Regulations and their Impact on the Ease of Doing Business, is the third in a series of ITI benchmark reports that score governments based on their national technical regulations on ITE and information and communication technology (ICT) products.<sup>2</sup> This report focuses on programs worldwide that address non-wireless, non-telecommunications regulatory requirements for EMC. This report is intended to be a gauge and a guide for policymakers to better understand the impacts of their technical regulatory requirements on 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, ITE trade and investment.

#### **Focus on ITE EMC**

Recent years have seen governments address EMC requirements under different regulatory schemes. Some have focused on information technology equipment (ITE) generally, and others incorporated EMC into telecommunications (telecom) product and wireless regulatory schemes to address the requirements of connected devices, including those in the Internet of Things (IoT).

This report focuses on regulations that address EMC in non-wireless and non-telecom regulatory schemes. Programs that address wireless and telecom product EMC regulatory requirements will be addressed in a subsequent ease of doing business report on telecom and wireless product regulations.

Every year, the World Bank publishes its "Doing Business

<u>Report"</u> which ranks economies around the world according to their ease of doing business.<sup>3</sup> The report provides a helpful snapshot and longer-term benchmark of how "business friendly" 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 certain 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 report is intended to provide an evaluation of countries' requirements for ITE EMC and to share industry insights to help regulators achieve their public policy objectives and protect their

<sup>&</sup>lt;sup>2</sup> The first in the series of reports was the <u>2017 Global Benchmark Report, ICT Product Safety Regulations and their Impact on the Ease of Doing Business</u> and the second is the <u>2020 Global Benchmark Report, ICT Product Safety Regulations and their Impact on the Ease of Doing Business.</u>

<sup>&</sup>lt;sup>3</sup> The World Bank scores countries using 10 criteria: starting a business, dealing with construction permits, getting electricity, registering property, getting credit, protecting minority investors, paying taxes, trading across borders, enforcing contracts, and resolving insolvency.

communications infrastructure and systems through good regulatory practices that eliminate unnecessary and unjustified impediments on trade, manufacturing, and supply chain operations.

#### The Importance of Electromagnetically Compatible Products

This report focuses on mandatory ITE EMC requirements (non-wireless and non-telecom) in 15 countries and the European Union (EU), Eurasian Economic Union (EAEU), and the Gulf Cooperation Council (GCC). Governments seek to ensure their countries' communications systems provide services free from interference and to provide their citizens with electrical and electronic products that operate as intended, free from disruptions caused by other equipment operating nearby, and without causing interference to any other equipment or devices. As a result, many countries have laws limiting the electromagnetic energy emanating from electrical and electronic products and, in some cases, establishing minimum levels of immunity to electromagnetic disturbances that may exist in the environment.

#### What are EMC and EMI?

**Electromagnetic compatibility (EMC)** is the ability of electrical equipment and systems to function acceptably in their electromagnetic environment, by limiting the unintentional generation, propagation and reception of electromagnetic energy which may cause unwanted effects such as electromagnetic interference (EMI) or even physical damage in operational equipment.

**Electromagnetic interference (EMI)**, also called radiofrequency interference (RFI) when in the radio frequency spectrum, is a disturbance generated by an external source that affects an electrical circuit by electromagnetic induction, electrostatic coupling, or conduction.

A manufacturer's fundamental objectives related to EMC for its ITE products are for the products to:

- operate safely and as intended when subjected to electromagnetic disturbing signals that exist in normal operating environments, and
- avoid disruption of the safe and intended operation of any other electrical or electronic equipment.

Of course, manufacturers also want these products to comply with all applicable laws and regulations of the country or region in which they are marketed and used. A company gains assurance that its products meet these goals by evaluating them against consensus-based international standards for emissions and immunity and applying adequate design elements to satisfy test limits or other requirements defined in those standards.

Prior to a product release, a company ensures its products are legally compliant by identifying which regulations apply to a particular product or family of products. For each country where the company plans to deliver a product, manufacturers ensure the completion of all necessary product regulatory testing and evaluation to demonstrate its products comply with applicable product regulations, including any relevant standards cited in regulations. A company employs engineers, procures laboratory resources, invests in testing facilities, and bears the costs of product testing and, where required, certifications by third-party organizations.

A company that fails in its commitment and delivers products that are not sufficiently immune, do not limit electromagnetic emissions to an acceptable level, or do not comply with legal requirements, will likely compromise its access to markets, diminish its relationships with government authorities, adversely affect its customers, reduce customer acceptance of its product, and potentially face legal action. 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 effects on citizens and business. Companies support product regulations that follow appropriate regulatory practices for establishing essential, risk-based EMC requirements and the necessary conformity assessment procedures to fulfill those requirements. Well-designed and well-implemented product regulations can set an essential baseline for manufacturers, create a growth-enhancing competitive environment, and establish a level playing field among both domestic and foreign companies.

As a rule, ITE 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. When governments pursue unnecessary 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 to different requirements. Unique and burdensome regulations are not just an inconvenience, they challenge profitability with new costs and create uncertainty about market access.

In response, a company may decide to pass these costs to consumers in the form of higher product prices, or a company may decide not to sell certain product models or 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 developed and developing economies are disadvantaged when regulations drive up the cost of ITE products and limit access to cutting-edge technology. For consumers this means a lack of access to critical technologies that bring important economic and social benefits.

### Overview of the 2021 Scores

The ITI member company representatives that contributed to this report agreed that regulatory uncertainty poses some of the greatest challenges to their companies' abilities to succeed in markets around the world, in addition to hindering global economic growth. To address this issue, we encourage the development and adoption of globally aligned, internationally recognized standards and regulatory best practices to help prevent an expanding patchwork of localized rules and regulations.

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 EMC requirements using criteria identified by the World Trade Organization's (WTO's) Technical Barriers to Trade (TBT) Committee as non-tariff measures that have a critical impact on companies' abilities to sell their products in the global marketplace. Among other factors, these criteria include an evaluation of a country's regulatory impact assessments, a determination of whether EMC 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 explanations are described in more detail in the "Criteria and Scoring" section of this report.

Table 1 provides an overview of the 2021 scores for EMC programs evaluated for this report. The following are some highlights of these scores:

- Four countries scored a perfect 30 points: Australia, Japan, Morocco, and New Zealand. The EMC programs in these countries feature aspects that are essential for ease of doing business, such as incorporating international standards by reference, including ample transition times, and allowing for supplier's declaration of conformity (SDoC). These countries also display high levels of transparency and predictability in their EMC regulatory schemes.
- Turkey and Ukraine missed a perfect score by only 2 points each. Turkey's EMC program
  portability could improve by harmonizing requirements for products from countries not in the
  EU or EAEU. Ukraine's program could achieve a perfect score by basing its surveillance on a
  customer-driven complaint system rather than initial and annual factory inspections.
- The United States' 24-point score was impacted by its inclusion of a unique emissions test standard for EMC testing, American National Standards Institute (ANSI) C63.4, whereas most countries in the world allow testing to International Special Committee on Radio Interference (CISPR) 22 and/or CISPR 32 requirements.
- The EU scored only 22 of 30 points. Although the EMC Directive allows the use of SDoC, EU scores in avoiding obstacles, international standards, and predictability are significantly hampered by the system of Harmonised Standards (HAS) consultants. We encourage the European Commission to review its current policies to ensure that the review of harmonized standards by HAS consultants does not unduly delay their development and publication or create divergences with international standards that could lead to market access barriers.
- Canada's ease of doing business score of only 20 points was influenced by the recent change in their EMC standard that has led to unique limits not aligned with any international standard. Additionally, Canada's unwillingness to allow continued compliance with the previous issue of

- the Interference-Causing Equipment Standard (ICES) that once satisfied Canada's legislation on interference causing equipment (also known as grandfathering) has impacted their score.
- The lowest scored countries are Vietnam and South Africa, both of which accrued only 18 of a possible 30 points. Vietnam's score was significantly impacted by their introduction of new requirements without ample transition times and promulgation of standards that require incountry testing without sufficient lab capacity in place. South Africa's score is diminished because of a lack of clarity around EMC certificate requirements and the convoluted nature of their certification process.

**Table 1. ITE EMC Regulations Scoring** 

Country	Regulatory Program	Ease of Doing Business Score
-	Australian Communication and Media Authority (ACMA)	
Australia	Mandated EMC Standards	30
Japan	VCCI Council	30
Morocco	Resolution No 2574-14	30
New Zealand	Radiocommunications (EMC Standards) Notice 2019	30
Turkey	EMC Regulation, 2004/108/AT	28
Ukraine	Technical Regulation on Electromagnetic Compatibility	28
Brazil	Inmetro Certification System	25
Gulf Cooperation Council (GCC): Bahrain, Kuwait, Oman, Qatar, United Arab Emirates (UAE),	GCC Standardization Organisation (GSO) Technical Regulation BD-142004-01	26
Yemen		
GCC: Saudi Arabia	Saudi Product Safety Programme (SALEEM)	24
South Korea	Radio Waves Act	24
United States of America (USA)	FCC Rules and Regulations, Title 47, Part 15	24
European Union (EU)	EMC Directive 2014/30/EU	22
Taiwan	Bureau of Standards, Metrology and Inspection (BSMI) Regulations Governing Electromagnetic Compatibility of Commodities	22
United Kingdom (UK)	Alignment with EU EMC Directive + UKCA mark	21
Canada	ICES-003 — Information Technology Equipment (Including Digital Apparatus)	20
China	China Compulsory Certification (CCC)	20
Eurasian Economic Union (EAEU): Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia	Technical Regulation CU TR 020/2011 on Electromagnetic Compatibility (EMC)	20
South Africa	NRCS + SABS Certificate of Compliance	18
Vietnam	Vietnam Ministry of Information and Communications (MIC) QCVN 118: 2018/BTTTT	18

### A Closer Look

To better understand the wide range of scores for each criterion, we provide a more detailed look at EMC regulations in several countries and economic regions, including the EU, GCC and EAEU. We highlight best practices and areas for improvement in the programs. Because regulatory systems continue to evolve, we note some recent changes to these programs, where applicable, and expectations for the future. At the end of this section, Figure 1 provides a graphical representation of the scores, and Table 3 provides a detailed look at how each program scored in each criterion.

#### **Australia (Overall Score: 30)**

The Australian Communication and Media Authority (ACMA) incorporates several international standards that are mandatory under Section 162 of the Radiocommunications Act 1992, as part of the ACMA's EMC Regulatory Arrangement. The incorporation by reference of international standards is a contributor to Australia's perfect scores (5 points each) in the criteria of international standards and portability of conformity assessment. Australia also scores high in the criteria of predictability and avoiding obstacles because ACMA provides sufficient transition time in which the expiry date of standards is two years after publication of the replacement standard. Under Australia's EMC rules, the supplier's declaration of conformity (SDoC) is valid for an unlimited time unless there is a product change or standards update, further adding to ACMA's perfect ease of doing business score. Finally, ACMA does not require samples for certification if the manufacturer can provide a test report from a lab accredited to the accepted standards referenced in the regulation.

#### **Brazil (Overall Score: 25)**

Brazil's Inmetro is the National Institute of Metrology, Standardization and Industrial Quality, which develops and implements certification systems in Brazil. Tasked with maintaining national standards, Inmetro is the national developer of conformity assessment programs as well as the main accrediting authority for certification bodies and laboratories. The agency has put in place voluntary EMC requirements based on international standards. However, these are coupled with a directive making the standards mandatory for sales to any government entity, a category which is defined broadly enough to include products intended for banking, machines used in data processing and storage, and general office equipment. Certification of these products means compliance with IEC (International Electrotechnical Commission) standards for EMC and the IEC CISPR (International Special Committee on Radio Interference) 22 and CISPR 24 standards. These references to international standards give Brazil a perfect score of 5 points in the relevant criterion.

Inmetro offers two models of certification, which can be selected by the manufacturer or local representative:

 Model 5 includes testing of three samples obtained from the manufacturer and an audit of the manufacturing quality management system. Even though a granted certificate is valid for three years, Inmetro requires annual re-evaluations on samples obtained directly from the

- manufacturer or from the retail market. These "maintenance evaluations" lead to a score of zero in the market surveillance criterion.
- Model 7 consists of testing two samples in a determined batch of products, composed of
  products with sequential serial numbers of the same model by the same manufacturer. Under
  Model 7, the quality management system is not evaluated. If the products are being imported
  into Brazil, it is necessary to submit the import license and batch number for the products.

Due to Brazil's acceptance of UL certification body (CB) test reports/certificates or third-party EMC test reports, the program scores 5 points in portability of conformity assessment. Finally, Brazil's predictability has been greatly enhanced in recent years, leading to a score of 5 points in the criterion.

#### Canada (Overall Score: 20)

Canada's Interference-Causing Equipment Standard (ICES-003) sets out technical requirements relating to radio noise generated by ITE. Several aspects of the EMC regulatory scheme in Canada, administered by Innovation, Science and Economic Development Canada (ISED), are problematic and have reduced Canada's ease of doing business score:

- Incorporation by reference (with Canadian deviations) of the standards CISPR 32:2015 and American National Standards Institute (ANSI) C63.4-2014 would have resulted in a score of 5 points in the international standards criterion. However, in 2020 ISED introduced a change in ICES-003 Issue 7 whereby the radiated emission limit below 1 GHz is a significant departure from international standards. This surprising change has left Canada with their own unique limits that are not aligned with any international standard. This lack of harmonization leads to a score of 1 point in the international standards criterion.
- In terms of avoiding obstacles, industry is disappointed with Canada's recent policy change to not
  allow products already being marketed in Canada (and the US) prior to the end of the transition
  period for ICES-003 Issue 7 to continue to comply with the previous issue of ICES that once
  satisfied Canada's legislation on interference causing equipment. The inclusion of grandfathering
  when there are standards changes can greatly enhance ease of doing business, and Canada's
  unwillingness to do so downgrades their score in the criterion of avoiding obstacles.
- Manufacturers, importers, or distributors of ITE subject to ICES-003 can submit a SDoC indicating
  compliance with all technical requirements prescribed by ICES-003 and compiling results into a
  test report. Although the allowance of SDoC enhances portability of conformity assessment and
  predictability, scores in these criteria are downgraded due to the issue with Canada-unique limits
  described above.

Canada fares better in the transparency criterion because the requirements of ICES-003 are very clearly delineated on the ISED website, and recent updates to ICES-003 have been transparent and highly participative.

#### China (Overall Score: 20)

The China Compulsory Certificate (CCC) mark is a mandatory safety/EMC mark required for certain products, including a wide range of ITE, imported and sold in the Chinese market. Certification must be obtained through the China Quality Certification Center (CQC), and certificates are valid for five years.

The CCC is based on Guobiao (GB) standards, which are the Chinese national standards issued by the Standardization Administration of China (SAC), the Chinese National Committee of the International Organization for Standardization (ISO) and IEC. The current Chinese EMC Standard is GB/T 9254:2008, "Test Method and Limits for Radio frequency disturbance from ITE" implemented in 2009. GB/T 9254-2008 is identical to CISPR 22:2006, leading to a perfect score of 5 points in the international standards criterion.

China's EMC regulatory scheme scored only 3 of 5 points in the portability of conformity assessment. Because CNCA has not put into place any mutual recognition agreements (MRAs), CCC testing must be performed at CNCA-accredited laboratories in China. This impact on industry is mitigated somewhat by recent allowances for DoC and use of manufacturers' test reports in China.

In terms of transparency and avoiding obstacles, standards are published in Mandarin Chinese language, and official English translations are not always readily available, leading to a score of only 3 points in these criteria. There are challenges with predictability in China as changes in standards are frequent due to technology changes. Products not meeting GB/T 9254-2008 may be held at the border by Chinese customs and manufacturers are subject to other penalties.

The EMC scheme in China scored 3 points for market surveillance, which requires one sample for EMC testing in a CNCA-accredited laboratory. In addition, customs, retail outlets, and manufacturers in China are all subject to auditing to ensure continued compliance, and any of these entities can be required to provide test samples.

# Eurasian Economic Union (EAEU): Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia (Overall Score: 20)

The Eurasian Economic Union (EAEU), consisting of Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia, requires declaration and certification to Customs Union (CU) Technical Regulation (TR) 020/2011 on EMC. Once a certificate is issued, it is valid for a period of one to five years, chosen by the manufacturer, which enhance predictability. However, once the initial term expires, the certificate must be renewed annually as long as the product is for sale in the market. This leads to a predictability score of 3 out of 5 points for the EAEU.

EMC standards in the EAEU are based on Russian GOST (abbreviated from Gosstandart (State Committee for Quality Control and Standardization)) standards, which are mostly identical to the European (EN) standards. Therefore, the EAEU scores a perfect 5 points in the international standards criterion.

The EMC certification scheme in the EAEU requires a local representative to hold the locally issued certificate, which adds to obstacles for foreign manufacturers. In addition, the certificate must be directly tied to the specific model and specific factory. This increases the number of samples needed for certification, because a unit from each factory must be provided for certification of each factory, regardless of whether the imported model is the same. Also, in practice, any products coming onto the EAEU market after customs clearance should include originals or certified copies of certificates or declarations of conformity. Penalties for non-compliance include civil and criminal penalties enforced by the Federal police. These factors all contribute to a score of 3 points in the criterion of avoiding obstacles.

There is some flexibility in the factory audit requirement, where ISO 9001 reports can be submitted in lieu of audits. However, samples are required for the in-country verification process and for re-testing at the five-year mark. These aspects lead to a relatively low score of only 1 point in the surveillance criterion.

#### **European Union (Overall Score: 22)**

The European Union (EU) regulates EMC under Directive 2014/30/EU, also known as the EMC Directive. Despite scores of 5 points in the criteria of transparency, portability, and surveillance, the EMC Directive scores a total of only 22 points, mainly due to issues that have arisen with harmonized standards. The EMC Directive score in avoiding obstacles has the potential to be high because of the allowance of SDoC using European standards (ENs), which convey a presumption of conformity, or non-European standards. However, the EU scores in international standards, avoiding obstacles, and predictability are significantly impacted by the Harmonised Standards (HAS) Consultant system. ENs are often based on existing international standards, such as CISPR standards. However, we are concerned with the recent trend whereby European standards sometimes diverge from standards developed by international standards development organizations (SDOs), which are vetted and voted on by international technical experts, including European experts. These divergences between ENs and widely adopted international standards, which are often preceded by delays and lengthy adoption process, are due to, among other factors, the particularities of the HAS Consultant system. As it is currently functioning, the system bestows power to the HAS consultant to essentially disregard the work of international standards bodies (e.g., CISPR) or Europe's own regional standard body for EMC (the European Committee for Electrotechnical Standardization, also known as CENELEC). This undermines the predictability and ease of doing business that are normally the case when harmonized standards are in place.

We encourage the European Commission to review its current policies to ensure that the review of harmonized standards by HAS consultants does not unduly delay their development and publication or create divergences with international standards that could lead to market access barriers. Doing so would better enable regulators to keep pace with technological developments while ensuring the necessary levels of protection, facilitating innovation, and preventing the potential emergence of technical barriers to trade in the ITE sector.

# Gulf Cooperation Council (GCC): Bahrain, Kuwait, Oman, Qatar, United Arab Emirates (UAE) and Yemen (Overall Score: 26)

The Gulf Cooperation Council (GCC) consists of the countries of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates (UAE), and Yemen. For the purposes of this report, we have scored the GCC as Bahrain, Kuwait, Oman, Qatar, UAE, and Yemen while Saudi Arabia is scored separately. The six countries evaluated as a group for this report seem to follow the GCC framework on regulating EMC, including the use of one standard, one test, supplier's declaration of conformity (1-1 SDoC) for equipment and appliances covered by the conformity assessment procedures of List 1, which is expected to include ITE. The GCC currently includes EMC requirements in the Gulf Technical Regulation for Low Voltage Electrical Equipment and Appliances BD-142004-01, to which EMC requirements were added in 2014 and became effective in 2016. ITI encourages alignment of all countries in the GCC with the Council's framework EMC regulation.

The GCC obtained a perfect score of 5 points in the criteria of international standards and portability of conformity assessment, due to the acceptance of IEC standards to demonstrate conformance to the essential requirements of the Gulf Technical Regulation. Furthermore, the regulation correlates closely with the EU EMC Directive (2014/30/EU). A score of 5 points was also given in the criterion of surveillance because the GCC performs market surveillance based on consumer complaints and only when deemed appropriate according to the risks presented by electrical equipment.

The GCC score in avoiding obstacles was downgraded to 3 points because of the requirement to ensure that the electrical equipment is accompanied by safety information and use instructions in Arabic language. Any requirement for multiple languages present obstacles to conformity.

Industry is encouraged by the GCC Standards Organization (GSO) announcement that a forthcoming EMC regulation will include acceptance of test reports from International Laboratory Accreditation Cooperation (ILAC) MRA labs or a manufacturer's lab if accredited by an ILAC body. GSO has also indicated the inclusion of flexibility in the conformity assessment process, including acceptance of reports of tests performed wholly by the manufacturer. To maximize the benefits of the upcoming GCC EMC regulation, member states should clarify that there is only one set of regional GCC requirements and that these supersede prior national regulations.

#### GCC: Saudi Arabia (Overall Score: 24)

For the purposes of this report, Saudi Arabia is scored separately from the other countries in the GCC.<sup>4</sup> Saudi Arabia has deviated from the GCC framework by developing and using their own systems: the Saudi Product Safety Programme (SALEEM) implemented by the Saudi Standards, Metrology and Quality Organization (SASO). Creating and implementing unharmonized programs significantly and negatively impacts ease of doing business. ITI encourages alignment of all countries in the GCC with the Council's framework EMC regulation.

<sup>&</sup>lt;sup>4</sup> We have scored the GCC as Bahrain, Kuwait, Oman, Qatar, United Arab Emirates (UAE), and Yemen while Saudi Arabia is scored separately.

Saudi Arabia's ease of doing business score differs from GCC in one criterion: avoiding obstacles. Under SALEEM, Saudi Arabia established Saber, a system that, as of July 2018, must be used to obtain certificates of conformity for products destined for the Saudi Arabia market. In theory, Saber is meant to connect importers, SASO-approved certification bodies, and Saudi customs and related trade authorities in one online system, thereby expediting and facilitating trade. In practice, the system has created significant extra burden without commensurate benefits in conformity assurance. In addition, the interface between users is not seamless. For instance, there have been situations where a harmonized system (HS) code in the Saber system will trigger a required certificate, but the product using the HS code would not require the certification based on SASO requirements. This conflicting information has been difficult to resolve. Issues such as these have led to a score of 1 point in the criterion of avoiding obstacles (as compared to GCC's score of 3 points in the criterion).

#### Japan (Overall Score: 30)

Japan's VCCI Council (formerly known as the Voluntary Control Council for Interference) forms policies for the voluntary control of electromagnetic disturbances emitted by multimedia equipment. The voluntary nature of the VCCI program, transparency of requirements, and smooth process all contribute to a perfect score of 30 for Japan.

Under the voluntary control measures, equipment must be tested at a VCCI-registered facility to verify compliance with emission (interference) standards prior to shipment of a product into the Japan market. Manufacturers submit their own conformity verification report (DoC) to VCCI prior to application of the VCCI mark to products and shipment into Japan. Further enhancing Japan's portability of conformity assessment score, under the framework of the 2007 Japan-US telecommunication MRA, VCCI and the US Federal Communication Commission (FCC) agreed to mutually accept test reports issued by accredited laboratories of the other country. Finally, in terms of surveillance, the VCCI Council may conduct market sampling tests on reported equipment to confirm their compliance with VCCI regulations. This complaint-driven system scores 5 points in the surveillance criterion.

#### **Morocco (Overall Score: 30)**

Morocco's Resolution No 2574-14 on EMC scores high marks in the criteria of international standards and portability of conformity assessment because it is based on the EU EMC Directive. Presumption of conformity applies to any equipment that meets the relevant national or international standards. Obstacles are avoided by providing an option for SDoC (in Arabic or French) by the manufacturer or supplier, backed up by a detailed Technical File for the products. Test reports can be from a manufacturer's own lab or a third-party lab. Industry applauds Morocco's establishment of a scheme that solidly relies on international standards and SDoC.

#### **New Zealand (Overall Score: 30)**

New Zealand's Radiocommunications (EMC Standards) Notice 2019 incorporates several international standards, contributing to the regulatory scheme's perfect scores in the criteria of international

standards and portability of conformity assessment. New Zealand also scores high in the criteria of predictability and avoiding obstacles because a supplier may continue to supply a product that has been tested to an expired industry standard, as long as the standard was in effect at the time the SDoC was signed. Retesting a product to an amended or replacement standard is not required as long as the product has not been modified. In addition, New Zealand gives a transition period of two years from publication of a revised or new standard. Other contributing factors in the perfect score are that, under New Zealand's EMC rules, the DoC is valid for an unlimited time unless there is a product change or standards update. Finally, New Zealand does not require samples for certification if the manufacturer can provide a test report from a lab accredited to the accepted standards referenced in the regulation.

#### **South Africa (Overall Score: 18)**

South Africa's regulatory landscape for ITE includes the South African Bureau of Standards (SABS), the Independent Communications Authority of South Africa (ICASA), and the National Regulator for Compulsory Specifications (NRCS). These agencies all have a role in regulating ITE in the South African market that requires a conformity assessment procedure along with mandatory certification. The roles of SABS and ICASA were delineated in a Memorandum of Understanding (MOU) signed by both agencies in 2016.

While the roles of all three agencies and their respective processes are defined, the details of their interactions and relationships with each other are not as clear, leading to confusion over which approval instruments from each agency are mandatory or if voluntary instruments become mandatory under certain circumstances. This confusion impacts South Africa's score in the criteria of predictability and avoiding obstacles. For example, SABS clearly defines the onerous process that must be followed to obtain a SABS EMC certificate, but it is unclear under what circumstances a SABS EMC certificate is mandatory, if at all. This lack of clarity, along with the convoluted and burdensome nature of the SABS process, contribute to South Africa's low score of only 1 point in avoiding obstacles.

#### **South Korea (Overall Score: 24)**

In South Korea, the Radio Research Agency (RRA) regulates EMC under the Radio Wave Law. Korean EMC Standards (KS) are heavily aligned with IEC/CISPR standards. However, RRA took an aggressive approach in adopting a failed CISPR 35 Committee Draft for Vote (CDV) version as its Korean national standard, which created some challenges at the time the standard was adopted. Although RRA aligned with the official CISPR 35 standard later, the chaos could have been avoided if RRA had initially referred to the final international standard. This situation leads to a score of only 3 points in the international standards criterion.

ITE products can obtain the Korean Certification (KC) Mark using EU EMC reports only from test labs specifically designated by RRA or via a limited number of international government-to-government agreements. Additionally, RRA requires several unique elements to be followed during testing, deviating from internationally accepted EMC test practices. These factors limit the score for portability of conformity assessment for ITE equipment to 3 points. Unlimited certificate validity and the option for

paperwork-only surveillance methods lead to 5 points each in the avoiding obstacles and surveillance criteria, thereby enhancing South Korea's overall score.

#### **Taiwan (Overall Score: 22)**

Taiwan's Bureau of Standards, Metrology and Inspection (BSMI) implements "Regulations Governing Electromagnetic Compatibility of Commodities." Although Taiwan's national standards are based primarily on ISO/IEC standards, BSMI requires that EMC testing be performed in accordance with the following National Standards of the Republic of China:

- CNS 13438 (2006) Up to 6 GHz
  - Although this standard follows the international norm, BSMI specifies several unique requirements for test modes and setup, deviating from the international standard on which it is based. This downgrades Taiwan's score in international standards from 5 to 3 points.
- CNS 14757-2 (2010) Uninterruptible Power Systems (UPS) Part 2: Electromagnetic compatibility requirements
- CNS 13439 (2004) Sound and Television Broadcast Receivers and Associated Equipment Radio disturbance characteristics - Limits and methods of measurement

Taiwan's score in avoiding obstacles is enhanced by allowing Declaration of Conformity (DoC), the least-trade-restrictive conformity assessment procedure, for low-risk products. Under the DoC scheme, manufacturers may have testing done by BSMI-designated laboratories, prepare their own technical documents, and draft the DoC form themselves.

In terms of market surveillance, Taiwan's program scores 3 out of a possible 5 points. Products specified by the Ministry of Economic Affairs (MOEA) must comply with inspection requirements before they are shipped from the manufacturing premises or imported and placed on the market. BSMI can detain and inspect shipments at the border, which significantly delays customs clearance and impacts customer delivery.

#### **Turkey (Overall Score: 28)**

In 2004, Turkey established its EMC regulation by adopting the EU's EMC Directive and EN standards which are developed by the European Committee for Standardization (CEN), CENELEC, and the European Telecommunications Standards Institute (ETSI). These CEN/CENELEC/ETSI standards are generally harmonized with IEC CISPR standards. Equipment subject to the EMC regulation in Turkey can show conformance through verified laboratory testing by an EU-approved notified body or through a manufacturer's SDoC. Companies selling to the Turkish market must submit evidence of conformity by providing either a notarized conformity certificate from a notified body or a manufacturer's issued certificate of conformity, which declares conformance to all relevant standards and directive annexes. The alignment with international standards and acceptance of SDoC lead to perfect scores in the criteria of international standards, avoiding obstacles, and predictability.

Turkey's EMC regulation is downgraded to 3 points in the criterion of portability of conformity assessment because there are separate requirements and a separate form for products coming from non-EU and EAEU countries. Making the documentation requirements consistent for all countries importing to Turkey would enhance this score and give Turkey a perfect 30 points in the ease of doing business under their EMC regulation.

#### **Ukraine (Overall Score: 28)**

Ukraine's "Technical Regulation on Electromagnetic Compatibility" has high marks in international standards, transparency, and predictability as the scheme is based directly on the EU EMC Directive. The program's score in avoiding obstacles is high because unlimited EMC declarations of conformity can be obtained based on documentation, with no sample necessary. Because Ukraine requires initial and annual factory inspections, their score in surveillance is only 3 points. Ukraine's ease of doing business score could be enhanced by basing surveillance on a customer-driven complaint system with proof of compliance available upon request, such as the system in place in the EU.

#### **United Kingdom (Overall Score: 21)**

The United Kingdom (UK) currently aligns with EU directives and harmonized standards, though this situation will change after "Day 1" of the UK's exit from the EU (in effect, 1 January 2021). At that point, the UK Department for Business, Energy and Industrial Strategy (BEIS) will require a unique UKCA mark on products coming into the UK. Usually, the EU would allow a minimum transition period of two years, but this mark requirement has been notified only 120 days before its effective date. Although the UK has granted a one-year grace period before labelling enforcement, certain products will be forbidden from entry and sales in the UK if not labeled with the UKCA mark as of 1 January 2021. As a result, the 1 January 2021 date is the required implementation date for UKCA markings at the factory for those types of products.

The UK score is expected to evolve as the nation finds its footing apart from the EU regulatory scheme. Absent practical experience with UK-specific regulatory schemes, we have scored the remaining aspect of the UK scheme in line with the EU score, but this is expected to change in future editions of this report.

#### United States of America (USA) (Overall Score: 24)

In the US, EMC is governed by Federal Communications Commission (FCC) Rules and Regulations. Title 47, Parts 2, 15, and 18 lay out the EMC equipment authorization requirements. EMC equipment authorization is completed through testing and SDoC or optional certification, which enhance the EMC scheme ease of doing business in the criteria of portability of conformity assessment and predictability. With an online system of public notification, ample comment periods, and clear responses from the agency, the US scores high in transparency.

The US is the one of two countries in the world that utilizes a unique emissions test standard for EMC testing for IT equipment (ANSI C63.4), impacting the US score in international standards. Most other

countries accept testing done to CISPR 22 and CISPR 32 standards. To enhance the US ease of doing business score, ITI recommends allowing the option for testing computers and peripherals to CISPR 22 and/or CISPR 32 requirements and eliminating the need for repetitive testing to both the US and international standards. If, upon further review, the FCC determines that C63.4 includes vital requirements that are missing from the CISPR standards, then the US could push for these additions and necessary changes to be made to the international standards, which could then be adopted in the US, thus leading to harmonization of standards. Without this reform, the FCC's requirement to test only to C63.4 will continue to add unnecessary cost and delay in getting IT products to the market for US manufacturers and create an unintentional technical barrier to trade for the rest of the world.

#### **Vietnam (Overall Score: 18)**

In 2019, Vietnam's Ministry of Information and Communications (MIC) promulgated the EMC standard, QCVN 118:2018/BTTTT based on international EMC standard CISPR 32:2015/COR1:2016. This reliance on international standards is commendable. Unfortunately, the country's EMC program scores low in the criteria of avoiding obstacles and predictability, mainly due to the very short transition times that industry is experiencing on a regular basis. In addition, there have been cases where Vietnam has promulgated a standard that requires accredited lab or in-country testing, when there are no labs accredited and no MRA in place to help achieve the testing. For example, MIC scheduled the transition to QCVN 118:2018/BTTTT for 1 July 2019, when only one lab had been accredited by that date. Vietnam currently requires lab recognition via an MRA or in-country testing. Acceptance of international test reports from labs accredited to international standards (e.g., ILAC) without an MRA requirement would enhance the program's score in the portability of conformity assessment criterion.

Vietnam can enhance its scores in avoiding obstacles and predictability by providing adequate notification of new standards, allowing at least one year of transition time (time between announcement and effective date of rule), and accepting international test reports.

#### Table 2. Scoring Legend

This table presents a quick reference overview of the criteria and scoring for Figure 1 and Table 3. More details on these criteria are presented in the following section "Criteria and Scoring."

Criterion	Sco	oring					
International	0	National requirements not aligned with relevant international standards.					
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 standar					
		without any national deviations or group differences.					
Transparency	0	No application					
	1	Some application but inconsistent or incomplete					
	3	Adequate application					
	5	Broad, comprehensive application					
Regulatory impact	0	No application					
assessments and	1	Some application but inconsistent or incomplete					
avoiding	3	Adequate application					
unnecessary	5	Broad, comprehensive application					
obstacles to trade							
Portability of	0	No application					
conformity	1	Some application but inconsistent or incomplete					
assessment results	3	Adequate application					
	5	Broad, comprehensive application					
Predictability of	0	Unpredictable. Companies regularly must escalate issues to address surprises.					
outcome	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.					
Surveillance	0	Annual or bi-annual product retesting by a laboratory in-country (Argentina					
program		model)					
	1	Two or more per year third-party factory audit of products (North American model)					
	3	•					
	5	Annual third-party factory audits based on quality management (EU model)					
	5	Market/customer sampling or complaint driven surveillance (global, EU model)					

**Figure 1. Global Scoring of ITE EMC Regulations** 

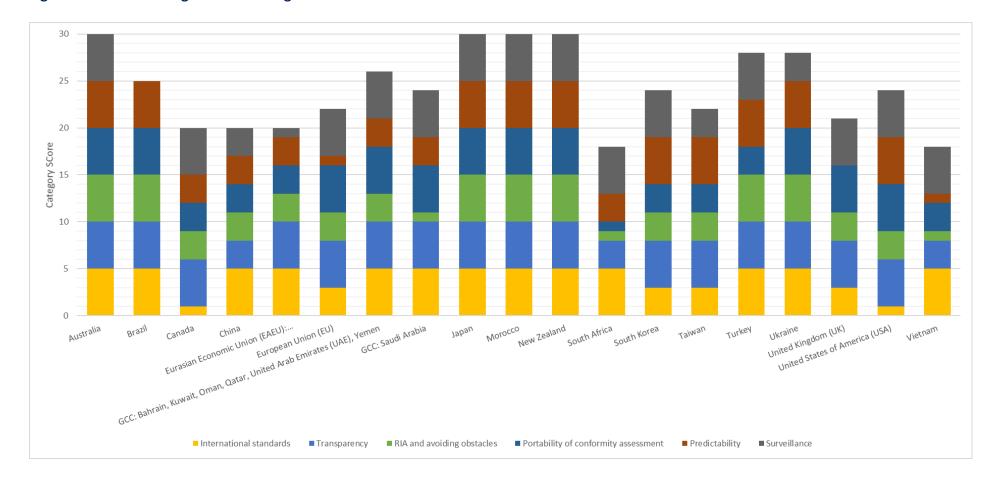


Table 3. Ease of Doing Business Scoring for ITE EMC Requirements

Country	International Standards	Transparency	Regulatory Impact Analysis/ Assessment and Avoiding Obstacles	Portability of Conformity Assessment	Predictability	Surveillance	Total Ease of Doing Business Score
Australia	5	5	5	5	5	5	30
Brazil	5	5	5	5	5	0	25
Canada	1	5	3	3	3	5	20
China	5	3	3	3	3	3	20
EAEU: Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia	5	5	3	3	3	1	20
European Union (EU)	3	5	3	5	1	5	22
GCC: Bahrain, Kuwait, Oman, Qatar, United Arab Emirates (UAE), Yemen	5	5	3	5	3	5	26
GCC: Saudi Arabia	5	5	1	5	3	5	24
Japan	5	5	5	5	5	5	30
Morocco	5	5	5	5	5	5	30
New Zealand	5	5	5	5	5	5	30
South Africa	5	3	1	1	3	5	18
South Korea	3	5	3	3	5	5	24
Taiwan	3	5	3	3	5	3	22
Turkey	5	5	5	3	5	5	28
Ukraine	5	5	5	5	5	3	28
United Kingdom (UK)	3	5	3	5	0	5	21
United States of America (USA)	1	5	3	5	5	5	24
Vietnam	5	3	1	3	1	5	18

# **Criteria and Scoring**

Since its implementation in 1995 with the establishment of the WTO, the <u>TBT Agreement</u> has been an essential tool to help prevent and address barriers to trade resulting from technical regulations aimed at ensuring the EMC of ITE products. 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) that determine whether a product meets such standards or regulations. The TBT Agreement requires WTO members develop and apply standards, technical regulations, and conformity assessment procedures on a nondiscriminatory and transparent basis, using relevant international standards and guidelines, when appropriate. <sup>5</sup> ITI considers international standards to be those developed in accordance with the principles outlined in the "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement" as published in the WTO's Decisions and Recommendations Adopted by the WTO Committee On Technical Barriers To Trade Since 1 January 1995. <sup>6</sup>

The TBT Agreement provides an appropriate model for many good regulatory practices, and 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 and guidance on how each criterion was 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. However, the TBT Agreement does not require the use of 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 regulations, 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.

<sup>&</sup>lt;sup>5</sup> See: https://ustr.gov/trade-agreements/wto-multilateral-affairs/wto-issues/technical-barriers-trade

<sup>&</sup>lt;sup>6</sup> See: Annex 2 of https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/TBT/1R12.pdf

National requirements fully harmonized with relevant international standards without any national deviations or group differences.

#### 2. Transparency

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 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 (the TBT Committee recommends "at least 60 days" (G/TBT/26)) and take into account comments it receives from other members (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 outlining 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 enquiry 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 also applies 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. Conformity assessment procedures

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 using data (such as quantitative and/or qualitative) to identify impacts of alternatives; conducting cost-benefit analysis of alternatives (considering 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
- 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. To promote the portability of conformity assessment results, the TBT Agreement requires that 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 (such as test
  results or certifications), provided the member is satisfied that those procedures offer an
  assurance of conformity that is equivalent as its own. 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
- 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 application of the rules by the authority and by test labs. Completion of conformity assessment services, such as testing, must be completed 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. Surveillance program

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

#### **Score Criteria:**

- O 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 audits based on quality management (EU model).
- 5 Market/customer sampling or complaint driven surveillance (global, EU model).

#### 7. Other considerations

**Product labeling:** Regulatory requirements that include mandatory product labeling can 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 there is flexibility to place labels 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 would allow for the use of electronic labeling (e-labeling), where label information can be displayed on a device's screen or via a machine-readable code (such as QR code) or web link on the product or packaging. The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) are developing a standard for e labeling. Once adopted, this standard will help in the effort to have countries align their e-labeling requirements globally.

## Recommendations

ITI supports regulatory approaches that are risk-based and address a demonstrated, real-world need. In addition, given the global nature of the ITE industry, we believe that regulatory requirements (or lack thereof) should reflect alignment with international norms and best practices. When considering a new regulation, we recommend that a government consider multiple objectives:

- Foremost, establish a clear and objective EMC goal that can best be achieved through regulation.
- Assess and seek to minimize the impact of the regulatory measure on both market access and on the manufacturers and importers that are subject to the regulation.
- 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.
- For new equipment approvals, we encourage adoption of the latest editions of international standards with appropriate transition periods (at least one year in most cases).

Before drafting regulatory measures, a government should conduct an impact assessment of relevant alternatives based on a balanced consideration of benefits and costs of the measure. The relevant alternatives should include the evaluation of non-regulatory options where feasible, including a "do nothing" option. This impact assessment should be evidence-based using the best available data, and all qualitative and quantitative factors 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 for ITE, a government has the option to align requirements with local, national, or international standards. Generally, a regulation that references or directly permits the use of international standards for its technical requirements improves the ease of doing business by harmonizing product requirements across borders. Doing so also increases the ability for the latest innovations and advances in technology to be available to the country's consumers in a timely manner. Alternatively, national standards can be considered where they have no, or limited, differences compared to the base international standard.

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 cost and unnecessary burdens on companies and may limit their citizens access to new products and innovative technologies. Ideally, a government should set a flexible CA approach that addresses the risks, minimizes 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 ITE product categories and its associated EMC risks (such as the likelihood of occurrence, the degree of interference, etc.). We recommend that governments consider exempting very low risk product categories from regulatory measures while providing for a range of CA alternatives

that may include type approval models for higher risk products and supplier's declaration of conformity (SDoC) for lower risk products.

In setting up its product regulation, a government's choices will either support an open market or hinder trade and competition. Regulatory measures can be designed to avoid unnecessarily divergent or duplicative requirements with other countries. We recommend governments participate in mutual recognition agreements (MRAs) with other governments or, ideally, leverage trustworthy and trade facilitative international schemes by recognizing the testing results and approvals of any qualified test labs who participate in mutual recognition agreements. For new equipment approvals, we encourage adoption of the latest editions of international standards with appropriate transition periods (at least one year in most cases).

ITI recommends governments to be open and transparent when drafting new or changing existing product regulations. Governments can benefit by including robust 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 prior to 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 (such as no product holds, on-time changes in design, components, manuals, and labels).

By keeping CA procedures simple, a government can minimize the resources needed to oversee and administer its CA program and assign more resources to appropriate market surveillance programs. The deployment of a good market surveillance program is a key means of controlling product compliance in the market. We recommend that market surveillance programs be complaint-driven and address consumer products, including random sampling of products in the marketplace. A visual inspection of a product can be conducted to determine if required labels and markings are in place. If an authority has doubts, it can contact the manufacturer with questions or require that a market sample unit undergo selective testing. We recommend that governments prioritize efforts on those companies and products that pose serious risks and on those who are most likely to fail to comply, with greater scrutiny 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 cause harmful interference and/or not conform to the requirements, we recommend that companies 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 appropriate intervention actions. Examples include, but are not limited to, formal warnings with a remediation plan, product holds, product recalls, discontinuation of sales and criminal fines and penalties. We recommend that the regulatory authority follow the principle of proportionality in considering the appropriate intervention action. For a non-compliance event that does not result in an EMC problem (such as minor administrative non-compliance or mislabeling) a warning with remediation plan may be appropriate. For a non-compliance event that directly poses EMC risks, the intervention action should be to quickly to determine which products pose the risk (such as by lot number or date code), remove them from the market, and deter future noncompliant products from being released into

the marketplace. In a case where a company is purposely circumventing requirements, criminal fines and penalties may be appropriate.

We recommend that governments monitor and evaluate the effectiveness of existing regulatory measures on a periodic basis through a transparent procedure. Governments can benefit when companies and stakeholders are allowed to provide input into these evaluations. Subsequently, the government can modify, expand, simplify, or repeal its regulatory measures based on 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 imposed by governments have almost twice the impact on ease of doing business as tariffs. Many of these non-tariff measures are the result of countries' unique requirements that, cumulatively, have created a global patchwork of standards and conformity assessment requirements, including those for ITE product EMC. Without regulatory certainty and predictability, costs increase for manufacturers as they navigate complex rules and for governments as they expend more resources to manage compliance. Perhaps the biggest cost is the reduced consumer access to technologies that enable fundamental social and economic benefits.

ITE 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 can choose to forego unique approaches to product EMC, 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 a country supports a stable, global regulatory environment that benefits all stakeholders while creating new societal and economic growth opportunities for their citizens who adopt and leverage the innovations created by the tech sector.

# Member Companies



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