

## **Chapter 2. Unilateral approaches to international regulatory co-operation: how Mexico embeds international considerations in its domestic rule-making processes**

*Countries may take unilateral steps to avoid regulatory divergences, notably in their domestic rule-making procedure. This is a foundational step towards regulatory quality and coherence and one that is likely to facilitate the development of more ambitious international regulatory co-operation (IRC) approaches. This chapter identifies the various avenues through which international considerations have been embedded into domestic rule-making, either through considering foreign and international standards in domestic rule-making, assessing international impacts in the RIA procedures, or engaging foreign stakeholders on regulatory developments.*

## Introduction

Mexico has an advanced and ambitious legal framework embedding international considerations throughout its domestic rule-making process. It has done so through the introduction of specific procedures, such as:

- Embedding questions and procedures in the *ex ante* impact assessment aimed at assessing the trade impacts of new regulatory measures or collecting the experience of foreign jurisdictions in the same field.
- Considering international standards in the development of regulation; legally and systematically required for technical regulations, and ad hoc for subordinate regulation more broadly.
- Reinforcing the connection between the notification procedure to the WTO and the RIA process to obtain feedback on draft measures from foreign stakeholders.

In addition, it has existing procedures for forward planning and *ex post* assessment which may offer avenues for further embedding IRC.

The GRP processes with IRC considerations are largely geared towards lowering impacts of regulations on international trade, in line with obligations Mexico has subscribed to under the WTO. Consequently and logically, IRC is more systematically embedded into the development of technical regulations (NOMs) which by definition have an effect on trade in goods, rather than the impacts stemming from non-technical subordinate regulations.

Nevertheless, regulators face challenges when implementing IRC practices. In particular, anecdotal evidence from interviews shows difficulties for regulators when estimating trade costs in regulatory impact assessments, or when looking for guidance on the applicable international standards. Furthermore, *ex post* evaluation (for subordinate and technical regulation) remains very little used to assess the international impacts of a regulatory measure or to identify divergence from international standards, norms or best practices.

This chapter identifies the various avenues through which international considerations have been embedded into domestic rule-making, whether by contributing to the assessment of impacts of regulations through specific questions in the RIA procedures, by considering inputs from foreign stakeholders, or by applying foreign and international experiences in rule-making. Overall, this chapter finds that numerous provisions have been included in what is becoming a comprehensive *de jure* framework on IRC.

### Regulatory impact assessment as a tool to consider the international environment

RIAs provide a practical tool to integrate international considerations within evidenced-based rule-making, following the 2012 OECD Recommendation to “give consideration to all relevant international standards and frameworks for co-operation”. RIAs may increase the attention of policy makers for trade impacts and thus ensure a conscious balancing of trade and other public policy considerations. In addition, the RIA process provides a point in time to reflect on alternative options, to consider how other jurisdictions are addressing similar challenges and to map the existence of international legal instruments and policy standards in the same field (OECD, 2017<sup>[1]</sup>).

Mexico has a procedure for *ex ante* RIA mandatory for all subordinate regulators, the quality of which is overseen by COFEMER. The RIA requirements differ depending on the estimated impacts of the RIA proposals. Indeed, Mexico’s RIA Manual distinguishes

between moderate- and high-impact regulatory proposals, and includes specific questions depending on whether the measure is estimated to have impacts on competition, on trade or aims at reducing risks for human, animal or vegetal health, for public security, labour hazards, the environment, or consumer protection.

In addition, Mexico introduced in 2016 specific procedures to take into account systematically, and when relevant, the trade impacts of regulation in its *ex ante* regulatory impact assessment. Mirroring the similar procedure to assess competition impacts through RIAs, this new procedure allows namely to ensure automatic co-ordination among relevant authorities to ensure notifications of regulations with trade impacts to the WTO, or FTA partners. This strong connection between the RIA and the notification processes is largely unprecedented among OECD countries (OECD, 2018<sub>[2]</sub>) as an effort to leverage the impact assessment procedure to identify measures with trade impacts.

Less than a year since the reform entered into force, it is still early to evaluate the impacts of its implementation. Nevertheless, it is already possible to identify a number of areas where the Mexican authorities could build on the strong existing regulatory improvement apparatus, to further the benefits of IRC for domestic rule-making. In particular, it seems that the new RIA procedures are used more to guarantee WTO notifications, and less to estimate (and potentially reduce) trade costs of new regulations.

It is worth noting that competition may be trade and investment enhancing in itself. Indeed, by ensuring that regulation is pro-competitive, this may create an enabling environment for foreign businesses to operate in Mexico in equal terms as Mexican firms. Ultimately, this may increase or improve choices for consumers, allowing them to choose between products or services with the price and quality characteristics that most closely match their needs (OECD, 2018<sub>[2]</sub>). Therefore, this report is complementary to the recent report on *Standard-setting and competition in Mexico: A Secretariat Report*, which provides an in-depth assessment into competition considerations in the Mexican regulatory process.

Finally, Mexico has procedures for *ex post* assessment of the impact of regulations. Individual examples show that they provide a strong mechanism to embed international considerations in the revision of laws and regulations. However, international considerations are not systematically embedded in these procedures, and more broadly, the use of these procedures remains very limited in practice. Mexico could benefit from tapping more systematically into the potential of *ex post* evaluation to learn from evidence gathered during the implementation of regulations on trade impacts and on the benefits and costs of deviating from international practice.

### ***IRC throughout the process of ex ante RIAs***

The RIA procedures in Mexico have been significantly developed to take into account international trade considerations. Until 2016, the RIA process required merely that regulators describe foreign and international practices relevant to the submitted draft for high-impact RIAs. The RIA procedure was reformed significantly on 22 December 2016, with the objective of establishing a system of alerts to comply with WTO TBT and SPS notification commitments, to identify regulations with an effect on trade and to avoid regulatory proposals that, unnecessarily, generate negative effects on Mexico's foreign trade. Beyond this procedure, COFEMER is also envisaging broadening this range of RIAs to other forms of specific impacts beyond the existing procedures on competition impacts and on risk prevention, such as impacts on human rights.

Today, the Mexican RIA procedures, overseen by COFEMER, embed references / considerations of the international environment at three stages of the process: i) when justifying the legal basis to issue a given regulation; ii) when filling in the regulatory impact calculator to determine the type of RIA to conduct; iii) when conducting the RIA itself if the trade impact calculator is positive, both for the assessment of impacts and as a benchmark of international regulations and practices as a source for policy alternatives.

The same impact assessment procedures apply both to subordinate regulations and technical regulations (NOMs) (art. 4 LFPA, art. 45 LFMN), and both are overseen by COFEMER. However, RIAs conducted for NOMs are submitted both to COFEMER and to National Advisory Committees (*Comites Consultivos Nacionales de Normalizacion*, or CCNN) responsible to develop and monitor implementation of a given NOM. In practice, NOMs are therefore subject to a double quality control.

As voluntary instruments, NMJs do not in principle fall under the RIA procedures. Their trade impact is therefore not considered systematically (OECD, 2018<sub>[2]</sub>).<sup>1</sup>

Beyond these general RIA procedures, a number of autonomous decentralised bodies have developed their own procedures. This is the case for example for the IFT, see Box 2.1. The IRC considerations within IFT's RIA procedures are similar to those of the general RIAs, but apply to IFT regulations – whether technical regulations or not. The RIA Guidelines do not have as detailed questions about trade impacts, but do ask for slightly more elements when identifying relevant regulatory approaches abroad. The IFT emits an average of 18 regulations per year following its own RIA procedure.

#### **Box 2.1. International considerations in IFT guidelines for RIAs**

As a constitutionally autonomous body, the IFT is not subject to the same regulatory improvement procedures as other regulatory bodies in Mexico.

In November 2017, the IFT published in the Official Gazette its Guidelines for Public Consultations and RIAs.

The international environment is taken into account in the consideration of alternatives to the regulatory proposal, as well as in the assessment of its impacts.

##### **Assessment of alternatives**

Question 7 in the IFT RIA Guidelines has a similar question as for high-impact RIAs under the general procedures. The IFT adds a number of options to fill in when replying to this question, incentivising more detailed responses.

*Include a comparative that contemplates the regulations implemented in other countries in order to solve the problem previously detected or something similar.*

*For each analysed case, include the following information:*

Analysed country or region
Name of regulation
Main results
Official legal reference of regulation
Electronic link
Additional information

**Assessment of impacts**

Question 11 of the IFT RIA Guidelines asks the regulator to identify the impacts of the regulation on national and international trade. This question is less detailed than the equivalent questions that are included in the general RIA procedures. However, the question applies to all IFT regulatory proposals, and not only to measures that have gone through a trade RIA calculator as is the case in the general procedures.

*Indicate and describe if the proposed regulation will affect national and international trade.*

*Select all that apply and add the rows that you consider necessary.*

*Source:* Author's development on the basis of information provided by IFT and publicly available information, [www.dof.gob.mx/nota\\_detalle.php?codigo=5503960&fecha=08/11/2017](http://www.dof.gob.mx/nota_detalle.php?codigo=5503960&fecha=08/11/2017).

*International experience to justify the regulation*

International commitments provide a justification in itself to issue a new regulation – it is a direct application of international law into domestic rule-making. Indeed, following guidelines for the emission of new regulation,<sup>2</sup> regulators can emit a regulation only if it falls under one of the following scenarios:

1. Regulation is directed at an emergency situation with the following conditions: not exceeding six months of validity, avoiding an imminent hazard (health, well-being, animal and plant health, environment, or the economy), and not being regulated previously.
2. The regulator fulfils a legal commitment that obliges them to issue certain regulations.
3. The regulation fulfils international commitments.
4. The regulation is in need of update(s).
5. The benefits of the regulation, in terms of competition and efficiency of markets, amongst others, are superior to the compliance costs.
6. It is a rule of operation that is emitted to comply with terms of reference of annual budget regulations.

In practice, when initiating the RIA procedure, regulators are asked to select among six scenarios to justify their regulation. COFEMER analyses the justification before proceeding to the assessment of the RIA and draft regulation. If it does not fulfil one of the six justifications, such as fulfilment of international commitments, the regulation is rejected by COFEMER directly.

By applying this requirement as a first step to all regulators, it is likely to encourage regulators to search for, identify and potentially apply international commitments, therefore facilitating their integration in domestic rule-making. In addition, it provides COFEMER the opportunity to monitor the share of Mexican regulation stemming from international commitments.

*International impacts in determining the type of RIA to conduct, i.e. in the “Regulatory Impact Calculator”*

A new trade RIA filter was added in 2016 to the RIA calculator, embedding international trade impacts in the RIA process from the outset of the process. The questions aim to guide regulators in determining whether their draft may affect international trade.

After the initial ‘justification’ phase, the actual RIA process in Mexico is launched with a “regulatory impact calculator”, which allows regulators to identify potential impacts of their draft regulation, and thus determine which type of RIA to prepare. This calculator comprises three verification filters: i) foreign trade impacts, ii) risk, iii) competition. The verification filter on foreign trade impacts consists of nine questions, which aim to determine whether the assessed draft has an impact on foreign trade (Table 2.1).<sup>3</sup>

**Table 2.1. Trade verification filter**

Indicate if the regulatory measure:	Answer
1. Creates or adds to measures or represents a burden to imports or exports of products, that implies additional monetary costs for economic agents?	Yes / No
2. Establishes a prohibition on imports?	Yes / No
3. Establishes a prohibition on exports?	Yes / No
4. Creates or restricts the requirements to obtain authorisations to trade or authorisations to commercialise a product on the domestic territory (for e.g. licences, certificates, permits, authorisation, certification)?	Yes / No
5. Establishes or modifies the technical characteristics, the process or production method related to a product or service, with which compliance is mandatory for the product to be commercialised or provided in Mexico?	Yes / No
6. Establishes or modifies a measure applied to protect health and life of people and animals or to preserve animals?	Yes / No
7. Establishes or modifies any measure related to the control of entry of goods to the national territory due to risks resulting from the presence of additives, pollutants, toxins, pathogen organisms in food products; spread of epidemics, sicknesses or organisms containing pathogens or sicknesses; or to prevent or limit the damages that could be caused as a result of the entry, establishment or spread of epidemics?	Yes / No
8. Creates or modifies conformity assessment procedures?	Yes / No
9. Creates or modifies the rules on packaging, marking or mandatory labelling for the import of goods and their commercialisation on the national territory?	Yes / No

Source: Based on RIA Guidelines, [www.dof.gob.mx/nota\\_detalle.php?codigo=5466670&fecha=22/12/2016](http://www.dof.gob.mx/nota_detalle.php?codigo=5466670&fecha=22/12/2016).

The result of this calculator will lead the agency to carrying out one of the 14 types of RIAs, 6 of which concern foreign trade, and are therefore referred to as “Foreign Trade RIAs”:

- Regular update
- High impact
- High impact with risk assessment
- High impact with foreign trade assessment
- High impact with risk and competition assessment
- High impact with competition assessment
- High impact with competition and foreign trade assessment
- High impact with risk and foreign trade assessment
- High impact with risk, foreign trade and competition assessment
- Moderate impact
- Moderate impact with foreign trade assessment

- Moderate impact with competition assessment
- Moderate impact with competition and foreign trade assessment
- Emergency

### *International considerations in conduct of RIA*

The RIA guidelines established by COFEMER require that regulators take into account the international environment both in the assessment of impacts, and in the assessment of regulatory alternatives. These questions do not however apply in all RIAs: as indicated below, they apply respectively to RIAs on foreign trade and to RIAs with a high impact.

As part of its oversight of the RIA procedure, COFEMER oversees the regulators' answers to both assessments, asking for regulators to substantiate their assessment if it considers it insufficient. It does not ask specific units of the Ministry of Economy specialised in trade to assess the regulators' trade impact analysis in the manner that it does on competition, for the RIAs with a competition assessment. The foreign trade RIA therefore differs from the procedure followed for the RIA procedures with effects on competition, for which COFEMER refers all RIAs with a positive or negative impact on competition to the competition authority (COFECE), to verify the accuracy of the assessment conducted by the regulator (OECD, 2018<sub>[2]</sub>).

### Assessment of impacts of RIAs on foreign trade

In all six RIAs on foreign trade, five specific questions on the impact of the regulation entail consideration of the international environment:

- Identify the regulatory actions (NOMs, import/export measures, SPS measures, conformity assessment procedures) of the draft text that have an effect on foreign trade, describe how they would affect trade, and justify why this effect on trade is necessary.
- Is the draft text related to any of Mexico's international commitments? If so, please indicate the international commitment with a specific reference.
- Was the draft text elaborated based on any international or foreign standards, and if so, which ones?
- Is the draft text different to NOMs, import/export measures, SPS measures, conformity assessment procedures, but still has an effect on foreign trade (e.g. quotas or safeguard measures)?
- List the principal effects of the proposal on the imports or exports of goods and/or services. Quantify the monetary impacts and incorporate the results at the end of the cost/ benefit analysis.

To help regulators answer these questions, the DGRCI and the COFEMER have organised specific workshops. However, specific guidance on the quantification of trade impacts is not available to the regulators. Indeed, they are not provided with a specific methodology to quantify, or monetise, trade impacts, although a generic cost-benefit analysis methodology is provided by COFEMER.<sup>4</sup>

### Assessment of alternatives in high impact RIAs

For RIAs with high impact, the assessment of alternatives requires a consideration of foreign and international practices. Indeed, a specific question asks to "*Describe the manner in which the problematic is being regulated in other countries and/or the good international practices in this matter*".

*Trade impacts in practice: the experience to date*

Since the reform entered into force in March 2017, and as of end October 2017, 10 Foreign Trade RIAs have been submitted to COFEMER (Table 2.2), a small share of the 292 total RIAs conducted between December 2016 and October 2017 (COFEMER, 2017<sup>[3]</sup>). Out of these 10 Foreign Trade RIAs, 7 were for NOMs and 3 were for subordinate regulation. For all foreign trade RIAs, regulators are asked to respond to the five questions specific to trade impacts. The trade impact analysis conducted by the regulators in this context allows namely to identify the international or foreign standards used as a basis and give an estimated quantification of the trade effects of the proposal.

**Table 2.2. Trade RIAs submitted in 2017**

List of RIAs with an impact on foreign trade submitted to COFEMER in 2017, by regulating agency

Agency	Name (with hyperlink included)	Type of regulatory instrument	Type of RIA	Status
SE	<a href="#">NOM-220-SCFI-2017, NOM on specificities and requirements of cellular phone signal blocking equipment for prisons</a>	NOM	Moderate impact with analysis on trade and competition	Concluded
SCT	<a href="#">NOM on driving and pausing times for drivers of the federal auto transports with the purpose of mitigating accidents</a>	NOM	High impact with analysis on trade and risk	Under revision by COFEMER
SCT	<a href="#">Federal Auto transport and Auxiliary Services Bylaw</a>	Subordinate regulation (bylaw)	High impact with analysis on trade, competition and risk	Concluded
SAGARPA	<a href="#">Ministerial agreement on the use of a national distinction for organic product and labelling criteria</a>	Subordinate regulation (agreement)	Moderate impact with analysis on trade	Pending regulators response to COFEMER opinion
SE	<a href="#">NOM on concrete revolving mixers. Mixers and agitators of front discharge and rear discharge, mounted on automotive vehicle - safety specifications and test methods</a>	NOM	High impact with analysis on trade, competition and risk	Under revision by COFEMER
SE	<a href="#">NOM on safety requirements and testing methods applicable to indoor and outdoor luminaries.</a>	NOM	High impact with analysis on trade, competition and risk	Concluded
SEMARNAT	<a href="#">NOM on maximum emission from new diesel motors.</a>	NOM	Moderate impact with analysis on trade and competition	Cancelled
SENER	<a href="#">Catalogue of equipment and appliances for which manufacturers, importers, distributors and marketers must include information on their energy consumption; and the forms to be included</a>	Subordinate regulation (catalogue)	Moderate impact with analysis on trade	Concluded
SEGOB	<a href="#">NOM on security measures for facilities intended for childcare, public or private</a>	NOM	Moderate impact with analysis on trade	Pending regulators response to COFEMER opinion
SEMARNAT	<a href="#">NOM on phytosanitary measures and internationally recognised labelling for Wood packaging</a>	NOM	Moderate impact with analysis on trade	Under revision by COFEMER

*Note:* This list includes RIAs submitted by 31 October 2017.

*Source:* Information provided by COFEMER.



However, in the absence of a specific methodology, the depth of the trade impact analysis carried out by regulators is heterogeneous. Certain foreign trade RIAs include detailed studies on estimated effects of measures. Others include a basic description of the possible provisions that may present an effect on trade. Finally, in some Foreign Trade RIAs, regulators have indicated that they see no effect on trade, contradictory with the very essence of the procedure they are undergoing. When describing trade impacts, regulators do not specify the methodology that they use in the quantification exercise. Indeed, they are not required to follow a specific methodology to quantify, or monetise, trade impacts (although a generic cost-benefit analysis methodology is provided by COFEMER).<sup>5</sup>

In the conduct of a high impact foreign trade RIA, regulators are asked to consider the foreign and international practices when assessing regulatory alternatives. Five high impact RIA following trade assessment have been conducted to date, on measures developed by the Ministry of Communications and Transport (2), the Ministry of Agriculture (1), and the Ministry of Economy (3). Among these, both international and foreign standards are considered as alternatives, namely from Australia, Canada (SOR/88-45 1 SOR/88-45 177), New Zealand and the European Union, United States, or the IEC.

### ***Ex post assessments and reviews***

After the implementation of measures, regulators may use a variety of tools to assess the use made of their instruments, their achievement of the intended objectives, the unintended impacts, and their relevance in light of possible evolutions in the regulated context. In this view, Mexico has made some approaches available to regulators, with guidelines and oversight ensured by COFEMER. In addition, COFEMER itself conducts a number of studies of certain specific sectors, to assess the regulatory framework, in particular in light of existing approaches abroad and internationally. Also, sporadic reviews commissioned by the Ministry of Economy from international organisations such as the OECD may help evaluate the existing regulatory framework for specific impacts. This is the case, for example, of the competition assessment carried out based on the OECD Competition Toolkit (see for e.g. (OECD, 2018<sub>[4]</sub>)). While several individual examples show that foreign approaches and international guidance, rules and standards are used as benchmarks in the various approaches, the use of *ex post* assessment and reviews remains occasional, making it difficult to conclude in systematic leveraging of international experience.

### ***Ex post assessments***

*Ex post* assessments may provide for a privileged avenue to observe the impacts of a regulatory measure once it is adopted, including the frictions generated on trade and other international flows, and to estimate the costs/ benefits of its potential deviation from international practice. However, *ex post* assessments are not yet fully exploited to this effect in Mexico. On one hand, *ex post* assessments remain a rarely used tool, systematically applied only for technical regulations regarding the need to update or not. On the other hand, the assessments conducted only consider the international environment when the same regulation had been subject to an *ex ante* RIA, and that questions on international considerations had been considered in this context.

*Ex post* evaluations are required for NOMs (at least) every five years (art. 51 LFMN). These evaluations do not comprise measuring the impact of the regulation but rather assessing if a given regulation needs to be updated or not. In addition, the CCNNs or

COFEMER can also recommend a regulatory agency to conduct an *ex post* assessment of a NOM's implementation, effects and compliance within the year after its entry into force.

In addition, COFEMER has set specific guidelines on *ex post* assessment<sup>6</sup> applicable to NOMs and subordinate regulation, which were previously subject to an *ex ante* RIA. As per these guidelines, however, only one question includes reference to international practices.

In identifying the possible alternatives to regulation, regulators are asked to identify the practice in other countries and/or as recommended by international organisations or associations, to explain the applicability of such approaches in Mexico, and the reasons for which they were not sustained. An example of a RIA procedure in which this is addressed is described in Box 2.2.

In the analysis of the impact of the regulation, regulators are asked about the actual effects that the regulation has had on consumers and trade and in particular, on the prices, quality and availability on goods and services. This question does not however specifically refer to international trade. This contrasts with the international environment and trade impacts considered in *ex ante* RIAs, and does not exploit the information basis acquired while conducting *ex ante* RIA.

#### **Box 2.2. International considerations in *ex post* assessment**

##### **Technical regulation on essential safety requirements in new motor vehicles – safety specifications (NOM-194-SCFI-2015)**

The Ministry of Economy (DGN) developed a NOM regarding the essential safety requirements in new motor vehicles. It was submitted to an *ex ante* RIA with high impact on competition and risk in November 2014.

In response to the question on regulatory approaches in foreign countries, the regulator listed similar existing regulations in the United States and in the European Union on motor vehicle safety. To justify the different position adopted from these two regulations, the regulator put forward the specific context of Mexico that differentiated it from other countries, namely as an important exporter country of motor vehicles and parts of motor vehicles, and due to the absence of previous regulations on safety of motor vehicles.<sup>1</sup>

In its opinion about the *ex post* assessment, COFEMER did not pronounce itself on the alternative approaches adopted in foreign countries, but recommended in particular that the regulator consider the relevance of including several safety requirements envisaged by the World Health Organisation.<sup>2</sup>

<sup>1</sup> [www.cofemersimir.gob.mx/mirs/44249](http://www.cofemersimir.gob.mx/mirs/44249).

<sup>2</sup> [www.cofemersimir.gob.mx/expediente/21179/emitido/47768/COFEME](http://www.cofemersimir.gob.mx/expediente/21179/emitido/47768/COFEME).

In practice, *ex post* assessments are seldom conducted, both for NOMs and subordinate regulations. Regarding technical regulation, the 5-year obligation to do an *ex post* assessment is in practice a decision made by the CCNN to update, maintain or repeal a given NOM without a detailed measurement of the impacts the NOM had during its implementation. Regarding subordinate regulations more broadly, five *ex post* assessments have been conducted to date, one regarding a subordinate regulation and four regarding technical regulations.<sup>7</sup> At this occasion, international considerations have been introduced both by the regulator in its assessment and by COFEMER in its opinion about the assessment (see Box 2.2).

### *Diagnostic studies of regulatory framework in place*

Separate from the *ex post* assessment procedures, COFEMER has the faculty to conduct studies on the national regulatory framework, and issue reform proposals drawing on its findings (art.69-E I LFPA). In recent years, COFEMER has conducted around 40 studies analysing the existing regulatory framework in different sectors, in order to promote options for regulatory improvement.<sup>8</sup> In some of these studies, the international context is considered as a benchmark to identify possibilities for reform.

For example, in a study from 2017, when considering a possible revision of the Mexican regulatory framework concerning e-commerce, COFEMER examined the existing framework applicable in Mexico, the United States and Canada. In addition, it gave an overview of relevant international *fora* with policies applicable to e-commerce, such as the OECD, the WTO, the United Nations Commission on International Trade Law, as well as the chapter on e-commerce of the Trans-pacific partnership.<sup>9</sup> This study helped identify areas of focus to improve the Mexican framework on e-commerce and resulted in broad conclusions, recommending among other things to co-operate internationally with foreign governments, specifically with regards to the development of an open and safe cyberspace to gain trust of consumers, and to harmonise border measures between Canada, Mexico and the United States to facilitate e-commerce of goods in North America.

### **Information and engagement of foreign stakeholders**

Mexico has a variety of means to inform and obtain feedback from foreign stakeholders on its draft regulations, both at the domestic level and the international, through notification to trading partners and the WTO on TBT and SPS matters. They include the systematic publication of forward planning agendas for NOMs, systematic co-regulation within the development of NOMs, consultations on RIAs for all subordinate regulations, and occasional multi-stakeholder working groups for subordinate regulations. Most significantly, all draft regulations available on COFEMER's website include a summary in English, a key undertaking for ensuring international outreach, still exceptional among OECD countries (Figure 1.5). The potential avenues for receiving foreign views on regulation are therefore significant.

At the same time, the procedures to receive such feedback are fragmented, and there is uneven openness to foreign stakeholders among them. As a result, the different avenues for foreign stakeholders to truly get their voice heard are unevenly effective. Without general monitoring of all foreign stakeholders consulted, the benefits of these different procedures are difficult to identify. In practice, evidence suggests that inputs from foreign stakeholders are consistently received through the WTO notification procedures, but less so through the national stakeholder engagement procedures. As a result, the foreign inputs received concern mainly the trade effects of the regulations.

### ***Forward planning***

Forward planning tools provide a basis to inform stakeholders of upcoming regulations, thus ensuring predictability of the regulatory framework. They are also an opportunity to inform stakeholders about upcoming consultations, thus increasing awareness of stakeholders about their opportunities to submit views.

Such transparency about prospective agendas is useful for trading partners. Indeed, the WTO TBT for instance requires that WTO Members developing a technical regulation or conformity assessment procedure which is not based on international standards and has a significant effect on trade:

*“...publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation” (art. 2.9.1. TBT Agreement).<sup>10</sup>*

Mexico has developed a forward planning tool made public through its official gazette, in line with its WTO obligations, specific for NOMs and NMXs. It is the first step in the development of NOMs and NMXs. The national standardisation programme (*Programa Nacional de Normalización*, PNN) is the instrument for planning, co-ordination and information with regards to the development of technical regulations and standards stemming both from the public and the private sector (art. 55 of bylaws of LFMN). The PNN includes the list of NOMs and NMXs to be developed, updated, modified or cancelled along an objective for each standard as well as a work calendar. There is a supplement where regulators can introduce new proposals to be approved and published in August (art. 55-58 Bylaw LFMN).

The PNN is developed by the Ministry of Economy and published in the Official Gazette once a year (a supplement can be issued mid-year) for informational purposes. The Official Gazette was therefore designated by Mexico to the WTO TBT Committee as the source to find planned technical regulations and standards (within the PNN), as well as the adopted texts. On its own initiative, Mexico is the only WTO Member to circulate its PNN as a WTO document to all WTO Members, going beyond TBT Agreement obligations and committee recommendations. This has the benefit of giving considerable visibility to this instrument, which has the potential of serving as a baseline for early consultations, including with foreign stakeholders.

### **Box 2.3. Forward planning in the European Union**

The European Commission uses the opportunity of the publication of its work programme to inform stakeholders about upcoming regulations and their potential impacts. The European Commission’s work programme sets out the overall planned action for the upcoming 12 months. For some specific measures, the European Commission publishes initial ideas for new laws or on plans for evaluations of individual laws and “fitness checks”. Proposed actions are set out in documents called roadmaps and inception impact assessments, which are publicly consulted on. These documents usually contain a section called “Consultation of citizens and stakeholders”, where the EC outlines how and what kind of stakeholders have been/will be consulted.

The inception impact assessments in particular provide with an initial overview of policy objectives, different solutions and an initial assessment of their possible impacts. They therefore offer stakeholders the opportunity to provide feedback on these elements in the early stages of development of legislation before a full RIA is prepared.

Source: [https://ec.europa.eu/info/strategy/strategy-documents\\_en](https://ec.europa.eu/info/strategy/strategy-documents_en).

Regarding subordinate regulation, regulators are required to carry out regulatory improvement programmes every two years for simplification purposes. The programmes are subject to COFEMER's oversight and require regulators to set out a list of regulation and/or administrative procedures foreseen to be created, modified or abolished. The regulatory improvement programme proposals are published only during the public consultation phase. After the consultation, COFEMER reviews the programmes and makes comments to which the regulators need to reply. The final regulatory improvement programmes are used for internal monitoring of commitments. COFEMER, along with the Ministry of Public Administration, carry out internal progress evaluations that are made public in COFEMER's annual report.

The General Law of Regulatory Improvement includes a provision introducing a new forward planning agenda mandatory for all subordinate regulations. The regulators are required to present their regulatory agenda during the first five days of May and November of each year. The proposed regulatory agenda will be submitted to public consultation for a minimum period of 20 days (cf. art. 11 and 64).

### ***Domestic stakeholder consultation procedures for subordinate regulations and “co-regulation” for NOMs***

Mexico has several different means for stakeholder consultation, during the process of development of subordinate regulations, technical regulations, or both (see Box 2.4).

#### **Box 2.4. Single consultation for subordinate regulation and triple consultation for NOMs**

##### **1) Stakeholder engagement for all subordinate regulations and NOMs**

All subordinate regulations and NOMs are submitted to public consultations as an integral part of the RIA process. As soon as COFEMER receives a regulatory draft and the accompanying RIA, both are submitted to public consultation, until the publication, in the Official Gazette, of the definitive regulation. In parallel, the regulatory project can be made public on the website of the Ministry or the regulatory agency. Quality is ensured by COFEMER who publishes and considers the comments and inputs from stakeholders, and submits a final opinion on the RIA.

In practice, beyond this procedure, regulators may choose to consult with stakeholders at their own initiative in the early stages of drafting. To verify whether regulators chose to do so, the RIA questionnaire includes a section to verify the conduct of prior consultations. Regulators are asked to indicate among others which means they used to conduct stakeholder consultations, and particularly if authorities from foreign countries or international organisations were consulted (question 18).

##### **2) Additional stakeholder engagement processes for NOMs**

The NOM development process opens various opportunities to engage with stakeholders. They are consulted both while drafting the NOMs and after the publication in of the drafts in the Official Gazette, as follows:

- Regulators developing NOMs must do so within the framework of an established National Advisory Committees for Standardisation (*Comites Consultivos Nacionales de Normalizacion*, or CCNN). These committees are

themselves composed of private stakeholders, as well as social, academic and consumers' representatives.

- When a draft NOM is published in the Official Gazette. This publication opens a consultation period of 60 days. After the 60-day period, each CCNN analyses the comments received and responds to them. The responses are also published on the Official Gazette. After this consultation, the final NOM is published on the Official Gazette. The process is overseen by the Ministry of Economy.

Beyond these procedures, regulators may receive feedback to their regulations from foreign stakeholders or countries through the WTO notification process.

There is a general consultation procedure applicable to all regulations that go through a regulatory quality appraisal, co-ordinated by COFEMER. Any stakeholder can participate in this public consultation process, regardless of their nationality. The consideration given to foreign stakeholders is the same as the national one. Still, to facilitate inputs from a broader range of foreign stakeholders, Mexico is one of the few OECD countries to have English summaries of all of draft regulations, with only two other countries providing translated texts for subordinate regulations (OECD, 2018<sup>[2]</sup>). All regulations available on COFEMER's website are accompanied by a summary in English.

The consultation process followed for NOM-setting has two more layers of engagement. The first one corresponds to a "co-regulation" with industry, social, academic and even consumers' representatives during the early stages of the drafting of the proposal within the framework of the National Advisory Committee for Standardisation. This procedure is not in principle open to participation of foreign stakeholders. The second one is a mandatory 60-day consultation after publishing the proposal in the Official Gazette. Given the public nature of the publication in the Official Gazette, comments through this 60-day consultation may be submitted by any stakeholder, including foreign stakeholders. Here, there is no specific effort to engage foreign stakeholders.

### *Stakeholder engagement through trade notification procedures*

Mexico stands out with well-developed domestic procedures to ensure notifications to the WTO and FTA partners, which are well embedded into its domestic regulatory improvement agenda. The recent reform in the RIA system introducing the trade RIAs strengthen even further this process, ensuring systematic alerts on new trade-relevant regulations and thus institutionalising the identification of technical regulations to report to the WTO or FTA partners.

#### *Mexico's domestic procedures to submit notifications to the WTO and other Free Trade Agreements (FTAs)*

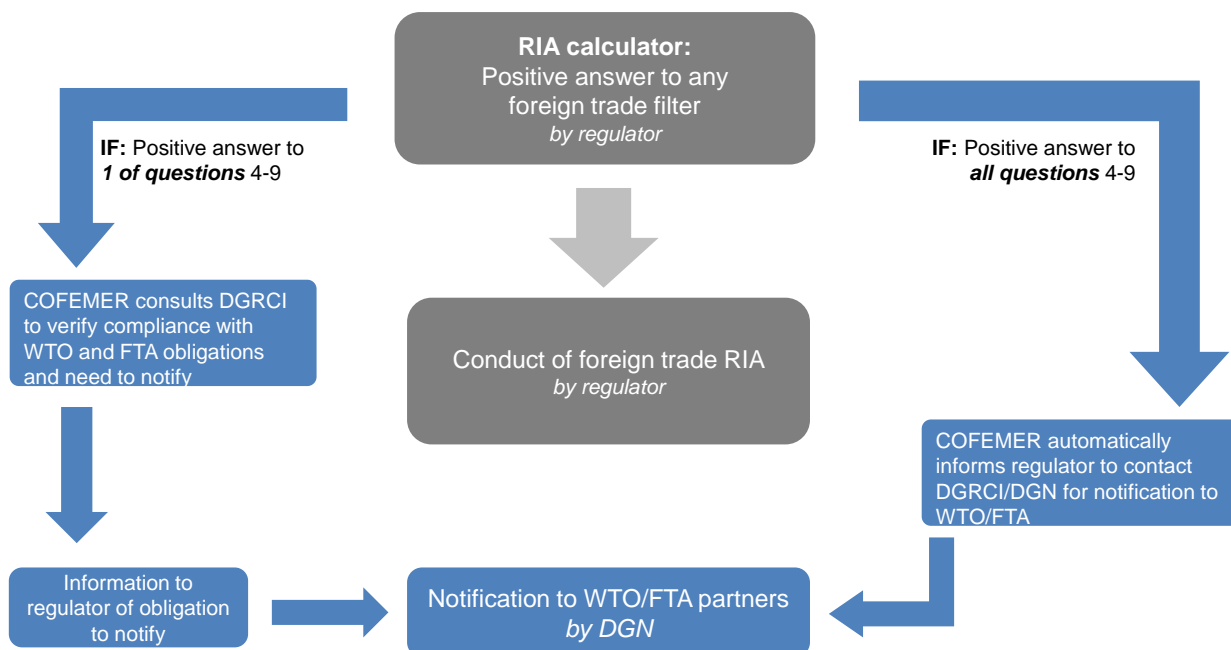
In Mexico, the notifications to WTO or FTA partners are under the responsibility of the Ministry of Economy. The General Direction of International Trade Rules, under the Vice-Ministry of Foreign Trade of the Ministry of Economy is responsible for negotiating and implementing the trade agreements signed by Mexico (*Dirección General de Reglas de Comercio Internacional*, DGRCI). The General Bureau of Standards (DGN) under the Vice Ministry of Competitiveness and Business Regulation of the Ministry of Economy has been appointed as the notification authority and enquiry point for the SPS and TBT Agreements.<sup>11</sup> Both authorities within the Ministry of Economy are therefore closely involved in the process of notifications to the WTO and FTA partners.

In practice, the DGN and DGRCI from the Ministry of Economy go through the Official Gazette to identify all regulations with potential trade effects. They chose to notify any regulations with potential effects on trade, whether they predict significant effects or not, and whether they comply with international standards or not. In particular, they notify by default all NOMs because their very nature of technical regulations implies an impact on trade.

Despite this practice, a specific procedure was created to ensure co-ordination prior to notifications and prevent any regulations with an effect on trade to go unnoticed. Since the 2016 reform of the RIA procedures, COFEMER plays an important role in identifying proposed measures with trade impacts. Based on the new trade filters introduced in the RIA procedure in 2016, COFEMER is able to systematically alert the Ministry of Economy (DGN and/or DGRCI) about new regulatory projects (*anteproyectos*) that may need to be notified to the WTO as well as to other specific trading partners in virtue of bilateral or regional FTAs.<sup>12</sup>

This alert takes place at the stage of the foreign trade filter, and launches a parallel procedure to the conduct of the RIA, as pictured in blue in Figure 2.1. A slightly different approach is launched depending if the measure may have an impact on trade and require further analysis, or measures that clearly have an impact on trade.

**Figure 2.1. WTO notifications embedded in Mexico's RIA Procedure**



*Notes:* The stages pictured in blue describe the specific steps followed to ensure notification to the WTO. These are conducted in parallel to the regular conduct of the RIA by the regulator, pictured in grey.

*Source:* Author's development, based on information provided by the COFEMER, DGRCI and DGN.

When the regulator has answered positively one of questions 4-9 of the trade filter, the effect of the measure is considered uncertain: the COFEMER asks the DGRCI to determine whether the measure complies with trade agreement obligations and must be notified. The DGRCI then has 7 days to assess the measure for moderate impact RIAs, and 20 days for high impact RIAs. When processing draft regulations, the DGRCI does

not have a specific methodology to estimate the impact that the draft may have on trade. This is determined on a case by case basis based on information provided by the regulators, and when a doubt remains on the significance of a trade impact, the DGRCI encourages notification. If DGRCI determines that the measure has a significant trade impact and deviates from international standards, it then sends an official letter to the regulating agency, with COFEMER on copy, requesting them to contact DGN to ensure the notification of the measure to the WTO and/or to FTA partners.

When the regulator has answered all questions 4-9 of the trade filter positively, the trade effect of the measure is considered more certain: COFEMER alerts the regulator directly about the need to notify the measure, keeping the DGRCI on copy, and encouraging them to contact the DGN. If the measure is notified to the WTO and/or FTA partners, COFEMER will attach the opinion of the Ministry of Economy to the RIA for transparency purposes.

Notification of Mexican measures to the WTO allows other WTO Members to comment on them. In practice, the public nature of the notifications enable interested stakeholders from other WTO Members to also submit comments, and specific alert mechanisms are also available to facilitate access to notifications by stakeholders globally.<sup>13</sup> The comments received from foreign stakeholders to WTO notifications do not go through the regular stakeholder engagement process overseen by COFEMER. They are processed by DGN, which shares them with the relevant regulatory authorities.

Conversely, Mexico also has domestic procedures in place to co-ordinate comments on foreign measures notified to the WTO by other WTO Members. All notifications to the SPS and TBT Committee are received by DGN and DGRCI, who share them with industry representatives within the special mirror Committees on SPS and TBT set up at the national level, under the authority of the Ministry of Economy. If these Committees express an interest on the measure, it is the DGRCI who submits the comments to the foreign counterpart, either bilaterally or by raising a specific trade concern in the relevant WTO Committee. Such comments may include a request for further information on the measure, a request for an additional delay before implementation, or manifestation of a specific concern with the effects that the measure may have on trade.

### *Mexico's notification practices to the WTO*

Notifications of draft regulations to international *fora* may inform foreign governments and interested stakeholders of the existence of new drafts. This is particularly the case of the transparency framework set up under the World Trade Organisation, under the agreements on Technical Barriers to Trade (TBT Agreement) and Sanitary and Phytosanitary measures (SPS Agreement). Both agreements require that WTO Members notify to other Members the drafts mandatory regulations which may have a significant effect on trade and are not based on international standards. In addition, both the SPS and TBT Committees encourage WTO Members to notify measures even when they are based on international standards (WTO, 2008<sub>[5]</sub>) (WTO, 2009<sub>[6]</sub>). Indeed, even if *based on* international standards they are not necessarily identical to them, and they may still have effects on international trade. This notification should be done at an early appropriate stage, when amendments can still be introduced and comments taken into account.<sup>14</sup>

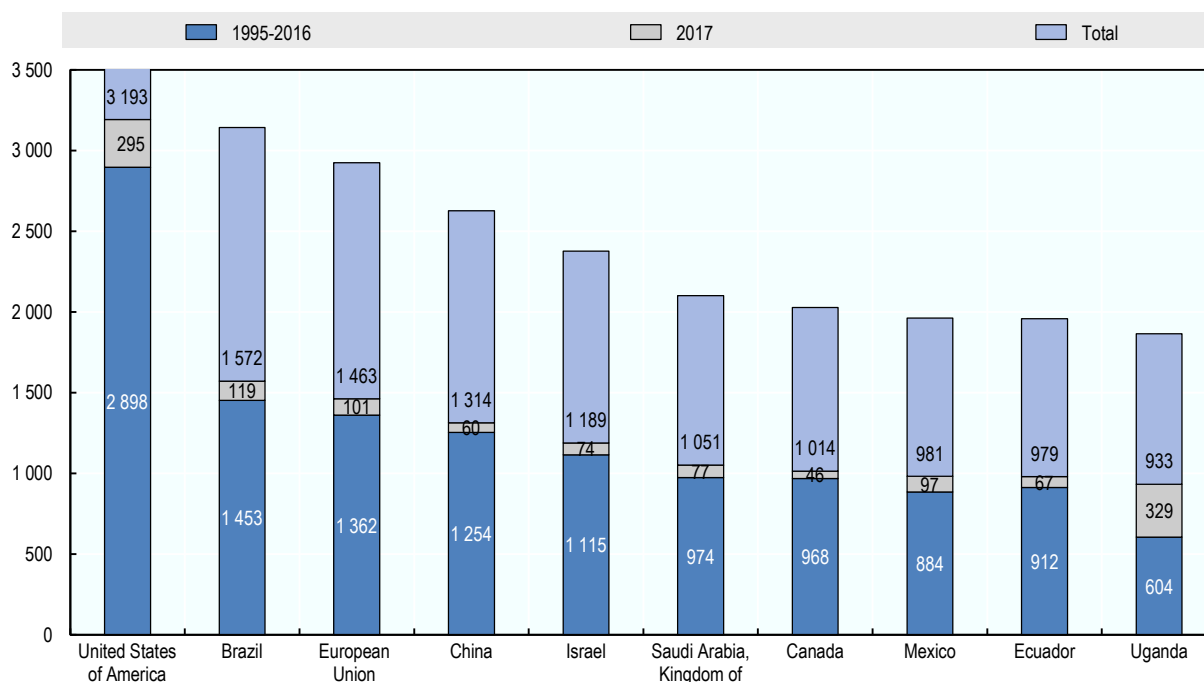
To ensure such notifications are effectively submitted, the SPS and TBT agreements required WTO Members to establish a single central government authority responsible for these notifications<sup>15</sup>. These procedures allow to centralise information about draft measures throughout all WTO Members within one information source (the WTO



website), thus facilitating the access to the draft regulations and related information. In practice, the draft texts are submitted by the relevant authorities in each WTO Member to the WTO Secretariat. Once draft measures are notified to the WTO, the WTO Secretariat makes these drafts publically accessible on its website, and provides the contact details of the enquiry points of all WTO Members.<sup>16</sup>

In practice, Mexico is an active notifier to the WTO and most of its measures which affect its trading partners are notified, whether their effect on trade is significant or not and whether they are based on international standards or not. To date, Mexico has submitted a total of 1046 notifications of TBT measures since 1995 and 516 of SPS measures.<sup>17</sup> It is among the top notifying WTO Members of both TBT and SPS measures (Figure 2.2 and Table 2.3), and this even before the reform on the new Foreign Trade RIA was introduced, to further enhance WTO notifications. It is still early to tell how the new Trade RIA procedure will impact Mexico's notifications to the WTO.

**Figure 2.2. Ten members that submitted most notifications to the TBT Committee**



*Notes:* The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

*Source:* (WTO, 2018<sup>[7]</sup>), “Twenty-Third Annual Review of the Implementation and Operation of the TBT Agreement”, Note by the Secretariat, G/TBT/40, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/TBT/40.pdf>, 12 March.

Both SPS<sup>18</sup> and TBT<sup>19</sup> information portals list the agency responsible for the draft measure and in some instances, when different, the agency responsible for handling comments. In 2017, the agency responsible for most SPS measures notified to the WTO was the Ministry of Agriculture (SAGARPA), with 16 out of 18 submitted SPS notifications. One was submitted by the Ministry of Environment (SEMARNAT) and one was notified without specification of a responsible authority.

**Table 2.3. Members which have submitted the most notifications to the SPS Committee since 1995**

Regular notifications			Emergency notifications		
Member	Number of notifications	Share of total	Member	Number of notifications	Share of total
United States	2 810	20%	Philippines	185	10%
Brazil	1 213	9%	Albania	166	9%
China, People's Republic of	1 162	8%	New Zealand	116	7%
Canada	1 069	8%	United States	83	5%
Peru	605	4%	Colombia	76	4%
Korea, Republic of	527	4%	Ukraine	74	4%
European Union	523	4%	European Union	65	4%
Chile	497	4%	Peru	64	4%
Japan	462	3%	Russian Federation	62	3%
New Zealand	426	3%	Saudi Arabia, Kingdom of	58	3%
Chinese Taipei	414	3%	United Arab Emirates	51	3%
Australia	369	3%	Thailand	46	3%
Mexico	267	2%	Chile	37	2%
Thailand	209	2%	Mexico	37	2%
Colombia	188	1%	Australia	32	2%

Source: Overview regarding the level of implementation of the transparency provisions of the SPS Agreement, 10 October 2016, G/SPS/GEN/804/Rev.9.

The authorities involved in TBT notifications are more diversified, because of the broader scope of the TBT Agreement. Table 2.4 shows the agencies that are responsible for the TBT notifications in 2017. The Ministry of Economy is most cited (10 TBT notifications), without precision of the body within the Ministry. The National Agency for Industrial Safety and Environmental Protection in the Hydrocarbon Sector, the Ministry of Communications and Transport and the Ministry of Environment and Natural Resources came second, with 3 notifications each.

**Table 2.4. Regular TBT notifications submitted by Mexico to the WTO in 2017**

Responsible Agency	Number of TBT Notifications in 2017 (excluding addenda, corrigenda and revisions)
Ministry of the Economy	10
National Agency for Industrial Safety and Environmental Protection in the Hydrocarbon Sector	3
N/A [Enquiry Point]	3
Ministry of Communications and Transport	3
Ministry of the Environment and Natural Resources	3
Ministry of Agriculture, Livestock, Rural Development, Fisheries & Food	2
Ministry of Energy	2
Ministry of Health	2
National Commission for Nuclear Safety and Safeguards	1
Energy Regulatory Commission	1
National Advisory Committee on Standardization of the Ministry of the Economy	1
Federal Telecommunications Institute	1
Ministry of Labour and Social Welfare	1

Note: Data gathered in October 2017.

Source: WTO TBT Information Management System, <http://tbtims.wto.org/>.

### *Leveraging multilateral co-operation for domestic rule-making*

Complementing the notification procedures which allow for consultations with foreign stakeholders, the TBT and SPS Committees provide the opportunity for discussions about draft regulations within a multilateral context. This helps improve transparency of measures and may result in useful inputs about the effects of measures perceived by other countries.

Since 2010, only two specific trade concerns (STCs) were raised in the TBT Committee against Mexican measures that were not notified (out of a total of eight STCs raised against Mexican measures).<sup>20</sup> In the SPS Committee, only three concerns were raised against Mexican measures since 2010, although all of them related to measures which had not been notified to the WTO. It is nevertheless a small number of concerns raised against Mexican measures, compared to the 238 notifications submitted in the same timeframe. Mexican authorities seem to prevent STCs from being raised as much as possible, by maintaining discussions bilaterally to the extent possible.

Mexico also makes active use of the WTO framework to raise Specific Trade Concerns regarding measures of other countries. Since 1995, it has raised 81 STCs in the TBT Committee, and 41 in the SPS Committee, participating in around 10-15% of all STCs. Although this is much less active than the United States or the European Union (responsible respectively for 233 and 255 STCs in the TBT Committee and 175 and 212 in the SPS Committee), it is close to Canada's activity (with 110 STCs in the TBT Committee and 74 in the SPS Committee). Overall, Mexico is among the 10 most active WTO Members raising concerns in both Committees (WTO, 2017).

**Table 2.5. Countries whose measures are most challenged by Mexico in TBT Committee**

1995-2017

WTO Member	Number of TBT STCs
European Union	18
Ecuador	10
United States	8
Brazil	7
Colombia	5
Korea	4

Source: <http://tbtims.wto.org/>.

In the TBT Committee, Mexico raises most concerns regarding the EU and Ecuador (Table 2.5), although US measures presumably have most trade impact on the Mexican market. This suggests that Mexico and the United States may have other *fora* for discussing such measures.

Mexico also raises more concerns about technical regulations than conformity assessment procedures, suggesting that the trade barriers affecting Mexican exporters tend to be more on foreign regulations themselves than on conformity assessment. This is contrary to the general trend in the TBT Committee, where a majority of STCs are raised regarding conformity assessment procedures (Karttunen and McDaniels, 2016<sup>[8]</sup>). It may reflect the fact that lack of harmonisation of Mexico's regulations with foreign and international standards remains a key concern for its trading partners.

*Mexico's notifications to other trade agreements*

Bilateral and regional trade agreements provide for an additional means for Mexico to engage more directly with foreign stakeholders. To date, it seems that these notifications are used in a similar way as WTO notifications, and no specific evidence indicates that a closer dialogue takes place despite the more direct relation that bilateral or regional trade agreements may entail.

Most of Mexico's bilateral and regional trade agreements include SPS and TBT chapters, including notification obligations. These allow to increase information sharing with FTA partners, and operate in parallel to WTO SPS and TBT notification obligations, without replacing them. Some of these require notification to the WTO (e.g. Pacific Alliance) but a majority of these obligations entail direct notification either in writing or electronically to the other party. In certain cases, the same obligation is reiterated (e.g. Mexico-Costa Rica FTA, Mexico-Bolivia FTA). In others, the notification obligation is more detailed, for example with a broader or more specific range of measures to be notified to trading partners (e.g. Mexico-Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua Free Trade Agreement). Finally, a number of agreements require the opening of stakeholder consultations to stakeholders from other party (e.g. NAFTA, Mexico-Chile), or provide for the creation of a SPS or TBT Committee, enabling a dedicated setting for the authorities to discuss concerns about notified measures directly (e.g. Mexico-Nicaragua).

**Adoption of international instruments in domestic regulations**

International instruments<sup>21</sup> may serve as a basis for regulators when developing a new regulation, to enhance their evidence-basis and align approaches with foreign countries. In particular, the adoption of voluntary international standards into domestic regulations is usually required from regulators in order to reduce unnecessary barriers to trade when developing new regulations, in line with WTO obligations.<sup>22</sup> The adoption of international standards in domestic legislation has significant potential to lower costs of international trade (OECD, 2017), and foster competition, by facilitating access to the Mexican market, including by foreign competitors (OECD, 2018) (see Box 2.5). It supports the harmonisation of technical specification of products across export markets, and may also help to harmonise conformity assessment procedures across countries. Beyond trade cost reduction, international instruments may allow regulators to adopt state of the art rules that benefit from the experience of other regulators in dealing with similar issues.

Mexico has various provisions encouraging the adoption of international standards, mostly bearing on technical regulations and standards (NOMs and NMXs). If international standards do not exist, the consideration of foreign standards is encouraged, in particular standards of two major trading partners, the United States and the EU. To support regulators in this obligation, a guidance document on how to embed international standards in domestic technical regulations or standards was developed, and some examples of international and foreign standards are listed in the legal obligation. In practice, however, only few of the existing technical regulations or standards are actually based on international standards.

Regulators are less systematically encouraged to consider international instruments or other jurisdictions' regulatory approaches in the drafting of subordinate regulations. The consideration of international instruments for subordinate regulations (beyond NOMs) intervenes after a first draft is submitted to COFEMER, during the RIA process. Little evidence exists on the actual use of international instruments or consideration of relevant foreign regulatory frameworks in subordinate regulation in general.

### Box 2.5. IRC for enhancing competition

IRC supports regulators in the development of effective regulations and improving the openness and efficiency of the Mexican market. (OECD, 2018<sub>[4]</sub>) includes recommendations on how to improve competition, particularly in the medicines and meat product sectors. Certain entail the enhancement of IRC practices, such as the selected examples below.

- **Adoption of international standards in NOMs and NMX on meat products and in the medicine sector:**

Non-harmonisation with international standards – be it partial or total – may hinder foreign competitors’ access to the Mexican market, as well as access to foreign markets by Mexican producers.

(OECD, 2018<sub>[4]</sub>) recommends that 27 NOMs and 1 NMX regarding meat products and 10 NOMs in the medicine sector are brought into line with international standards.<sup>1</sup> Interviews with industry participants revealed that some current practices may already be in accordance with international standards, which would significantly ease the transition, but confusion among market participants might result if the legal text is not updated. The NOMs and NMX should also contain mentions when there are no existing international standards or best practices.

- **Eliminating double authorisation requirements for import of animals, their products and sub-products through mutual recognition agreements:**

Animals, their products and sub-products must come from authorised establishments within authorised countries. For a foreign country to be authorised, its veterinary services must be recognised by SAGARPA as working to standards at least equivalent to the ones applied in Mexico. In addition, SAGARPA must authorise and inspect establishments in foreign countries, which might be seen as an unnecessary additional barrier to entry for foreign producers.

(OECD, 2018<sub>[4]</sub>) recommends eliminating that additional establishment authorisation. However, this should be based on bilateral agreements with countries that abolish additional requirements for authorisation of Mexican exporters by their sanitary authorities. In these bilateral agreements, each country’s sanitary authorities will ensure the quality of all exporting establishments and their products within their jurisdiction.

- **Recognition of foreign test results of interchangeability studies on generic medicines conducted abroad by equivalent control systems:**

When introducing a new generic to the Mexican market, tests performed to determine whether the generic medicine produces a similar effect to the reference product, known as interchangeability tests, must be performed by authorised third parties in Mexican territory with a Mexican population sample, even if similar studies have already been performed before abroad. This requirement may impose unnecessary extra costs on pharmaceutical companies that operate abroad, discouraging them to sell generic medicines in Mexico.

The OECD recommends abolishing the requirement that pharmaceutical companies conduct tests on the Mexican territory and population and accept interchangeability studies that have been accepted by foreign authorities as long as their control systems are regarded as at least equivalent to the Mexican one. COFEPRIS should recognise those authorities (similar to COFEPRIS recognising eight foreign authorities for the issuance of Good Manufacturing Practice certificates). Only in exceptional cases, for which there must be guidelines, should the Ministry of Health order additional tests with the Mexican population.

1. See full list of NOMs and NMX to be harmonised in (OECD, 2018<sub>[4]</sub>).

Source: (OECD, 2018<sub>[4]</sub>), *OECD Competition Assessment Reviews: Mexico*, OECD Competition Assessment Reviews, OECD Publishing, Paris, <http://dx.doi.org/10.1787/9789264288218-en>.

### *The consideration of international instruments in domestic regulatory regulations*

International instruments are considered at various stages in the Mexican regulatory process, albeit differently depending on the regulatory tools at stake. By law, international standards should be systematically considered in the drafting stage of technical regulations and standards. As a result, regulators developing technical regulations and standards are required to take into account international standards at an early stage and therefore have stronger incentive to choose regulatory approaches compatible with international instruments. For subordinate regulations more broadly, the requirement to consider international instruments is much less systematic. It intervenes when undergoing RIAs, and only if the draft regulation is submitted to certain types of RIA procedures.

For international standards to become applicable in Mexico, they must be incorporated into the Mexican regulatory framework through a technical regulation or standard (NOM or NMX), and thus go through the Mexican regulatory process. The law does not however prescribe the specific form in which international standards should be adopted/incorporated in domestic legislation. Guidance is given to regulators on different forms through which they can adopt international standards:<sup>23</sup>

- **Reproduction (*reimpresión*):** the international standard is adopted as a NOM or NMX by directly reproducing the original standard, for example by photography, scan or electronic archive. This does not exclude that the Mexican measure includes an introduction, is translated to Spanish, has a different title, has minor technical modifications or editorial changes, or annexes additional informative material.
- **Translation (with or without reproduction of original international standard):** the international standard may be published in Spanish or in both relevant languages.
- **Redrafting:** if the international standard was not adopted through reproduction or translation, it is considered to be redrafted.

Regulators are free to choose the form through which they adopt an international standard. They are encouraged to adopt them by “reproduction”. They are discouraged to redraft international standards, as the level of conformity with the international standard is more difficult to establish.

In the development of technical regulations and standards, under the LFMN, regulators are required to systematically consider international standards:

- Mexican technical regulations (NOMs) must be elaborated in consideration of international standards and guidelines. In so doing, regulators must indicate the level of compliance with these international standards and guidelines, and with Mexican standards used as a basis for its elaboration (art. 41 VI LFMN). The NOMs must therefore specify whether the NOM is identical, equivalent or non-equivalent<sup>24</sup> and the NOM's Bibliography Chapter must include the international/foreign standards or guidelines that were considered to develop a NOM (art. 28 LFMN bylaws). In addition, each NOM has a reference to the "international classification for standards", helping facilitate understanding of Mexican technical regulations abroad.<sup>25</sup> When international standards are not an efficient or appropriate means to meet the objectives of the NOM, the regulator will have to communicate it to the Ministry of Economy prior to publication (art. 44 LFMN).
- Mexican voluntary standards (NMX) must be elaborated "... based on international standards, unless these international standards are inefficient or inadequate to fulfil its objectives and this is duly justified." (art. 51-A.II LFMN)

Finally, the laws governing the mandate of specific regulators also reiterate the obligation to adopt international standards in the development of technical regulations. For example, art. 6.I.a, ASEA's law states that, when regulating operational and industrial safety matters, ASEA should ensure the adoption and observance of the best national and international technical standards.

DGN monitors the references to foreign and international standards in technical regulations (NOMs) and standards (NMXs), and may return to the regulators if an existing international standard is not referenced. In practice, DGN may be informed about existing international standards by the private sector. DGN may also return to the regulator if there is an issue with the standard that is referenced. For example, it examines whether it considers the standard referred to as an international standard, and whether it can serve as a basis for the NOM or NMX.

By contrast, there is no systematic requirement for regulators to consider relevant international instruments (standards or other) in the drafting of new primary and subordinate regulations more broadly, beyond technical regulations. However, they must be considered as part of the RIA procedure in case of the high-impact RIAs. Indeed, regulators are required to identify relevant international and foreign standards when conducting RIA, to estimate the impact of the regulation or consider alternatives to the regulation. This obligation is similar to practice in Australia, where the Best Practice Regulation Handbook recommends that a Regulatory Impact Statement should "document any relevant international standards and, if the proposed regulation differs from them, identify the implications and justify the variations".<sup>26</sup>

### ***Relevant international instruments***

The legal provisions do not set a clear definition or set of criteria to determine the relevance of international standards for the purposes of the LFMN or the LFPA in the rule-making process of NOMs and subordinate regulations. A number of examples are listed to guide regulators in considering international standards, and if relevant, regulators are also encouraged to look towards foreign standards.

In 2015, a standard (NMX) was developed on the adoption of international standards in NOMs and NMX,<sup>27</sup> based on the relevant ISO standard.<sup>28</sup> In particular, this NMX defines the different intensities of compliance with international standards (identical, modified, not equivalent), which are to be specified when submitting the NOM or NMX and remain in the adopted text available to the public.

The LFMN defines international standards as:

*“The standard, guideline or normative document issued by an international standardization body or other international organisation, recognized as such by the Mexican government according to international law.” (Article 3, fraction X-A)*

This definition is broad, and seems to go beyond technical standards. Indeed, it does not limit the international standardisation bodies to public or private bodies, or to bodies with certain governance structures. The LFMN does provide that further details be given in order to assist regulators in finding relevant international standards (art. 39 LFMN). A list has been developed by DGN in which 17 bodies are listed as international standardisation bodies “recognised by the Mexican government”.<sup>29</sup> In addition, a searchable online database exists for Mexican NOMs and NMX (SINEC). The same website includes links towards standards developed by ISO.<sup>30</sup>

For subordinate regulations, the questions in the RIA Guidelines include some examples on international instruments, which may be considered. In particular, they list the Codex Alimentarius, the IPPC, the OIE, ISO, IEC or IMO, but also to international export-control agencies such as the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies, or to free trade agreements broadly speaking.

Foreign standards are also mentioned as relevant models for regulators by the RIA Guidelines for all regulations. The approach to identify useful standards is also case by case, depending on the subject matter. The Guidelines include broad examples, namely from the US, the EU and Japan. In particular, the Guidelines explicitly mention standards developed by the European Commission, by Underwriters Laboratories (UL), American National Standards Institute (ANSI), ASTM International, Discipline Core Ideas (DCI), or Japanese Industrial Standards (JIS).

### *Use of international instruments in practice*

In practice, the evidence shows that the use of foreign and international instruments remains limited, although beneficial when it is the case (Box 2.6). According to DGN data, 30% of NMX and only 18% of the NOMs contain a reference to international or foreign standards.<sup>31</sup> 7% of NOMs contain partial references to international or foreign standards, and 11% adopt the international or foreign instruments identically (see further details in Figure 2.3). Concretely, no Mexican technical regulation or standard has entirely “reproduced” an international standard as defined by NMX-Z-021, as in practice certain elements are always added to the text when adopting into a Mexican NOM or NMX.

Among the 133 NOMs that reference either totally or partially international standards, a large majority reference ISO standards, followed by Codex Alimentarius, IEC, ICAO, UNECE and OIML (Figure 2.4). Foreign standards are more anecdotally referenced by NOMs, as it is indeed not a legal obligation to do so according to LFMN. However, in 16 cases there is complete or partial reference to foreign standards. Thirteen of these



reference US standards, three reference EU standards, and one reference a standard from New Zealand (one references both a US and an EU standard).

### Box 2.6. Examples of NOMs using international instruments

#### **NOM-003-SCFI-2014** **NOM-003-SCFI-2014, Safety specifications for electrical products** (*productos eléctricos: especificaciones de seguridad*).

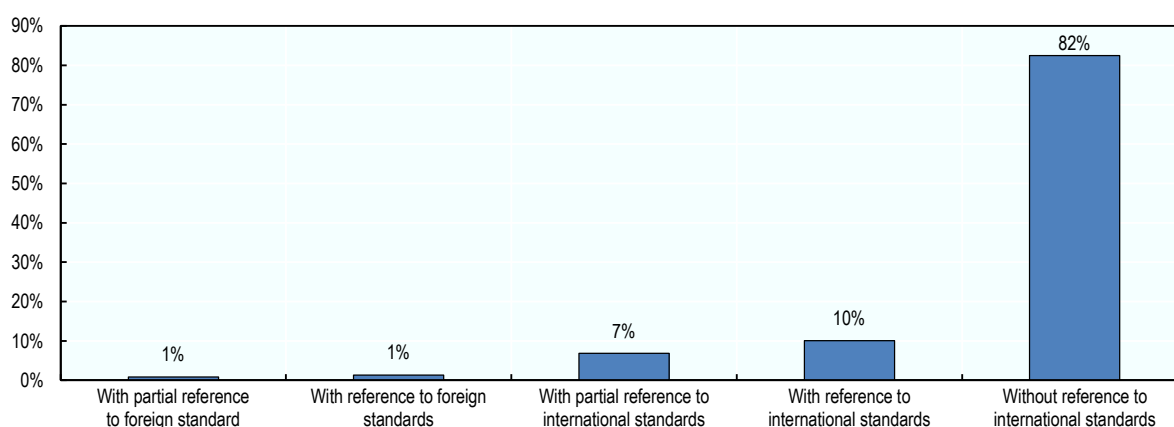
This technical regulation was developed based on the safety aspects of the international guideline IEC Guide 104:2010 The preparation of safety publications and the use of basic safety publications and group safety publications. Likewise, this Mexican official standard is based on other pre-existing Mexican standards, which in turn were based on the international standards IEC 60335-1, IEC 60745-1, IEC 60974-1, and IEC 60598-1, respectively. DGN estimates that such adoption has contributed to limit the market entry of unsafe products and reduce the damages of seasonal and electrical items such as fires and electric shocks.

#### **NOM-010-SCFI-1994, Measuring instrument; instruments for weighing non-automatic operation; technical and metrological requirements** (*instrumentos de medición; Instrumentos para pesar de funcionamiento no automático; Requisitos técnicos y metroológicos*).

This technical regulation was developed on the basis of International Recommendation R-76-1 of the OIML. DGN considers that the use of this OIML International Recommendation has helped to reduce the specification costs of duplicative weighing requirements, which was estimated to amount in losses of the order of MEX 300 million prior to the adoption of the NOM.

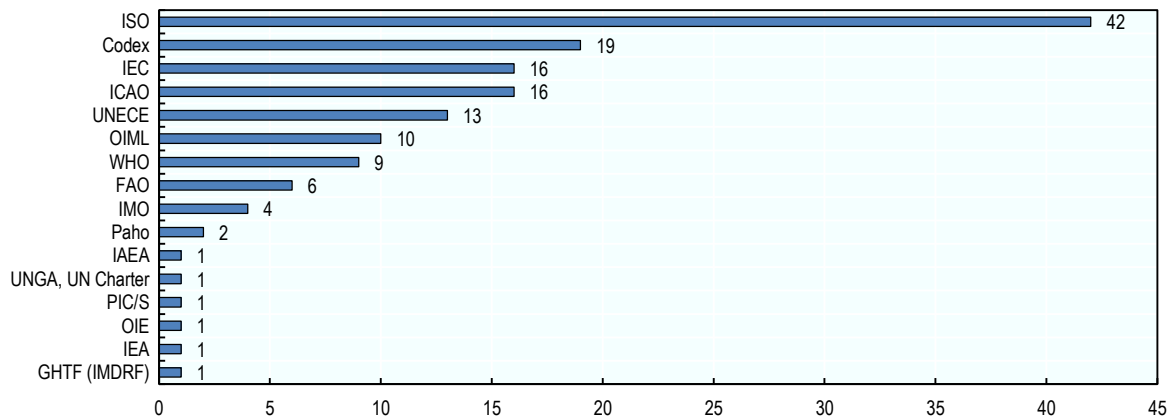
The limited reference to international instruments may be explained by the broad definition, the lack of centralised availability and difficulty to access existing international instruments, as well as by the limited guidance on the identification of international instruments.

**Figure 2.3. NOMs based on international and foreign standards**



*Notes:* The total does not add up to 100% because some NOMs refer to both foreign and international standards. The dataset does not specify the time period nor the stock of listed instruments. The most recent NOMs listed date back to 2017 and the oldest to 1993.

*Source:* Data provided by DGN.

**Figure 2.4. International standards referenced by NOMs**

Notes: Based on same dataset as Figure 2.3. Some NOMs may refer to standards of several organisations at once. Excludes references to foreign standards.

Source: Data provided by DGN.

The information about international standards and their consideration are in practice decentralised. *De facto*, regulators follow standard development in their own area. For example, the Federal Telecommunications Institute (“IFT”) looks at standards produced not only by intergovernmental organisations such as International Telecommunications Union, but also at standards produced by private standard-setting bodies such as ETSI,<sup>32</sup> recognised as a European Standards Organisation, or 3GPP,<sup>33</sup> which originated from US industry demand. The Secretariat of Communications and Transportation relies essentially on standards developed under the framework of the IMO, and has a special unit monitoring the adoption of international new standards in that field.

Some regulators are informed about relevant international standards mostly through industry representatives, who inform them of the benefits of aligning the Mexican standards with international standards. CONUEE for example benefits from information brought to them by CANAME or CANIETI on international standards in the sector of energy efficiency. ASEA also finds out about international standards through the private sector, namely in the context of the CCNNs set up to develop NOMs on energy safety. In particular, given ASEA’s recent creation, has developed a pragmatic approach to identifying relevant international standards, based on those implemented by its industry (see Box 2.7).

The DGN, as a participant in relevant international standard-setting bodies, has in principle access to all of these standards. However, the business model of international standard-setting limits the scope of activity DGN may have in making international standards available to Mexican regulators. Indeed, because many international standards are sold, and therefore not publically available, the DGN is not able to make them publically available. It shares the relevant standards with regulators on request. This requires however that regulators are already aware of the existence of a standard in the regulated field.

### Box 2.7. ASEA Safety and Environmental Management Systems

ASEA has developed a unique approach to identify relevant international standards applied by the industry.

Before granting Mexican companies the possibility to engage in any activities within the hydrocarbons sector, ASEA requests them to submit a Safety and Environmental Management Systems (SEMS), where they have to observe 18 elements related to Environmental Protection and Industrial Safety. When presenting the SEMS, companies must identify and incorporate international best practices and standards, in order to improve their performance. If the company complies with the needed requirements, ASEA approves and follows-up the System's implementation, throughout verifications and inspections.

Through this means, ASEA becomes aware of relevant foreign and international standards and builds a reference database for the area of energy safety.

Source: <https://www.bsee.gov/newsroom/latest-news/statements-and-releases/press-releases/us-mexico-regulators-workshop-convened> (accessed 2 May 2018).

Finally, some stakeholders raised the lack of translation of standards in Spanish as a challenge to the incorporation of international standards in national legislation. In this regard, it is noteworthy that a special Translation Management Group for Spanish was set up in 2006 at ISO, chaired by Spain. Mexico is a member of this Translation Group. The number of standards translated is limited but chosen on a strategic basis. It is determined by the group in a work programme for the year (i.e. the list of standards they want to translate, based on market need in their countries).

## Notes

<sup>1</sup> For broader information on the regulatory improvement disciplines that apply to NMX and those that do not apply, see (OECD, Forthcoming<sub>[11]</sub>) spec. p. 58.

<sup>2</sup> According to the Presidential Agreement on setting guidelines for the emission of new regulation, which replaces the previous Agreement of Regulatory Quality. See official Gazette, March 8th, 2017, [www.dof.gob.mx/nota\\_detalle.php?codigo=5475498&fecha=08/03/2017](http://www.dof.gob.mx/nota_detalle.php?codigo=5475498&fecha=08/03/2017).

<sup>3</sup> See art. 4 of update of RIA Guidelines.

<sup>4</sup> [www.cofemer.gob.mx/presentaciones/espa%flol\\_vol%20i.%20metodos%20y%20metodologias\\_final.pdf](http://www.cofemer.gob.mx/presentaciones/espa%flol_vol%20i.%20metodos%20y%20metodologias_final.pdf).

<sup>5</sup> [www.cofemer.gob.mx/presentaciones/espa%flol\\_vol%20i.%20metodos%20y%20metodologias\\_final.pdf](http://www.cofemer.gob.mx/presentaciones/espa%flol_vol%20i.%20metodos%20y%20metodologias_final.pdf).

<sup>6</sup> Acuerdo de evaluación *ex post*.

<sup>7</sup> NOM-012: [www.cofemersimir.gob.mx/expedientes/13391](http://www.cofemersimir.gob.mx/expedientes/13391).

NOM-133: <http://cofemersimir.gob.mx/expedientes/20309>.

NOM-194: <http://cofemersimir.gob.mx/expedientes/21179>.

NOM-005: [www.cofemersimir.gob.mx/expedientes/21403](http://www.cofemersimir.gob.mx/expedientes/21403).

NOM-193 : [www.cofemersimir.gob.mx/expedientes/19234](http://www.cofemersimir.gob.mx/expedientes/19234).

Regulation: [www.cofemersimir.gob.mx/expedientes/17526](http://www.cofemersimir.gob.mx/expedientes/17526).

<sup>8</sup> [www.gob.mx/cofemer/acciones-y-programas/estudios-y-diagnosticos](http://www.gob.mx/cofemer/acciones-y-programas/estudios-y-diagnosticos).

<sup>9</sup> [www.cofemer.gob.mx/documentos/transparencia/Diagnostico\\_05.pdf](http://www.cofemer.gob.mx/documentos/transparencia/Diagnostico_05.pdf).

<sup>10</sup> See also art. 5.6.1 TBT Agreement for conformity assessment procedures.

<sup>11</sup> See list of enquiry points and notification authorities at [www.epingalert.org/en#/enquiry-points/](http://www.epingalert.org/en#/enquiry-points/).

<sup>12</sup> Art. 14 Annex VII of High Impact RIA on risk, foreign trade and competition assessment, 2016 RIA Guidelines.

<sup>13</sup> [www.epingalert.org/en](http://www.epingalert.org/en).

<sup>14</sup> See Art. 2.9 TBT Agreement; Annex B para. 5 SPS Agreement.

<sup>15</sup> Art. 1.10 TBT Agreement; Annex B para. 10 SPS Agreement.

<sup>16</sup> See TBT Information Management System <http://tbtims.wto.org/>; and SPS Information Management system <http://spsims.wto.org/>.

<sup>17</sup> As of 31 May 2018. This includes notifications of draft measures, emergency measures as well as addenda and corrigenda.

<sup>18</sup> <http://spsims.wto.org/>.

<sup>19</sup> <http://tbtims.wto.org/>.

<sup>20</sup> Data from 2010-2018, as of 31 May 2018.

<sup>21</sup> For the purpose of this review, international instruments cover legally binding requirements that are meant to be directly binding on member states and non-legally binding instruments (including technical standards) that may be given binding value through transposition in domestic legislation or recognition in international legal instruments. This broad notion therefore covers e.g. treaties, legally binding decisions, non-legally binding recommendations, model treaties or laws, declarations and voluntary international standards.

<sup>22</sup> See for example obligations to use international standards as a basis for domestic measures formulated in framework of the World Trade Organization: for e.g. article 2.4 of the Agreement on Technical Barriers to Trade, “Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.” or article 3 of the Agreement on the Application of Sanitary and Phytosanitary Measures, “To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist (...)”. See also article 5.4 TBT Agreement for a similar obligation regarding conformity assessment procedures.

<sup>23</sup> NMX-Z-021/1-SCFI-2015.

<sup>24</sup> NMX-Z-013-SCFI-2015.

<sup>25</sup> About the International Classifications System of ISO, see [www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/international\\_classification\\_for\\_standards.pdf](http://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/international_classification_for_standards.pdf).

<sup>26</sup> [www.finance.gov.au/obpr/proposal/gov-requirements.html#handbook](http://www.finance.gov.au/obpr/proposal/gov-requirements.html#handbook).

<sup>27</sup> NMX-Z-021/1-SCFI-2015.

<sup>28</sup> ISO/IEC Guide 21-1:2005 Regional or national adoption of International Standards and other deliverables-Part 1: Adoption of International Standards.

<sup>29</sup> [www.dof.gob.mx/nota\\_detalle.php?codigo=5266340&fecha=04/09/2012](http://www.dof.gob.mx/nota_detalle.php?codigo=5266340&fecha=04/09/2012).

<sup>30</sup> [https://dgn.isolutions.iso.org/es\\_MX/sites/dgn-nws/home.html](https://dgn.isolutions.iso.org/es_MX/sites/dgn-nws/home.html).

<sup>31</sup> This is estimated on the basis of database of NOMs and NMX received from DGN in June 2018.

<sup>32</sup> [www.etsi.org/](http://www.etsi.org/).

<sup>33</sup> [www.3gpp.org/about-3gpp](http://www.3gpp.org/about-3gpp).

## References

- COFEMER (2017), *Informe Anual de Desempeño - COFEMER*, COFFEMER, Mexico, [3]  
[http://www.cofemer.gob.mx/docs-bin/dg/Informe\\_anual\\_2017.pdf](http://www.cofemer.gob.mx/docs-bin/dg/Informe_anual_2017.pdf).
- Karttunen, M. and D. McDaniels (2016), “Trade, Testing and Toasters: Conformity Assessment Procedures and the TBT Committee”, *Journal of World Trade*, Vol. 50/3. [8]
- OECD (2018), *OECD Competition Assessment Reviews: Mexico*, OECD Competition Assessment Reviews, OECD Publishing, Paris, [4]  
<http://dx.doi.org/10.1787/9789264288218-en>.
- OECD (2018), *OECD Regulatory Policy Outlook 2018*, OECD Publishing, Paris, [2]  
<http://dx.doi.org/10.1787/g2g90cb3-en>.
- OECD (2017), *International Regulatory Co-operation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies*, OECD Publishing, Paris, [1]  
<http://dx.doi.org/10.1787/9789264275942-en>.
- WTO (2018), *Twenty-Third Annual Review of the Implementation and Operation of the TBT Agreement*, Note by the Secretariat, G/TBT/40, [7]  
<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/TBT/40.pdf>.
- WTO (2009), *Fifth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade Under Article 15.4*. G/TBT/26. [6]
- WTO (2008), *Recommended Procedures for Implementing the Transparency Obligations of the SPS Agreement (Article 7)*, G/SPS/7/Rev.2. [5]



**From:**  
**Review of International Regulatory Co-operation of Mexico**

**Access the complete publication at:**  
<https://doi.org/10.1787/9789264305748-en>

**Please cite this chapter as:**

OECD (2018), “Unilateral approaches to international regulatory co-operation: how Mexico embeds international considerations in its domestic rule-making processes”, in *Review of International Regulatory Co-operation of Mexico*, OECD Publishing, Paris.

DOI: <https://doi.org/10.1787/9789264305748-6-en>

This work is published under the responsibility of the Secretary-General of the OECD. The opinions expressed and arguments employed herein do not necessarily reflect the official views of OECD member countries.

This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

You can copy, download or print OECD content for your own use, and you can include excerpts from OECD publications, databases and multimedia products in your own documents, presentations, blogs, websites and teaching materials, provided that suitable acknowledgment of OECD as source and copyright owner is given. All requests for public or commercial use and translation rights should be submitted to [rights@oecd.org](mailto:rights@oecd.org). Requests for permission to photocopy portions of this material for public or commercial use shall be addressed directly to the Copyright Clearance Center (CCC) at [info@copyright.com](mailto:info@copyright.com) or the Centre français d'exploitation du droit de copie (CFC) at [contact@cfcopies.com](mailto:contact@cfcopies.com).