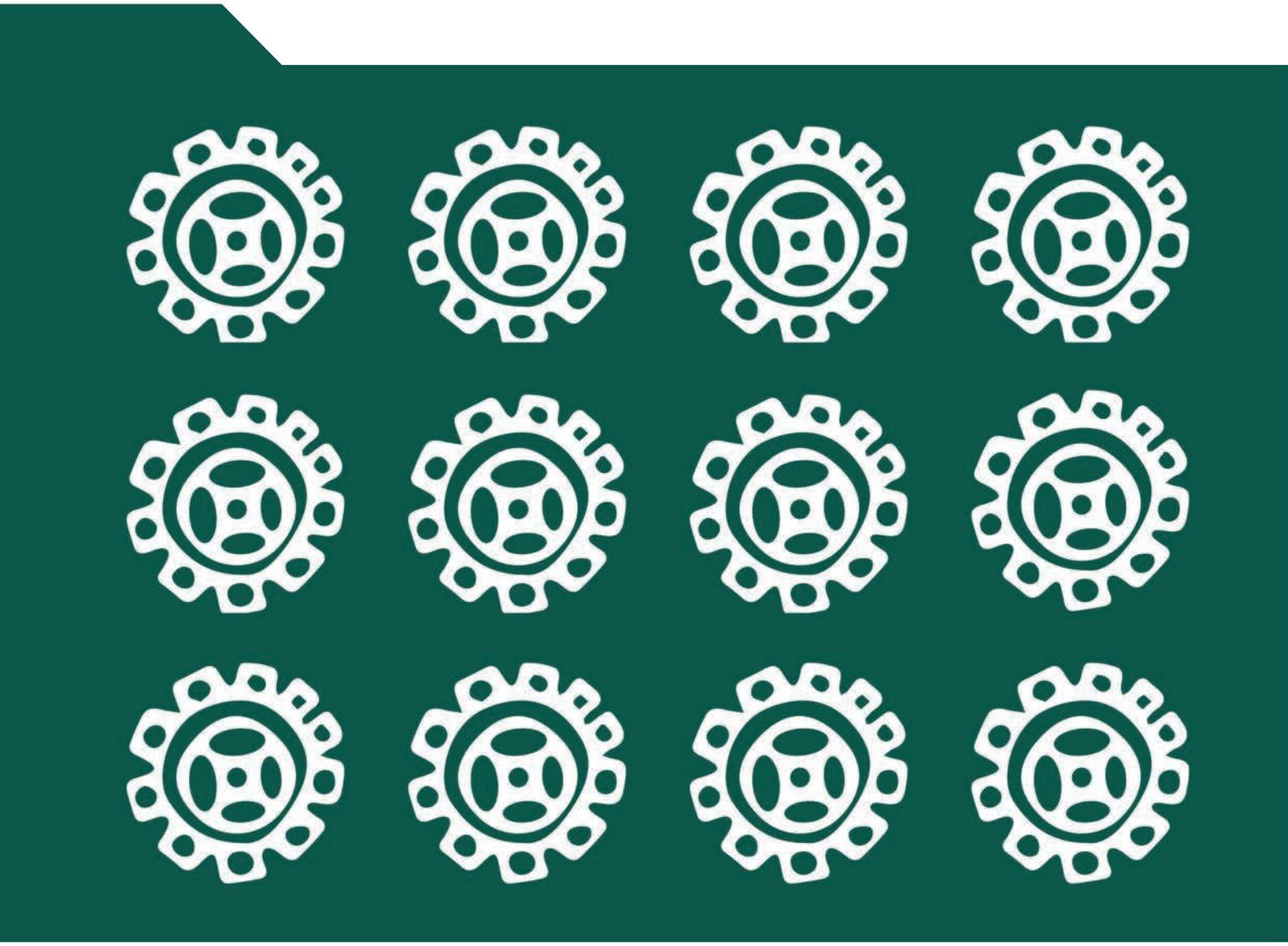
Implementing Technical Regulations in Mexico



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Preface

The regulatory function of the State has a significant impact on economic performance. Technical regulation is an indispensable tool for transforming public policies and international trade, both of which revolve around markets characterised by technological innovation, global value chains and the diversification of sectors. Properly designed technical regulations contribute to legal certainty, prevent risks to public health, promote well-being, protect the environment and natural resources and, more generally, foster productivity.

More than 20 years after its creation, our country's framework around technical regulations (NOMs) still presents opportunities for enhancing their enforcement. Many NOMs lack the proper conformity assessment infrastructure or are rarely overseen by the responsible authority.

The main challenge facing Mexico's system around technical regulations is awareness and compliance with NOMs. The public is unaware of technical regulations and fails to demand their enforcement. Moreover, authorities are only just beginning to disseminate NOMs. Finally, there is only limited exchange of best practices among institutions around implementation of technical regulations. This puts us at the start of a long path for planning, designing, developing and implementing NOMs in Mexico.

One of the most significant actions taken by the Ministry of Economy in its efforts to lead the improvement in Mexico's system is its co-operation with international organisations such as the Organisation for Economic Co-operation and Development (OECD). This co-operation seeks to adopt the OECD recommendations targeting Mexico's national quality infrastructure and specifically the implementation of NOMs in the proposed National Quality Infrastructure Law and in the roll-out of the Law to Promote Citizens' Trust. Both laws are considered by this Administration as critical instruments for achieving the inclusive growth needed by the country.

The Ministry of Economy seeks to promote the collaboration of all parties across the regulatory lifecycle by creating technical capacities, and actions and strategies for developing, disseminating, promoting and implementing NOMs. It also strives to strengthen their legal framework and create strategies to address the human resources and economic shortcomings faced by conformity assessment and inspections in key areas. This aims to mitigate the challenges faced by NOMs developing a coherent, consistent and risk-based approach to conformity assessment and regulatory inspections in order to secure and promote compliance with technical regulations.

NOMs need to align with the public policy objectives set in the National Development Plan. They should be open and accessible to all economic and social sectors in harmony with international standards in order to avoid unnecessary barriers to trade and internal competition. Regulations and their correct implementation promote commercial and industrial performance and with it, the inclusive economic development and well-being that Mexico requires.

Dr. Graciela Márquez Colín
Minister of Economy, Mexico

Foreword

Regulations are indispensable for the proper functioning of society and markets. They encompass different levels of rules, including technical regulations that set specific safety and quality requirements for products across sectors ensuring that laws and regulations deliver on their policy goals. Together, they create the "rules of the game" for citizens, businesses, government and civil society. Laws and regulations benefit society only if they are appropriately implemented and enforced, and do not impose undue costs. Yet, most countries remain largely focused on the design of regulations rather than on the later stages of delivering and reviewing them.

This *Review on Implementing Technical Regulations in Mexico* provides the first OECD assessment of the challenges of applying technical regulations. It analyses the delivery of Mexican technical regulations, focusing on policies and practices around conformity assessment and regulatory inspections. It identifies key areas for improvement and provides recommendations for Mexico to develop a whole-of-government and systemic approach to their implementation.

This review is based on answers provided by the Ministry of Economy and several Mexican agencies to OECD questionnaires, and on various interviews conducted during three fact-finding missions in Mexico City. The review benefited from the insight of peer-reviewers from Canada and the United Kingdom. Two preliminary versions of this report were discussed in policy workshops with a wide range of Mexican public officials and stakeholders. The report was also peer-reviewed in the OECD Regulatory Policy Committee.

This report supports the broader ambition of Mexico to improve the effectiveness of its regulatory framework to ensure more efficient and competitive markets. It was commissioned by Mexico's Ministry of Economy.

The review was carried out under the auspices of the OECD Regulatory Policy Committee whose mandate is to assist both members and non-members in building and strengthening capacity for regulatory quality and regulatory reform. The review builds on the OECD *2012 Recommendation of the Council on Regulatory Policy and Governance,* which makes regulatory enforcement an integral part for regulatory effectiveness. The review further draws from the OECD Best Practice Principles on Inspections and Enforcement and its toolkit, and the OECD body of work on international regulatory co-operation developed since 2012 including a 2018 *Review of International Regulatory Co-operation of Mexico*. This report was peer reviewed by the OECD Regulatory Policy Committee, approved on 7 November 2019 and prepared for publication by the OECD Secretariat.

Acknowledgements

This study was prepared by the OECD Public Governance Directorate (GOV) under the leadership of Marcos Bonturi, Director and Nick Malyshev, Head of the Regulatory Policy Division in GOV. This report was co-ordinated by Céline Kauffmann and prepared by Camila Saffirio, Eric Thomson and Florentin Blanc. Inputs were provided by Manuel Gerardo Flores, Adriana García, Marianna Karttunen, Gloriana Madrigal and Daniel Trnka (OECD Regulatory Policy Division). The report was prepared for publication by Jennifer Stein, and administrative assistance was provided by Claudia Paupe.

The assessment by peers with unique experience in regulatory delivery was instrumental to drafting the key conclusions of this report. The OECD Secretariat is very grateful for the invaluable inputs provided by James Crawford, Director General, Ontario Operations Canadian Food Inspection Agency (Canada); and Sara Smith, Deputy Chief Executive, Office for Product Safety and Standards of the Department for Business, Energy and Industrial Strategy (United Kingdom).

Special thanks go to the Ministry of Economy of Mexico and its staff; in particular to Minister of Economy, Graciela Márquez, and Vice Minister of Industry, Commerce and Competitiveness, Ernesto Acevedo. We are also very grateful to César Hernández, National Commissioner from the National Commission for Regulatory Improvement, CONAMER for his commitment throughout the review process.

We also express our gratitude to the many government officials who provided inputs, including (but not limited to): Jorge Arreola, Head of the Competitiveness and Competition Unit, Ana Lilia Martínez and Juan Carlos Rivera, Ministry of Economy; Alfonso Guati Rojo, General Director of Standards, General Bureau of Standards; and Julio Rocha, General Coordinator of Regulatory Improvement, CONAMER.

Critical insights were also received from Mexican authorities and actors that helped inform the preparation of this review, particularly from the Ministries of Foreign Affairs (SRE), Health (SSA), and Environment and Natural Resources (SEMARNAT); the Federal Attorney´s Office of Consumer (PROFECO); the National Metrology Centre (CENAM); the National Service of Health, Food Safety and Agri-food Quality (SENASICA); the Federal Commission for the Protection of Sanitary Risks (COFEPRIS); the National Commission for the Efficient Use of Energy (CONUEE); the Federal Economic Competition Commission (COFECE); the Mexican Accreditation Entity (EMA); Mexican Council of Standardisation and Conformity Assessment (COMENOR); and National Chamber of the Cosmetic Industry (CANIPEC).

The report was submitted for comments to the OECD Regulatory Policy Committee, and received useful feedback from colleagues from the OECD Public Sector Integrity Division, as well as from other international organisations, namely the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).

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Acronyms and abbreviations

APAC	Asia Pacific Accreditation Cooperation
ASEA	Agency for Safety, Energy and Environment (*Agencia de Seguridad, Energía y Ambiente*)
BEIS	Department for Business, Energy & Industrial Strategy, United Kingdom
CAP	Conformity assessment procedure
CASCO	ISO Committee on Conformity Assessment
CCNN	National Advisory Committees for Standardisation *(Comités Consultivos Nacionales de Normalización)*
CENAM	National Metrology Centre (*Centro Nacional de Metrología*)
CNH	National Hydrocarbons Commission (*Comisión Nacional de Hidrocarburos*)
CNN	National Standardisation Commission *(Comisión Nacional de Normalización)*
COFECE	Federal Economic Competition Commission *(Comisión Federal de Competencia Económica)*
COFEPRIS	Federal Commission for the Protection of Sanitary Risks (*Comisión Federal para la Protección de Riesgos Sanitarios*)
CONAMER	National Commission for Regulatory Improvement *(Comisión Federal de Mejora Regulatoria)*
COMENOR	Mexican Council of Standardisation and Conformity Assessment *(Consejo Mexicano de Normalización y Evaluación de la Conformidad, A.C.)*
CRE	Energy Regulatory Commission (*Comisión Reguladora de Energía*)
CTNN	National Technical Committees for Standardisation *(Comités Técnicos Nacionales de Normalización)*
DGN	General Bureau of Standards *(Dirección General de Normas)*
DOF	Official Gazette *(Diario Oficial de la Federación)*
EMA	Mexican Accreditation Entity *(Entidad Mexicana de Acreditación)*
HSE	Health and Safety Executive, United Kingdom
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission

IFT	Mexican Federal Telecommunications Institute *(Instituto Federal de Telecomunicaciones)*
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standardisation Organization
LCE	Law on Foreign Trade *(Ley de Comercio Exterior)*
LFMN	Federal Metrology and Standardisation Law *(Ley Federal sobre Metrología y Normalización)*
LFPA	Federal Administrative Procedure Law *(Ley Federal de Procedimiento Administrativo)*
LFPC	Federal Consumer Protection Law *(Ley Federal de Protección al Consumidor*)
MSNetwork	Market Surveillance Network, United Kingdom
NAFTA	North American Free Trade Agreement
NIST	National Institute of Standards and Technology, United States
NMX	Mexican Standards *(Normas Mexicanas)*
NOM	Mexican Official Standards *(Normas Oficiales Mexicanas)*
NQI	National Quality Infrastructure
OECD	Organisation for Economic Co-operation and Development
OMB	Office of Management and Budget, United States
ONN	National Standard Bodies (*Organismos Nacionales de Normalización*)
OPSS	Office for Product Safety and Standards, United Kingdom
PEMEX	Mexican Petroleum (*Petróleos Mexicanos*)
PROFECO	Federal Attorney´s Office of Consumer *(Procuraduría Federal del Consumidor)*
RIA	Regulatory Impact Assessment
RLFMN	Regulation of the Federal Metrology and Standardisation Law (*Reglamento de la Ley Federal sobre Metrología y Normalización)*
SADER	Ministry of Agriculture and Rural Development *(Secretaría de Agricultura, y Desarrollo Rural)*
SCT	Ministry of Communications and Transportation *(Secretaría de Comunicaciones y Transportes)*
SDoC	Suppliers Declaration of Conformity
SE	Ministry of Economy (*Secretaría de Economía)*
SENASICA	National Service of Health, Food Safety and Agri-food Quality (*Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria*)
SENER	Ministry of Energy (*Secretaría de Energía)*
SPS	Sanitary and Phytosanitary
SRE	Ministry of Foreign Affairs (*Secretaría de Relaciones Exteriores*)

STPS	Ministry of Labour and Social Protection (*Secretaría del Trabajo y Previsión Social*)
TBT	Technical Barriers to Trade
UKAS	United Kingdom National Accreditation Body
USMCA	United States-Mexico-Canada Agreement
WADA	World Anti-doping Agency
WTO	World Trade Organization

Executive summary

Mexico has demonstrated a strong commitment to ensuring that its laws and regulations are of high quality. This concern for regulatory quality includes technical regulations (known as NOMs), instruments that set specifications for products, services and, at times, production processes. Mexico's efforts have centred on the early stages of the "regulatory lifecycle", targeting mainly the design of laws and regulations. Nonetheless, achieving the desired outcomes from NOMs requires proper enforcement. Currently, a number of challenges create a gap between the development of technical regulations and their implementation and enforcement. This review identifies areas for improvement based on a thorough assessment of the implementation of technical regulations in Mexico. Implementation takes place through two complementary sets of instruments: conformity assessment, carried out to demonstrate compliance with NOMs; and regulatory inspections, including market surveillance activities, which may focus on both the production stage and/or on products available in the market.

Mexico has put in place a strong framework around NOMs led by the Ministry of Economy through its General Bureau of Standards (DGN). In addition, the National Commission for Regulatory Improvement (CONAMER) plays a key role in overseeing the quality of regulations. Numerous additional stakeholders, including public sectoral bodies, technical entities, and businesses in a range of industry sectors, are involved in the regulatory delivery of NOMs. A set of legal instruments spearheaded by the Federal Law on Metrology and Standardisation (*Ley General sobre Metrología y Normalización*, LFMN) are the backbone of Mexico's system for NOMs. Still, fragmentation across different legal sector-specific regimes means there is no cohesive and coherent vision to promote compliance with NOMs and strengthen the national quality infrastructure, the system comprising metrology, standardisation, accreditation, conformity assessment, and market surveillance that ensures that the requirements set under NOMs are fulfilled.

Mexico recognises a range of conformity assessment procedures that are critical to effectively connect the requirements set in NOMs with the products and services available in the market. It also has an accreditation set-up to provide an extra layer of assurance over the impartiality and capabilities of conformity assessment bodies to perform their functions. However, there are a number of sector-specific approaches to conformity assessment and no common methodology for developing these procedures. Regulators have limited guidance to select conformity assessment procedures that effectively account for the complexity and level of risk that a NOM is to manage, and/or ensure that suitable infrastructure is in place to achieve the objectives of a NOM.

Regulatory inspections, including market surveillance, are essential for making sure that products, services and production processes (when applicable) continue to meet the requirements set under technical regulations. Regulatory inspections of technical regulations are undertaken by the government authority responsible for the NOM. While Mexico has successfully built trust in some sectors through the reliable and trustworthy surveillance of NOMs, particularly in export markets, the situation varies considerably across regulatory sectors. A number of significant challenges remain in enhancing the effectiveness of inspections, particularly in managing and targeting resources and improving co-ordination and data sharing among agencies.

Based on an analysis of the framework and implementation policies and practices around NOMs, the review identifies three broad areas for improvement. First, Mexico could strengthen its technical regulation framework by systematically including implementation needs in the design stage of NOMs and by making better use of the DGN as overseer and co-ordinator of the system. Simultaneously, the limitations in the conformity assessment infrastructure could be addressed, including by providing guidance documents on the design of conformity assessment procedures. Finally, Mexico may wish to invest in developing a more coherent, risk- and evidence-based approach to regulatory inspections.

Recent and ongoing legislative initiatives to reform the technical regulation system and regulatory inspections are creating the momentum for Mexico to strengthen the implementation of NOMs. These initiatives could be accompanied by measures to promote co-ordination among relevant authorities and actors and provide guidance on a risk-based approach to conformity assessment and inspection. Improving the regulatory delivery of NOMs will require a shift in the enforcement culture among all parties. This review provides avenues for possible solutions and suggests some critical elements of a whole-of-government and systemic approach to implementing technical regulations.

Assessment and recommendations

Mexico has an extensive system of technical regulations (NOMs) and follows a number of good regulatory practices (GRPs) in their development. The range of regulatory fields covered under the Mexican framework of technical regulations goes beyond what other countries usually address through this instrument. While not necessarily an issue in itself, this may nevertheless make international comparisons difficult and create confusion among stakeholders on key concepts and processes. Mexico's system of NOMs is also fragmented across different legal frameworks and actors. A certain lack of unifying principles, combined with the breadth of issues covered, contribute to a disjointed and at times confusing approach to the use and implementation of NOMs.

This background creates areas for improvement across the implementation stage of NOMs, notably in the conformity assessment system and in regulatory inspections. The specific weaknesses vary across sectors – in some fields, the regulatory framework is still not fully in place; in others, enforcement of the existing framework is weak. Overall, Mexico presents the case of a dual economy where most efforts around the compliance and enforcement of technical regulations are channelled to the export sectors to provide the necessary confidence to trade partners on the safety and quality of products.

In the face of the challenges met in the downstream phase of the rulemaking cycle and to reduce fragmentation, there is a need for a whole-of-government policy and a systemic approach to the implementation of technical regulations. This involves building on the strong *ex ante* use of good regulatory practices to embed more systematic consideration of implementation and enforcement of technical regulations and anticipating the conditions and resources needed for their appropriate application. Similarly, there are areas for systemic improvement in the use of regulatory inspections to promote compliance with technical regulations. There is a need to shift towards a more strategic and co-ordinated implementation policy built on risk-based approach and active data collection to inform conformity assessment processes and regulatory inspections.

Recent and on-going legislative initiatives to reform the technical regulation system and regulatory inspections[1] may well mark a turning point in policy makers' awareness of the issues at stake and provide an important opportunity for Mexico to transition from a largely reactive approach focused on patching the most blatant gaps to a pro-active implementation policy. Nevertheless, to make a substantial impact these important reforms should be pursued together with proper accompanying measures – including clarifying roles and responsibilities, greater co-ordination, guidance and training of relevant authorities. Strengthening the implementation of technical regulations in Mexico will require a shift in the culture of enforcement across all players involved.

This review provides an overview of how key aspects of the delivery of technical regulations are organised in Mexico and highlights the challenges faced. Based on this assessment, the review proposes avenues for possible solutions and provides for the critical elements of a whole-of-government policy and the building blocks of a systemic approach to the implementation of technical regulations. It builds on previous work identifying areas of improvement, such as the Review of International Regulatory Co-operation of Mexico (OECD, 2018[1]) and the Report on Standard Setting and Competition in Mexico (OECD, 2018[2]).

Key diagnostic elements

This assessment section is organised around the two key pillars of regulatory delivery of NOMs: the conformity assessment framework set in place to demonstrate compliance with NOMs; and regulatory inspections, including market surveillance activities. Both pillars are complementary and necessary to ensure the effective implementation of NOMs.

CAPs in Mexico in practice

Conformity assessment procedures (CAPs) and the infrastructure around them are key to reap the benefits from technical regulations, as they ensure that the requirements set under NOMs are fulfilled. In Mexico, as in other countries, a large number of public and private actors are involved in the different components of the technical regulations system. However, the dispersion of approaches to CAPs across a number of sector-specific regimes has resulted in the absence of an articulated vision that promotes compliance with NOMs and addresses the gaps in quality infrastructure.

Mexico has set up a strong system around the development of NOMs, including a thorough development process that follows GRPs, notably RIA, stakeholder consultation and *ex post* assessment. To integrate, monitor and evaluate the activities of the technical regulation system, Mexico has developed a digital platform named the System for Norms and Conformity Assessment (SINEC). Mexico also deploys its public procurement system to promote products and services that comply with technical standards. Yet, compliance culture in Mexico continues to be weak, with limited knowledge and awareness of the importance of technical regulations among the public and even some sectoral regulators.

Absence of a cohesive and coherent approach to conformity assessment

Currently, the development of CAPs in Mexico is governed by different sector-specific legal frameworks and actors. This fragmentation makes it difficult to establish a clear rationale for how different assessment techniques should be selected, designed and implemented. Further, the diversity of regimes involving numerous stakeholders from the public sector, technical bodies and businesses, results in a regulatory system that may be difficult for market actors and consumers to understand and to abide by, creating risks of capture and conflicts of interest. Risks of conflict of interest arise as certain actors play dual roles in conformity assessment, performing fee-based conformity services under specific NOMs while also tasked with the surveillance some bodies or actors operating in the system.

In addition, a number of regulators choose to separate the design of NOMs from that of their corresponding conformity assessment processes. This occurs as the LFMN allows for CAPs to be designed as part of a NOM or at a later stage once a NOM has been issued. As such, a number of NOMs currently in force lack the relevant assessment techniques to evaluate that the requirements prescribed are being fulfilled. Without this, these NOMs become *de facto* unenforceable. In practice, the absence of CAPs for a specific NOM has at times resulted in the postponement of their effects. While the DGN has taken steps to ensure that new NOMs are developed simultaneously with their corresponding CAP, looking forward Mexico could take steps to reduce the existing stock of technical regulations for which a CAP is needed but has not been developed.

Mexico has made efforts to strengthen the design of laws and regulations, yet there is no common methodology for developing CAPs. The current framework for technical regulations does not include guidance for regulators on, for instance, selecting an adequate approach for the complexity of the product and level of risk that the NOM is trying to manage, and/or ensuring that suitable infrastructure is in place to perform a CAP. International examples of relevance on guidance for designing and issuing CAPs that may serve as inspiration to build a more coherent and consistent use of this tool include the EU framework based on modules (Box 2.3), and the Conformity Assessment Considerations for Federal Agencies

provided by the National Institute of Standards and Technology (NIST) in the United States (National Institute of Standards and Technology, 2018[3]). Considerations in the ISO/CASCO toolbox (ISO, 2014[4]) and APEC's Information Notes on Good Regulatory Practice (APEC, 2000[5]) may also provide useful elements.

Gaps in Mexico's conformity assessment infrastructure

When designing NOMs and CAPs, regulators need to assess whether a conformity assessment body exists to perform a specific CAP or if the market can support its future existence. If no conformity assessment body is in place, technical regulations may include a transition period before entry into force to allow time to establish the required infrastructure. In Mexico, a number of CAPs embedded in NOMs currently in force have no supporting conformity assessment infrastructure. Recently, DGN has made efforts to ensure that the existence of CABs is considered when inserting CAP provisions in a NOM. In addition, institutions such as CONUEE and SENER often work directly with CABs during the design of a new NOM to ensure that the relevant conformity assessment architecture is in place to secure its implementation.

Conformity assessment relies on third-party approaches and is relatively costly

Depending on risk, conformity assessment approaches may range from first-party (self-assessment) to third party evaluation by accredited bodies. From this range of approaches, the Mexican framework favours third-party techniques (mainly certification, verification, calibration, and testing). These techniques provide greater confidence to buyers that their purchase complies with the regulatory requirements. They are also more costly and not necessarily commensurate to the risks. By comparison, first-party conformity assessment allows manufacturers and/or suppliers to self-attest the fulfilment of technical specifications in cases when the negative effects from non-conformity are low, but they necessarily entail a degree of confidence in the self-assessment – and a liability system that adequately puts the onus on producers and distributors to ensure compliance and safety. As Mexico's conformity assessment system continues to develop and mature, there is room to extend the implementation of first-party techniques in certain low risk products. Some regulators have recently explored the use of this approach by introducing Suppliers' Declaration of Conformity (SDoC) as an alternative for assessment of specific products.

A 2007 World Bank report noted that costs for a CAP in Mexico could be three to four times higher than the United States and EU (Guasch et al., 2007[6]). A number of factors may affect the cost of conformity assessment. In Mexico, a weak conformity evaluation culture may hinder the development of a stronger market for conformity assessment bodies. Additional factors may include the high upfront cost of the equipment required under certain assessment techniques. In certain cases, only one or very few CABs may be able to perform the CAP, so they may charge a monopoly price to the few businesses requiring the service and/or simply need to recoup their investment on a far smaller number of clients.

Assessment of regulatory inspections of NOMs

Regulatory inspections are meant to safeguard the public from risks to health and safety, among others, by ensuring that specific products and services are in compliance with applicable regulations. Through effective surveillance and regulatory inspections, government authorities help strengthen consumer trust that products and services available on the market meet regulatory requirements, thus protecting their safety and well-being. It also should contribute to a level playing field for businesses who are participating in the market.

In Mexico, the government authority in charge of the NOM is usually also responsible for its surveillance, including developing a regulatory inspections and enforcement programme. Both the LFMN and the LFPA, which defines the requirements for inspection visits, regulate inspections based on NOMs. However, the level and types of sanctions for non-compliance are often set in sectoral laws.

Mexico has had some discrete successes in building trust in some sectors through reliable and trustworthy delivery of NOMs, particularly in export markets for agricultural products, automotive products and others. Nevertheless, a number of significant challenges remain in enhancing the effectiveness of inspections in Mexico to foster compliance with NOMs and build trust more broadly and consistently. The need for further efforts is critically evident in the limited trust that Mexican citizens have in their government – only 28% of citizens trust their government compared to an average of 42% in the OECD (OECD, 2017[7]).

The situation is overall quite contrasting between different regulatory areas. Generally, non-food products are subject to well-defined NOMs covering the most significant issues, and there do not appear to be significant regulatory gaps. However, the enforcement of a large number of NOMs is left to PROFECO, which is essentially a law enforcement institution focusing on consumer protection rather than a body with strong technical competence. By contrast, on the food side the lack of an over-arching food safety law is a real issue, as is the division of competences between different bodies, but technical competence in bodies such as SENASICA and COFEPRIS appear stronger. Some inspection services (in particular within SENASICA) also have risk-based targeting approaches that are significantly more developed than average in Mexico.

Effectively managing and targeting resources for regulatory inspections

The first challenge is using resources for regulatory inspections more effectively and efficiently. Mexico overall spends the least per capita of any government in the OECD (OECD, 2019[8]). Although disaggregated data for inspections alone is not available, this is indicative of relatively low government resources available. It is, therefore, critical for Mexico's government authorities and inspectorates to target their scarce resources to the most high-risk regulations and business, using risk assessment tools, data and co-ordination. In some sectors, notably energy and hydrocarbons, Mexico has developed programs aiming to target inspections to the riskiest businesses and most critical elements of regulations. However, in other areas, for example consumer products, inspections are performed randomly or based only on complaints. Complaints are generally considered (by regulatory practitioners and experts alike) as a poor source of targeting – as they inherently come "too late", and often do not reflect the highest risks or harms but rather the readiness to comply – when they are not entirely futile or malicious, as also happens.

Building better co-ordination and data sharing to target regulatory inspections

Co-ordination and data sharing could allow government authorities in Mexico to reduce the duplication of inspection efforts and overlaps, and more effectively target businesses with the most severe or harmful non-compliance issues. Unfortunately, government authorities largely work independently of one another with relatively little co-ordination or data sharing, even within the same ministry. Most government authorities track the number of actions, fines, and visits, but they have not yet integrated more information into a broader evidence-based inspections strategy. The relatively high number of inspection bodies in Mexico may also play a role in the difficulties for co-ordination purposes. Among the countries that have developed co-ordination frameworks for market surveillance the UK's MSNetwork provides an example (Box 3.6).

Reinforcing the compliance culture in Mexico

Finally, the compliance culture in Mexico represents a major challenge to reaping the benefits of technical regulations. Several notable incidences of fraud and corruption have reduced the level of trust in the system, although the Mexican government has already taken some corrective actions. For example, PROFECO has been able to reduce significantly the prevalence of fraud for gas pump measurements and has introduced a new Code of Ethics to limit conflicts of interest.

Recommendations

Based on the overview of Mexico's framework and practices for the implementation of NOMs, this review identifies three broad areas of improvement in the regulatory delivery of NOMs:

- Strengthening the NOMs framework by:
  - systematising the consideration of implementation needs in the design stage
  - introducing a unified risk-based approach to conformity assessment and regulatory inspections
  - increasing consistency and coherence of the regulatory framework for food safety
- Addressing the limitations in the conformity assessment infrastructure; and
- Developing a more coherent approach to regulatory inspections to secure and promote compliance with technical regulations.

Strengthening the technical regulations framework

- **Leverage further the role of the DGN as overseer and co-ordinating authority of the technical regulation system.** The DGN could build on its role to ensure a whole-of-government approach to NOMs including by:
  - Issuing guidance to promote a coherent and cohesive approach to conformity assessment across sectors;
  - Promoting further co-ordination among the different actors in the system. In particular, enabling dialogue and co-operation between regulators with joint competences over specific NOMs; and
  - Ensuring a strategic relationship with EMA to strengthen the operation of the technical regulations system around accredited conformity assessment bodies. The model of the United Kingdom Accreditation Service (UKAS) interaction with the UK Government based on a Memorandum of Understanding (MoU) presented in Box 2.7 may provide a useful lesson in this regard.
- Promote a systematic dialogue between authorities responsible for implementation of technical regulations to avoid duplication, and exchange experiences and best practices across sectors.
- Avoid decoupling the issuance of NOMs and their CAPs by systematising their joint development where required. The reform to the LFMN provides an opportunity to discuss how to secure that CAPs are designed together with NOMs in cases where a specific CAP is needed.
- Systematise the consideration of regulatory delivery in the RIA process of NOMs. The rollout of the new Law on Regulatory Improvement, including through a RIA process overseen by CONAMER, provides an opportunity to ensure that the selected conformity assessment approach is aligned with the level of risk, and that the relevant conformity assessment infrastructure is in place to demonstrate compliance with the NOM.
- Promote the participation of actors involved in the implementation of NOMs from the early stages of their design phase. When relevant, enable the involvement in the design stage of NOMs of stakeholders that play a role in metrology, accreditation and CAPs, and of the actors that will be responsible for complying with the requirements. Allow them to provide feedback on potential challenges to implementation to identify possible obstacles or bottlenecks early on.
- Ensure that NOMs include provisions for entry into force/applicability that take into account the time needed for different actors to secure compliance with a new technical regulation. In particular, this involves recognising the timeframes that sectoral regulators need to set up or update the relevant procedures, and that addressees of NOMs require to adjust to the upcoming regulation. This could help avoid undue and repeated delays in the applicability of NOMs.

- Address the stock of NOMs that are *de facto* unenforceable for lack of a corresponding CAP. The DGN could develop a plan to work together with sectoral regulators to design and issue remaining CAPs targeting key areas or sectors.
- Leverage further the 5-year *ex post* review of NOMs to address implementation challenges, including those related to conformity assessment. A systematic collection of data on conformity assessment and regulatory inspections could provide essential input for the *ex post* assessment.
- Promote awareness of the benefits of NOMs and the importance of compliance with technical regulations across stakeholders. Mexico should continue promoting a culture of quality among citizens and businesses by highlighting the benefits of NOMs, particularly in key areas. Compliance is still a major challenge in Mexico and should be promoted across firms and, perhaps most importantly, SMEs that may have more difficulty understanding and/or implementing NOMs. DGNs and the various sectoral regulators have a key role to play to foster compliance through greater education and guidance, rather than sanction (see also below).
- Continue to use Mexico's public procurement system to promote products and services that comply with technical standards. Detect and address the obstacles faced by sectoral regulators to reference technical standards in public procurement, including by disseminating mechanisms for identifying relevant NOMs (including through the SINEC platform).
- Improve and strengthen the legal framework for food safety. While, internationally, food safety issues are seen as distinct from technical regulations, they are handled in Mexico within the NOM framework. The review shows that there are co-ordination challenges among relevant sectoral regulators and a lack of an overarching legal framework. This results in inadequate risk management. International experience – including FAO recommendations ("Model Food Law") and *Codex Alimentarius* – provide useful reference points to strengthen the existing legal framework.

Strengthening the conformity assessment infrastructure

- Ensure a coherent approach to conformity assessment across relevant sectors, including through guidance documents on the design of CAPs. In particular:
  - The DGN should develop a common methodology with step-by-step guidance for designing and issuing CAPs to help build a common understanding. This methodology should include, *inter alia*, guidance on: choosing adequate approach depending on risks, selecting among CAPs, considering the costs arising from conformity assessment and ensuring that suitable infrastructure is in place to perform an assessment technique. For this purpose, the expertise of other countries and international organisations presented in Box 2.3 could be of relevance;
  - As Mexico's conformity assessment framework continues to develop, regulators could explore the use of additional approaches including first-party assessment techniques for products with low risk of negative effects from non-compliance. The recent experience introducing a SDoC alternative into the assessment process for NOM-199-SCFI-2017 on Alcoholic Beverages may offer an example on how regulators can gradually incorporate the use of this approach;
  - Promote consistency with relevant international obligations and standards; and
  - Organise training courses for regulators to clarify steps for the development of CAPs, and allow them to exchange experience on the issue.
- Encourage improvements in Mexico's conformity assessment infrastructure to promote the role of CABs and use of NOMs. In particular:
  - **Promote the development of capacities in areas where CABs are currently lacking.** In particular, this involves building capacities to limit reliance on CENAM and PROFECO to perform fee-based conformity services that could be undertaken by CABs.

  - **Ensure absence of conflicts of interest and address potential risks of capture.** The ongoing investigation by COFECE may shed light on possible areas for improvement in the Mexican system to further enhance the independence of operation among participants in the NQI system and promote competition.
- In sectors and for NOMs which only correspond to a very limited "niche" market, and where demand is insufficient to make the setup and operation of Mexican CABs viable or cost-competitive, **recognition of qualified foreign CABs** (following procedures similar to those used for Mexican ones) may be considered.
- The Ministry of Economy may wish to use the opportunity of the on-going legislative initiatives to reform Mexico's NOM system **to develop a pilot / demonstration project to test the implementation of some of the measures foreseen in these reforms**.

Develop a more coherent approach to regulatory inspections

- **Government authorities responsible for enforcing NOMs must target regulatory inspections to make them more effective at reducing risks to citizens.**
- **Mexico could create a clear, government-wide enforcement policy with a focus on risk-based inspections that target real harms to society.** This would give all government authorities and inspectorates a common policy framework, whereas this is now limited to the legal requirements of the LFPA and LFMN, with different approaches for individual sectors.
- **Professionalism and methods should be strengthened.** This is particularly true for non-food products, where the main actor (PROFECO) is more focused on consumer law than on technical aspects, which can be a problem when it comes to ensuring safety of products. The lack of methods for risk-based targeting or to guide inspectors during inspection visits (e.g. checklists) is also an issue across regulatory areas. Best examples in country (e.g. the risk-based approach of some departments of SENASICA) and internationally should be taken as basis for developing risk-based tools for all inspection fields.
- **Mexico could create a co-ordination body, like the Energy Regulators Group in the energy sector, but for the food and manufacturing areas.** Better co-ordination could reduce the overlaps that create a high burden on businesses in some sectors. Mexico could combine this with a plan to reduce the number of surveillance bodies as many other countries have successfully done to make inspections more efficient.
- **Mexico should ensure that sectoral regulators collect and share data on inspections**. The upcoming creation of the National Registry of Visits (*Registro Nacional de Visitas Domiciliarias*) overseen by CONAMER could allow government authorities to make use of new inspections data to target businesses that are more likely to create risks for citizens and identify patterns of non-compliance with NOMs. International experiences in introducing and using such systems can be looked at to ensure that the Registry becomes a useful tool for risk-based inspections, rather than a purely additional "*ex post*" step for inspection bodies.
- As part of the LFMN reform, **Mexico should build a flexible sanction system that focuses on promoting compliance rather than punishment.** This may include aligning sanction powers and fines with the gravity of non-compliance**,** specifically the magnitude of the harm or risks to citizens, as well as differentiating depending on the overall compliance record, intent and profit from the violation or absence thereof, etc. The most severe penalties should be reserved for violations that are the most likely to cause real harm to citizens.
- Of course, sanctions are only one means to encourage compliance. Mexico should generally rely less on sanctions and warnings that require businesses to "comply; or else". **Mexico should allow inspectors to take a clear but flexible, risk-based approach during visits.** This might include

not checking the entire NOM, but rather only focusing on serious violations and risks. Regulatory inspections should aim to promote compliance and find solutions, particularly for SMEs.

- Corruption during inspections has been a problem in Mexico. **Mexico should have clear and effective codes of ethics and training on conflicts of interest for inspectors**. Mexico may also consider developing a government-wide HR strategy for inspectors that tackles such issues as ties to industry and sets inspectors' wages appropriately to attract and retain qualified professionals and help reduce corruption.
- **Mexico should ensure that in-country inspections and border inspections are linked, and that data is shared between authorities**. There should be a systematic exchange of data and information between competent authorities in-country and customs to ensure that findings from controls indicating non-compliance lead to effective action to better target subsequent inspections and block/remove hazardous goods, be it at import or market stage. The data from customs should also be made available to the relevant government authorities. For specific high-risk cases, this information exchange process could allow customs officials to obtain verification of the reliability of certificates directly from the responsible government authority. Further work on assessing and improving the situation with border controls is needed. This review's findings show that this is a key priority to ensure the effectiveness of the technical regulation system.
- **The new Law to Promote Citizens Trust is an opportunity – if followed up by a robust implementation programme.** The law could enable the use of key good practice principles and instruments, for instance risk-based planning, responsive regulation, consideration of businesses' track records, among others. It is essential, however, to remember that such laws are never self-implementing. Transformations in inspections and enforcement methods and practices will require an implementation programme covering all aspects (structures, resources and skills, data, methods and tools, etc.).

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Note

[1] Namely, the Law to Promote Citizens Trust and other initiatives to reform the Mexican system around technical regulations including the Executive's project for a Law on Quality Infrastructure.

Introduction

Mexico's technical regulations (NOMs)

The scope of this review covers the implementation and delivery of "NOMs", the Mexican technical regulations. NOMs are one of the regulatory instruments that the Mexican Executive branch can deploy to pursue its policy objectives, together with primary laws and subordinate regulations (Table 1). They are defined as the binding instruments issued by public bodies of the federal public administration that establish rules, specifications, attributes, directives, characteristics, or provisions applicable to a product, process, installation, system, activity, service or production or operation method, as well as rules regarding terminology, packaging, use of marks and/or labelling.[1] Together with Mexican Standards (NMXs), NOMs contribute to the Mexican "standardisation system". However, NMXs are voluntary instruments that fall outside of the scope of this review.

The Federal Law on Metrology and Standardisation (*Ley Federal sobre Metrología y Normalización*, LFMN) establishes a broad scope of application for technical regulations. Articles 52 and 53 state that all products, processes, methods, facilities, services, or activities domestic or imported must comply with NOMs. As of January 2020, there were 702 NOMs in force. The Ministries of Health, Economy, Agriculture, Environment and Communications and Transport are responsible for over 75% of all NOMs (Figure 1).

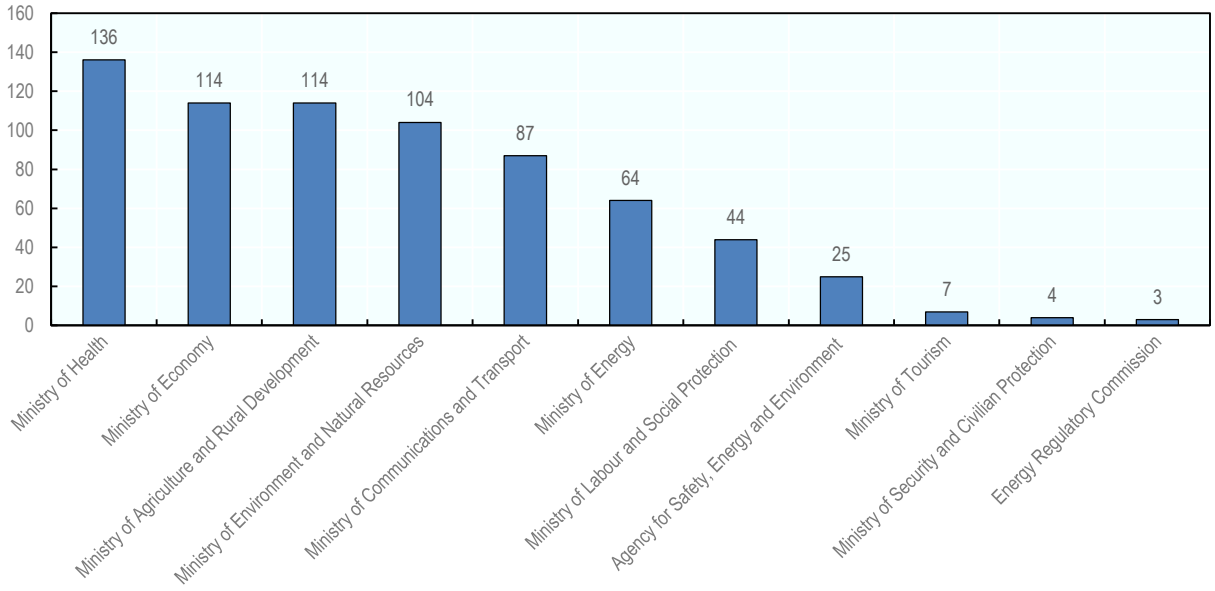
This approach grants a broader scope to "technical regulations" than usually contemplated in other countries (Box 1), in particular by going beyond product regulation and including a range of non-industrial services and food. This difference in scope explains why some aspects of international experience may be more-or-less difficult to match with elements of the Mexican system. In an attempt to map the range of measures covered by NOMs in Mexico, Box 2 organises them in a number of broad families with similar features.

Table 1. Mexico's regulatory instruments

Regulatory instruments
Primary laws
Primary laws initiated in the executive branch (approximately 9% of the total universe of primary laws)
Subordinate regulation
Bylaws
Decrees
Ministerial agreement or notice
Circulars
Manuals, methodologies, calls, programmatic rules of operation
Technical regulation
Official Mexican Standards – NOM
Standards
Mexican Standards – NMX

Source: (OECD, 2018[1]), *Review of International Regulatory Co-operation of Mexico*, Paris, https://dx.doi.org/10.1787/9789264305748-en.

Figure 1. NOMs per Ministry or Federal Agency



Source: DGN (2020).

Box 1. Definitions of technical regulations

In the EU, Directive 2015/1535/EU1 defines technical regulation to mean "technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 7, prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider."

De facto technical regulations under the EU definition include:

1. laws, regulations or administrative provisions of a Member State that refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to technical specifications or to other requirements or to rules on services, compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions;
2. voluntary agreements to which a public authority is a contracting party and which provide, in the general interest, for compliance with technical specifications or other requirements or rules on services, excluding public procurement tender specifications; and
3. technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services; technical specifications or other requirements or rules on services linked to national social security systems are not included.

The World Trade Organization (WTO) Agreements on Technical Barriers to Trade (TBT) and on the Application of Sanitary and Phytosanitary Measures (SPS) provide a notification system for regulatory measures with potentially significant trade effects as well as for agreements on technical regulations, standards or conformity assessment procedures between members. For the purposes of WTO disciplines, technical regulations are defined as: "Documents which lay out product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method".[3]

ISO/IEC Guide 2:2004[4] defines technical regulations as "a regulation that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice".

Generally, "technical regulations" are understood as covering industrial products and equipment – and, in some cases, services directly associated with them. These "technical regulations" cover primarily safety aspects, as well as environmental protection, but may also regulate product information and labelling, as well as other issues. Typically, food safety is not covered under the "technical regulations" term, given the very different way in which food safety is to be guaranteed, compared to industrial products – and likewise "conformity assessment" and other elements are mostly applied to non-food items.

[1] Directive 2015/1535/EU, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L1535&from=EN.
[2] 1998 Office of Management and Budget Circular A-119 defines standards for the purposes of 1995 National Technology Transfer and Advancement Act, https://www.whitehouse.gov/wp-content/uploads/2017/11/circular-119-1.pdf.
[3] Annex 1.1. to the TBT Agreement.
[4] ISO, *Standardization and related activities - General vocabulary*, https://isotc.iso.org/livelink/livelink/fetch/2000/2122/4230450/8389141/iso_iec_guide_2_2004_%28multilingual%29_-_standardization_and_related_activities_--_general_vocabulary.pdf?nodeid=8387841&vernum=-2 (accessed 9 September 2019).

Box 2. Overview of the use of NOMs in Mexico

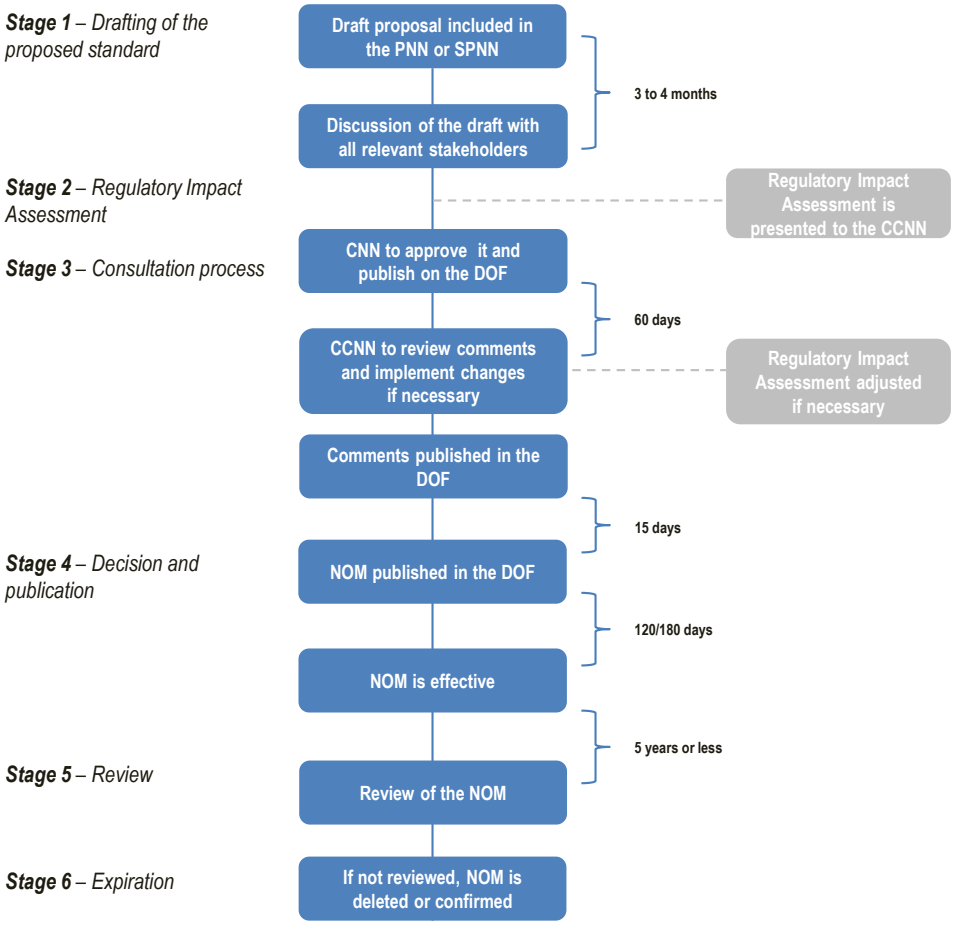
The use of NOMs in Mexico extends beyond the scope of "technical regulations" in other systems, covering not only product requirements and including a range of non-industrial services and food. These uses include the following, *inter alia*:

- *NOMs that set technical requirements for non-food and non-agricultural products.* In Mexico, NOMs may contain specifications and other requirements or rules on non-food and non-agricultural products and services for use by consumers or professionals. These NOMs are typically oriented at guaranteeing a high level of safety protection for consumers, the environment, among others. A number of these NOMs deal exclusively with the labelling requirements of such products. Oversight of these technical regulations typically falls on the relevant sectoral regulators and/or PROFECO.
- *NOMs that set technical requirements for medical products (drugs and medical devices).* A range of NOMs are aimed at ensuring a high level of protection of human health, setting requirements for approval of drugs and medical devices, as well as labelling rules, and requirements on manufacturing (GMP), among others. COFEPRIS, the sectoral regulator responsible for health in Mexico, oversees compliance with these NOMs.

- *NOMs that set requirements for food and agricultural products.* These issues are covered by a range of NOMs that can relate to the final product composition and contents, production process, labelling and storage, handling, transport, trade, service, among others. COFEPRIS and SENASICA, as well as State authorities, are responsible for overseeing compliance with most of these NOMs.
- *NOMs that set content for standard form contracts*. A number of NOMs in Mexico provide mandatory key elements for standard form or boilerplate contracts used in a variety of regulated sectors. These include agreements or language for transactions such as certain loans, real estate and vehicle purchase, car rental services, time-share agreements, and online sells, among others. Most of these NOMs are under the responsibility of the Ministry of Economy and their compliance is supervised by PROFECO.

The development of NOMs follows a systematic process regulated in the LFMN and led by the General Bureau of Standards (DGN) within the Ministry of Economy. This process involves six stages (Figure 2) that include an impact assessment procedure overseen by the National Commission for Regulatory Improvement (*Comisión Nacional de Mejora Regulatoria* or CONAMER) and the National Advisory Committees (CCNN) responsible for the development and monitoring of a specific NOM, a 60-day public consultation phase, and an *ex post* review 5 years after a NOM has entered into force.

Figure 2. NOM life cycle

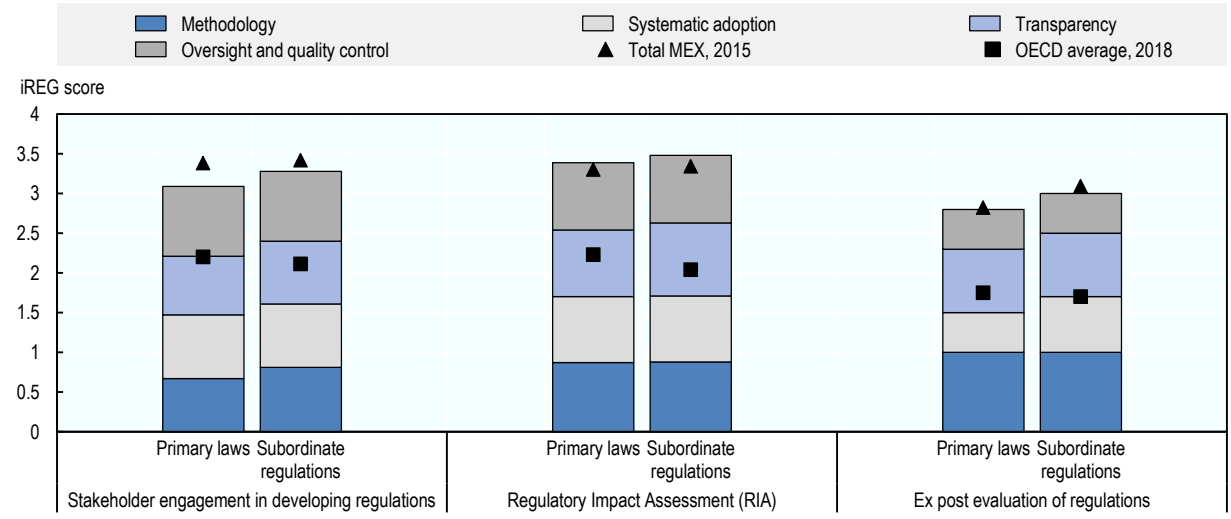


Note: Annex A includes a full description of the process for NOM development.
Source: (OECD, 2018[2]), "Standard-setting and Competition in Mexico: A Secretariat Report", OECD, Paris.

Mexico has put in place a strong regulatory policy framework (for primary and secondary legislation originating from the executive) led by CONAMER (Figure 3). However, similar to other OECD countries, Mexico's efforts to strengthen its regulatory policy framework have centred in the early stages of the "regulatory lifecycle", targeting mainly the design of laws and regulations. This is the case notably of the 2018 reform of the General Law of Regulatory Improvement that focused on reinforcing good regulatory practices such as RIA. Similarly, a proposal currently under discussion in Congress aims to reform the LFMN including the process of design and development of NOMs.

In Mexico and across OECD countries there is much room for improvement in order to reap the full benefits of good regulatory quality (OECD, 2018[3]). In particular, there is a need to bridge the gap between the design and the implementation and enforcement of regulations. The way in which governments enforce regulations and standards is critical. Inflexible or inefficient enforcement increases administrative burdens needlessly, affects compliance and reduces the benefits of regulations (Hampton, March 2005[4]).

Figure 3. Indicators of Regulatory Policy and Governance (iREG): Mexico, 2018



Notes: The more regulatory practices as advocated in the OECD Recommendation on Regulatory Policy and Governance a country has implemented, the higher its iREG score. The indicators on stakeholder engagement and RIA for primary laws only cover those initiated by the executive (34% of all primary laws in Mexico).
Source: Indicators of Regulatory Policy and Governance Surveys 2014 and 2017, https://oe.cd/ireg.

Addressing challenges in the implementation of technical regulations

Good regulation and their appropriate delivery are key factors to promote the trust needed to build markets. In particular, the enforcement of and compliance with technical regulations have critical implications for domestic markets and international trade.

A sound framework for technical regulations benefits consumers by guaranteeing safety, and the normal functioning of markets (including price signals). It allows manufacturers and suppliers to demonstrate the quality of their products across markets and avoid unnecessary inspections. Promoting the implementation of technical regulations allows governments to reduce unnecessary market surveillance, streamline public procurement, foster technological development and increase industrial quality levels.

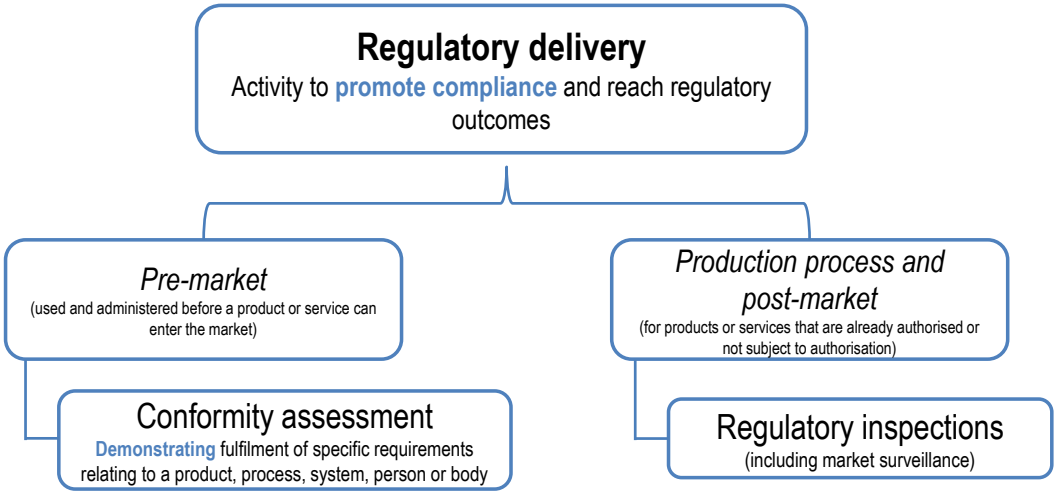
A strong regulatory framework enables domestic producers to become trusted partners for foreign markets – be it as direct suppliers of consumer products, or as participants in the international supply chain. Conversely, poor use of technical regulations creates barriers to trade and innovation, and hurts

competiveness and growth. A lack of trust in the CAP system will result in poor recognition internationally and lowered foreign demand for Mexican products. This issue is especially important for Mexico, for which trade represents more than a third of its GDP.

However, Mexico has faced challenges in encouraging the implementation of technical regulations at the local level. A high proportion of products in Mexico do not meet the requirements and standards set out in NOMs. PROFECO reports that about 20% of products were in non-compliance with Mexican NOMs in 2018 (PROFECO, 2018[5]). More broadly, the informal sector or shadow economy (i.e. businesses operating outside official frameworks) is very large in Mexico. Mexico has one of the largest grey markets among OECD countries, second only to Greece as of 2015. In 2018, the IMF reported that Mexico's shadow economy[2] represented between 24.8% to 31.7% of GDP, a figure far greater than any other OECD country (Schneider, 2018[6])[3]. These businesses are likely unexposed to the rigorous government processes and requirements set under NOMs. Indeed, the large informal sector – primarily sole traders – could be hard to convince of the benefits of NOMs.

Regulatory delivery of NOMs in Mexico is in practice structured around two pillars: conformity assessment which takes place in the pre-market phase and regulatory inspections carried out during the production process and/or post-market phase. (Figure 4). The first pillar are conformity assessment procedures (CAPs), typically performed by conformity assessment bodies (CABs). This relates to demonstrating *ex ante* the compliance of proposed products (or, in exceptional cases, services) with the requirements established in each NOM, before such products are effectively placed in the market. The second pillar are regulatory inspections carried out by the government authority responsible for each NOM and/or by PROFECO. Regulatory inspections focus on products or services that are authorised to enter the market and/or are not subject to pre-approval. They can target production processes and conditions or the actual conformity of the product or service with the requirements set in a NOM (*ex post*). Both pillars are complementary and necessary to ensure the effective functioning of markets and the delivery of the policy goals set in each NOM.

Figure 4. Schematic of regulatory delivery of NOMs



Source: Author's elaboration.

Governments use technical regulations to ensure the safety and well-being of citizens. These allow to guarantee the particular specifications of a product or service to reduce risks to the health, safety or well-being of citizens. However, the mere existence of technical regulations is not enough to secure these objectives. A successful technical regulations system requires a coherent and functional national quality

infrastructure (NQI), i.e. the interplay of metrology, standardisation, accreditation, conformity assessment, and market surveillance that ensures that the requirements set under NOMs are fulfilled.

Conformity assessment procedures (CAPs) are critical to effectively connect the requirements set out in technical regulations with the products and services available in the market. Conformity assessment is the demonstration that a product, process, service, system, person or body meets the relevant regulatory requirements (ISO/IEC 17000:2004). Accreditation provides an additional layer of assurance to verify that conformity assessment bodies (CABs) have the competences and impartiality to perform their functions.

Once a product is placed on the market, governments engage in regulatory inspections (including market surveillance) to monitor that products sold continue to meet the requirements set under technical regulations. Regulatory inspections of technical regulations may include:

- Testing the quality of products;
- Checking stores to ensure that products continue to meet the technical regulations;
- Removing non-compliant products from the market; and/or
- Inspecting factories, power plants, and industrial equipment that must meet technical regulations.

Governments must be very careful in how they design the implementation and enforcement of technical regulations and other legal requirements. The implementation of regulatory inspections itself can have significant impacts on society because of the potential costs for the public administration, possible burdens on businesses, and the impacts on consumers. Poorly designed inspections or surveillance programmes may create high costs for businesses or consumers, reduce competition/choice, or ineffectively assure citizens' safety. To support countries in this endeavour, the OECD developed Best Practice Principles and a Toolkit on Regulatory Enforcement and Inspections. The Toolkit presents a checklist of 12 criteria to help officials, regulators, stakeholders and experts assess the development of inspections and enforcement systems across a country or in a particular sector (Box 3).

Box 3. The OECD's Best Practice Principles on Regulatory Enforcement and Inspections

1. Evidence-based enforcement: Regulatory enforcement and inspections should be evidence-based and measurement-based: deciding what to inspect and how should be grounded in data and evidence, and results should be evaluated regularly.
2. Selectivity: Promoting compliance and enforcing rules should be left to market forces, private sector actions and civil society activities wherever possible: inspections and enforcement cannot take place everywhere and address everything, and there are many other ways to achieve regulations' objectives.
3. Risk focus and proportionality: Enforcement needs to be risk-based and proportionate: the frequency of inspections and the resources employed should be proportional to the level of risk, and enforcement actions should aim at reducing the actual risk posed by infractions.
4. Responsive regulation: Enforcement should be based on "responsive regulation" principles; that is, inspection and enforcement actions should be modulated depending on the profile and behaviour of specific businesses.
5. Long-term vision: Governments should adopt policies on regulatory enforcement and inspections, and establish institutional mechanisms with clear objectives and a long-term strategy.
6. Co-ordination and consolidation: Inspection functions should be co-ordinated and, where needed, consolidated: less duplication and fewer overlaps will ensure a better use of public resources, minimise the burden on regulated subjects, and maximise effectiveness.

7. Transparent governance: Governance structures and human resources policies for regulatory enforcement should support transparency, professionalism, and results-oriented management. The execution of regulatory enforcement should be independent from political influence, and compliance promotion efforts should be rewarded.
8. Information integration: Information and communication technologies should be used to maximise a focus on risks, promote co-ordination and information sharing and ensure an optimal use of resources.
9. Clear and fair process: Governments should ensure that rules and processes for enforcement and inspections are clear. Coherent legislation to organise inspections and enforcement needs to be adopted and published, and the rights and obligations of officials and of businesses, clearly articulated.
10. Compliance promotion: Transparency and compliance should be promoted through the use of appropriate instruments such as guidance, toolkits and checklists.
11. Professionalism: Inspectors should be trained and managed to ensure professionalism, integrity, consistency and transparency. This requires substantial training focusing not only on technical but also on generic inspection skills, and official guidelines for inspectors to help ensure consistency and fairness.
12. Reality check: Institutions in charge of inspection and enforcement, and the regulatory enforcement and inspection system as a whole, should deliver the levels of performance expected from them – in terms of stakeholder satisfaction, efficiency (benefits/costs), and overall effectiveness (safety, health, environmental protection etc.).

Source: (OECD, 2018[7]), OECD Regulatory Enforcement and Inspections Toolkit, Paris, https://doi.org/10.1787/9789264303959-en.

The structure of the review

This report highlights the opportunities and entry points to secure better regulatory delivery of technical regulations (NOMs) in Mexico. For this purpose, Chapter 1 provides an overview of the legal and institutional frameworks governing the implementation and enforcement of technical regulations. It describes the main laws and policies that govern technical regulations, outlines the institutions that are involved in their development and implementation, and provides an overview of recent and ongoing reforms affecting NOMs. Chapter 2 focuses on the pre-market regulatory delivery of NOMs, presenting the conformity assessment and accreditation frameworks applicable in Mexico and specific sectoral illustrations of conformity assessment techniques. Finally, Chapter 3 discusses the regulatory inspection mechanisms used to supervise, promote and enforce compliance with NOMs (including market surveillance activities). The chapter delivers an overview of the resources and approaches used to organise inspections and enforcement activities, and discusses the challenges of the Mexican system against the OECD Best Practice Principles and Toolkit on Regulatory Enforcement and Inspections.

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Notes

[1] Article 3, XI Federal Law on Metrology and Standardisation.

[2] For the paper, the authors defined the shadow economy as all economic activities that are hidden from official authorities for monetary, regulatory, and institutional reasons.

[3] The OECD country with the smallest shadow economy is Switzerland at 6.94% in 2015.

1 The organisation of the implementation and enforcement of technical regulations in Mexico: framework and actors

This chapter outlines the legal and institutional context for the implementation and enforcement of technical regulations in Mexico. It provides an overview of the Mexico's standardisation and metrology system, describing the main laws and policies that govern technical regulations and the institutions that are involved in their development, implementation and enforcement.

Introduction

The Mexican Technical Regulations and Standardisation System is underpinned by the Federal Metrology and Standardisation Law (*Ley Federal sobre Metrología y Normalización*, LFMN), passed in 1992 in a context of increasing trade and economic integration in Mexico. Since its creation, the LFMN has been subject to a number of amendments. Following the adoption of the North American Free Trade Agreement (NAFTA) in 1994, the LFMN was modify in 1997 to align the Mexican standardisation system to the frameworks of its main trade partners: the United States and Canada. Since 2017, Congress has been discussing a reform proposal that seeks to reduce the timeframes for development and revision of NOMs and to ensure better quality of conformity assessment procedures.

Together with the LFMN, the default regime for the implementation and enforcement of NOMs is governed by the Federal Law of Administrative Procedure (*Ley Federal de Procedimiento Administrativo*, LFPA) and certain provisions in the Consumer Protection Law (*Ley Federal de Protección al Consumidor*, LFPC), the new General Law on Regulatory Improvement and the Law on Foreign Trade. However, in certain sectors special laws create alternative regimes for technical regulations under the purview of decentralised and deconcentrated government authorities.

To understand the context of the implementation and enforcement of technical regulations in Mexico, this chapter identifies the main laws and policies that govern NOMs and the institutions that are involved in their development, implementation and enforcement. The process is mainly co-ordinated by the Ministry of Economy (*Secretaría de Economía*, SE) through its General Bureau of Standards (DGN) but it involves numerous additional stakeholders that include public sector bodies with powers to issue and implement NOMs, technical entities and firms from a range of industry sectors.

The legal frameworks governing the implementation and enforcement of NOMs in Mexico

The default system for implementation and enforcement of NOMs is spearheaded by the LFMN together with its Regulation (*Reglamento de la Ley Federal sobre Metrología y Normalización*, RLFMN). Specific actions on inspections are regulated by the LFPA and the LFPC. In addition to these three laws, both the new General Law on Regulatory Improvement and the Law on Foreign Trade include provisions related to the enforcement of NOMs.

This default system is applicable only to the extent that there is no special law governing the implementation and enforcement of NOMs. In certain sectors, special laws supersede the provisions of the default regime and create alternative regimes for decentralised and deconcentrated government authorities. This is for instance the case of NOMs applicable under the General Health Law.

The legislation for implementation and enforcement of NOMs

The Federal Law on Metrology and Standardisation (Ley General sobre Metrología y Normalización, LFMN) is the backbone of the Mexican Technical Regulations system. The system set-up in the LFMN is structured around four key components (OECD, 2018[1]):

- Standardisation – for the development of mandatory NOMs and voluntary NMXs;
- Metrology – for a reliable measurement system;
- Accreditation – for an adequate competence of certification bodies; and
- Conformity assessment – for proof of compliance with NOMs and NMXs.

In the area of metrology, the LFMN creates the National Metrology Centre (*Centro Nacional de Metrología*, CENAM) responsible for maintaining appropriate reference measurement standards at the national level. The law also sets the rules for measurement units and outlines the National Calibration System responsible for the reliability and uniformity of measurements in the country. Finally, the LFMN also establishes the requirements for the manufacture, commercialisation and use of measurement instruments and patterns.

The LFMN outlines the procedures and entities involved in the development and implementation of mandatory NOMs and voluntary NMXs and the related key definitions (Box 1.1). The law introduces: i) an open 60-day consultation process; ii) a biannual forward planning agenda for NOMs and NMXs; and iii) systematic *ex post* evaluations (at least) every 5 years. In addition, the LFMN regulates the accreditation set-up and the conformity assessment procedures applicable in Mexico. The law sets the powers and duties of the Ministry of Economy and other competent sectoral regulators to oversee compliance with its dispositions and establishes details of the inspection procedures and a framework of sanctions applicable for breaches.

The LFMN is currently under revision, Congress is discussing a proposal to reform the law first presented in 2017. The proposal seeks to reduce the timeframes for development and revision of NOMs and to ensure better quality of conformity assessment procedures.

Box 1.1. Key concepts in the LFMN

- **NOM.** "Mandatory technical regulation issued by the competent regulatory agency for the purposes defined in the LFMN that establishes rules, specifications, attributes, guidelines, characteristics or dispositions applicable to a product, process, facility, system, activity, production or operation service or method, as well as those related to terminology, symbols, packaging, labelling and those concerning their compliance or enforcement."
- **NMX.** "Those developed by a national standardisation body or the Ministry of Economy according to the LFMN, establishing a common and iterative use of rules, specifications, attributes, testing methods, guidelines, characteristics or dispositions applicable to a product, process, facility, system, activity, production or operation service or methods as well as those related to terminology, symbols, packaging, labelling."
- **Conformity assessment.** "Determination of degree of compliance with NOMs or conformity with NMXs, international standards or other specifications, dispositions or characteristics. It includes, among others, the procedures of testing, sampling, calibration, certification and verification."
- **Accreditation.** "Act through which an accreditation entity recognises the technical competence and reliability of certification bodies, testing laboratories, calibration laboratories and verification units for the purposes of conformity assessment."
- **Certification.** "Procedure through which it is ensured that a product, process, system or service adjusts to the rules, guidelines or recommendations or national or international standardisation bodies."
- **Verification unit.** "Individual or entity that performs verification acts."
- **Verification.** "Eye inspection or verification via sampling, measurement, laboratory testing or examination of documents performed for conformity assessment at a given time."

Source: LFMN, Article 3.

The Federal Law of Administrative Procedure (*Ley Federal de Procedimiento Administrativo* or LFPA) is the main legal body addressing good regulatory practices in Mexico. It generally governs the inspection activity undertaken by administrative authorities. Chapter Eleven of the LFPA grants these authorities powers to check compliance with laws and regulations and explicitly sets out the inspection requirements that must be observed by public officials. Title Fourth of the LFPA establishes general principles on administrative infractions and sanctions, including a non-exhaustive list of administrative sanctions that authorities may apply and the procedures for appeal such sanctions.

The Federal Consumer Protection Law (*Ley Federal de Protección al Consumidor*, LFPC) provides the legal framework for consumer protection in Mexico, including consumer's rights and the corresponding duties of the Ministry of Economy and PROFECO. The LFPC gives the DGN responsibility to develop NOMs and NMXs on a range of issues including, inter alia, product labelling, advertisement and standard-form contracts. In addition, the law empowers PROFECO to oversee compliance with NOMs issued by the Ministry of Economy when no specific sectoral regulator is tasked with the enforcement by a special law or through a specific provision in a NOM.

The Law on Foreign Trade (*Ley de Comercio Exterior*, LCE) sets the legal framework for Mexico's trade practices including certain provisions on technical regulations. In particular, it grants the Ministry of Economy with powers to determine the NOMs that custom officials must enforce at entry points and the tariffs applicable to exports covered by NOMs (LCE, article 26). It is noteworthy that the specific legal provisions regarding WTO commitments in the area of regulations (notably notification under SPS and TBT, equivalence and mutual recognition) fall under the LFMN and its bylaw.

The General Law on Regulatory Improvement approved in 2018 establishes the scope and the basis for the development of regulatory policy in Mexico. The law creates the National System on Regulatory Improvement and revamps the role of the CONAMER. The rollout of certain provisions under the law relevant for the enforcement of technical regulations is currently ongoing. The law foresees the creation of a National Registry of Visits (*Registro Nacional de Visitas Domiciliarias*) that lists all public officials authorised to carry out inspection and verification activities, including on NOMs.

Finally, the Law on Acquisitions, Leases and Services by the Public Sector (*Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público*) and the Law on Public Works and Related Services (*Ley de Obras Publicas y servicios relacionados con las mismas*) setting the Mexican public procurement framework provide for compliance with NOMs in public purchases and public works.

Implementation and enforcement of NOMs under specific sectoral laws

Special legal frameworks exist for the implementation and enforcement of NOMs issued by certain decentralised and deconcentrated government authorities. These special regimes are established under sectoral laws and alter some of the regulations that govern the accreditation and/or inspection of NOMs under the LFMN. In practice, they empower specific sectoral regulators to establish conformity assessment processes that diverge from the system under the LFMN or create ad-hoc procedures for the development of instruments similar to NOMs. Table 1.1 includes a list of laws that provide exceptions to the LFMN or set-up special regimes for the implementation and enforcement of NOMs. Table 1.2 summarises some of these special regimes.

Table 1.1. List of laws with exception to the LFMN or special regimes for implementation and enforcement of NOMs

Name of law
General Health Law
Federal Law on Vegetal Health
Federal Law on Animal Health
General Law on Sustainable Fishing and Aquaculture
Law on Organic Products
Federal Law on Telecommunications and Broadcasting
Hydrocarbons Law and Law of the Coordinated Energy Regulators
Federal Labour Law
Law on Biosafety of Genetically Modified Organisms
Law on Livestock Associations
General Wildlife Law
Federal Law on Sustainable Rural Development
Federal Law on Seed Production, Certification and Trade
Federal Law on Plant Varieties
Law on the Production and Sell of Roasted Coffee
Federal Oceans Law
Law for Sustainable Development of Sugarcane
Public Works and Related Services Law
Intellectual Property Law

Table 1.2. Summary of selected special regimes for implementation and enforcement of NOMs

	Sectoral regulator	Law	Scope of special regime
Health	*Secretaría de Salud* COFEPRIS	General Health Law	Verification and sampling of products, activities and services regulated by the General Health Law.
Food and agriculture	SADER SENASICA	Federal Law on Vegetal Health Federal Law on Animal Health General Law on Sustainable Fishing and Aquaculture Law on Organic Products	Certification of products and inspection.
Energy	Agency for Safety, Energy and Environment (ASEA), National Hydrocarbons Commission (CNH), the Energy Regulatory Commission (CRE)	Hydrocarbons Law and Law of the Coordinated Energy Regulators	Inspection of NOMs; and development and inspection of NOM-like instruments (general administrative dispositions).
Telecommunications	Federal Institute on Telecommunications (IFT)	Federal Law on Telecommunications and Broadcasting	Development of NOM-like instruments, the certification and conformity assessment of products, recognition under MRAs and inspection.

Note: General administrative provisions are legal instruments not subject to the LFMN and different from NOMs but at times similar in content.
Source: Author's own elaboration.

Implementation and enforcement of NOMs in the health sector

The legal framework related to the implementation and enforcement of NOMs in the health sector is provided by the LFMN and LFPA together with the following sectoral laws and regulations:

- General Health Law (*Ley General de Salud*, LGS);
- Regulation of the Federal Commission for the Protection Against Sanitary Risks (*Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios*);
- Regulation on the Health Control of Products and Services (*Reglamento de Control Sanitario de Productos y Servicios*); and
- Regulation on the Health Control of Activities, Facilities Products and Services (*Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios*).

The LGS sets specific enforcement mechanisms as well as sanctions for non-compliance with health-related NOMs that are recognised under the LFMN as a special regime (LFMN, article 108). The Ministry of Health (*Secretaría de Salud, SSA*) and Federal Commission for the Protection of Sanitary Risks (*Comisión Federal para la Protección Contra Riesgos Sanitarios*, COFEPRIS) are responsible for NOMs in the health sector. COFEPRIS oversees the enforcement of four regulations on medical devices, health control of products and services, environmental health and pesticides. In total, COFEPRIS has 81 NOMs under their authority. Further, a number of these NOMs do not embed a specific CAP, since their assessment is performed by the default sanitary inspection and testing mechanisms set forth in the LGS.

Implementation and enforcement of NOMs in the food and agriculture sector

The legal framework applicable to food and agriculture NOMs also recognises exceptions from the default regime under the LFMN and LFPA. This special regime includes, *inter alia* the following laws:

- Federal Law on Vegetal Health (*Ley Federal de Sanidad Vegetal*, LFSV)
- Federal Law on Animal Health (*Ley Federal de Sanidad Animal*, LFSA);
- General Law on Sustainable Fishing and Aquaculture (*Ley General de Pesca y Acuacultura Sustentables*, LGPAS);
- Law on Organic Products (*Ley de Productos Orgánicos*);
- Law on Bio Safety of Genetically Modified Organisms (*Ley de Bioseguridad de Organismos Genéticamente Modificados*); and
- Law on Livestock Organisations (*Ley de Organizaciones Ganaderas*).

Some of these laws give powers to establish conformity assessment processes outside of the LFMN to the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (*Secretaría de Agricultura, y Desarrollo Rural*, SADER) through the National Service of Food and Agriculture Health, Safety and Quality (*Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria*, SENASICA). In use of these powers, SENASICA can authorise special third parties to perform certain assessment techniques. These third parties, known as “Terceros Coadyuvantes”, are specially regulated by SENASICA and not always accredited by EMA. This is the case under the Federal Laws on Animal and Vegetal Health. Similarly, the Law on Organic Products sets forth a special regime for control and certification, noting that the LFMN acts as a supplementary system.

Notably, there is no over-arching food safety law in Mexico governing the entire food chain, whereas the presence of such a law is generally held to be accepted good international practice (Cf. FAO *Model Food Law* and *Codex Alimentarius*). Evidence from interviews shows that this corresponds to a situation where some issues, which are important for safety, are not currently subject to clear mandatory regulations. Rather, regulators (in particular SENASICA) have to make do with guidance documents based on

international practices and norms. While, overall, technical capacity for enforcement appears stronger in the food sector than in non-food consumer products, the legal framework (NOMs) appears more developed and comprehensive for non-food than for food products.

Implementation and enforcement of NOMs in the energy sector

Following a 2014 reform, Mexico has three regulatory agencies in the energy sector: Agency for Safety, Energy and Environment (*Agencia de Seguridad, Energía y Ambiente*, ASEA); the National Hydrocarbons Commission (*Comisión Nacional de Hidrocarburos*, CNH); and the Energy Regulatory Commission (*Comisión Reguladora de Energía*, CRE). These agencies are empowered under the National Law on Hydrocarbons and the Law of the Coordinated Energy Regulators to develop NOMs or other instruments not governed by the LFMN such as mandatory general administrative provisions (*Disposiciones Administrativas de Carácter General*, DACGs) similar to NOMs. The CRE oversees the two National Advisory Standardisation Committees (CCNNs) responsible for the development of NOMs on electricity and hydrocarbons, oil resources and petrochemical. ASEA leads the work of the committee responsible for NOMs for industrial safety and environmental protection in the hydrocarbon sector.

The agencies are also tasked with the enforcement of these NOMs and DACGs, yet at times this function can be delegated to authorised third parties that operate under a parallel system from the LFMN. For example, the Electrical Industry Law (*Ley de la Industria Eléctrica*) provides that verification units accredited under the LFMN are responsible for the demonstration of compliance with certain NOMs whereas inspection units approved by the CRE certify compliance with other types of technical specifications. ASEA has the authority to provide and suspend licenses and authorisations, conduct inspections and quality control, and issue recommendations for corrective action in the area of industrial safety and environmental protection. ASEA also permits inspections from certified third parties who are authorised and evaluated by both ASEA itself and EMA. Third party inspectors may, for example, verify a deep-water oil project's safety (Garcia, 2017[2]).

Implementation and enforcement of NOMs in the telecommunications sector

The Federal Law on Telecommunications and Broadcasting (*Ley Federal de Telecomunicaciones*, LFTR) authorises the Federal Institute on Telecommunications (*Instituto Federal de Telecomunicaciones*, IFT) to issue mandatory technical provisions setting the characteristics of telecommunication and broadcasting products and services as well as the evaluation process and technical requirements needed for the installation of equipment, systems and/or infrastructure. These technical provisions are subject to a development process led by the IFT outside of the LFMN. In addition, the IFT has powers to oversee the implementation and enforcement of these technical dispositions including their certification and other conformity assessment processes as well as the application of mutual recognition agreements (MRAs)[1]. Since 2013, the IFT has issued 15 technical provisions. For example, IFT-011-2017 establishes the technical specifications for Mobile Terminal Equipment allowed to use of radio spectrum or be connected to telecommunications networks; and sets the test methods to verify compliance with said specifications.[2]

Institutions involved in the implementation and enforcement of technical regulations in Mexico

A large number of public and private actors are involved in the different components of the Mexican Technical Regulations and Standardisation system. Overall, the system includes 13 sectoral regulators, 15 federal agencies, 10 private entities, 10 national standardisation bodies (responsible for NMXs) and more than 2 800 highly-specialised private entities involved in conformity assessment (Cámara de Diputados del Congreso General de los Estados Unidos Mexicanos, 2017[3]). Table 1.3 summarises the key actors involved in the lifecycle of NOMs in Mexico.

Table 1.3. Actors involved in the lifecycle of NOMs

	Development of NOMs	Metrology	Accreditation	Conformity Assessment Procedures	Regulatory Inspection and/or market surveillance
DGN	●	●			
CONAMER	●				
Sectoral Regulators	●			●	●
CENAM	●	●		●	●
EMA	●		●		
Conformity Assessment Bodies	●			●	●
PROFECO	●			●	●
Civil society and business	●				●
Customs					●

Note: CENAM inspection powers fall over measurement equipment.
Source: Author's elaboration.

The Ministry of Economy (*Secretaría de Economía*), through the General Bureau of Standards (*Dirección General de Normas*, DGN), plays a key role in the Mexican Technical Regulations System with broad responsibilities that include co-ordinating with other entities to secure compliance with the LFMN and overseeing the process for development and implementation of NOMs and NMXs. The Ministry of Economy leads the relationship between the Government and the Mexican Accreditation Entity (EMA).

The DGN leads the National Standardisation Program (PNN), a forward planning agenda for technical regulations and voluntary standards; oversees the adoption of international standards; and is responsible for the 60-day consultation period for NOMs and their 5-year *ex post* review (Annex A). In addition, it is in charge of maintaining a record of all NOMs, NMXs, ONNs, accreditation entities and accredited and approved organisms. DGN also oversees the conclusion of Mutual Recognition Agreements (MRAs) and Arrangements (MLAs).

On top of its co-ordinating functions, the DGN is also empowered by the LFMN to issue NOMs and oversee their implementation and enforcement. DGN is responsible for 136 NOMs. In addition, the Internal Regulations of the Ministry of Economy give the DGN powers to verify and inspect compliance with metrology and standard-setting regulations and authorising national accreditation entities.[3]

The National Commission for Regulatory Improvement (*Comisión Nacional de Mejora Regulatoria* or CONAMER) is the central oversight body for better regulation in Mexico. It is responsible for ensuring the regulatory quality of laws, subordinate regulations and NOMs by deploying tools such as *ex ante* and *ex post* regulatory impact assessment and stakeholder engagement. NOMs are subject to a double quality control as their regulatory impact assessments (RIA) are reviewed by CONAMER and by National Advisory Committees (*Comités Consultivos Nacionales* or CCNN) established to design and oversee the implementation of specific NOMs.

The National Metrology Centre (*Centro Nacional de Metrología*, CENAM) is a decentralised body created by the LFMN to act as reference laboratory for national measurement standards. To date, CENAM has developed a number of national measurement standards used as references to ensure uniformity and reliability of national measurements. CENAM is the key actor in the Mexican metrology system. CENAM also occasionally performs conformity assessment services such as calibration, verifications and approval of software and prototypes. For example, CENAM is the competent body for verifying compliance with some of the requirements established under a technical regulation on gas measurement and supply (NOM-005-SCFI-2011). Similarly, CENAM is authorised to issue certificates for companies undergoing

environmental audits under the General Law on Ecologic Balance and Environmental Protection (*Ley General del Equilibrio Ecológico y la Protección al Ambiente*).

Thirteen **sectoral regulators** are involved in the implementation and enforcement of technical regulations in Mexico. According to the LFMN, sectoral regulators are in charge of developing the conformity assessment procedures for NOMs under their purview and undertake inspections to secure that the products and services comply with technical regulations (LFMN, articles 68 and 91). In addition, sectoral regulators are required by the LFMN to co-ordinate with other agencies to secure compliance with NOMs. Yet, co-ordination for the implementation of technical regulations where two or more regulators have oversight powers is scarce and occurs on an ad-hoc basis.

The Mexican Accreditation Entity (Entidad Mexicana de Acreditación, EMA) is a private non-profit organisation established in 1999 to grant formal recognition to conformity assessment bodies in Mexico through accreditation. The EMA is authorised by the Ministry of Economy and additionally approved by the National Standardisation Commission (*Comisión Nacional de Normalización*, CNN). To date, the EMA remains the only accreditation body for conformity assessment bodies in Mexico, which comprise testing laboratories, calibration laboratories, medical laboratories, inspection bodies and certification bodies, proficiency testing providers and the greenhouse gas emissions verification/validation bodies. The EMA is recognised by the main international accreditation organisations, including the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).

The LFMN allows sectoral regulators to take on conformity assessment procedures directly or to approve and authorise **conformity assessment bodies (CABs)** accredited by EMA to perform these tasks. CABs in Mexico, include *inter alia*, testing laboratories, calibration laboratories, verification bodies and certification bodies. According to EMA's responses to an OECD questionnaire, the landscape of conformity assessment bodies in Mexico has increased both in number (from nearly 989 in 1999 to roughly 6,043 in 2019) and in the range of sectors covered, recently including for instance forensic, clinical laboratories and verifications for greenhouse gas emissions, producers of reference materials and proficiency testing providers.

The Federal Attorney´s Office of Consumer (*Procuraduría Federal del Consumidor*, PROFECO) is a decentralised public entity that has a broad mandate to perform inspections and surveillance under the Federal Consumer Protection Law. PROFECO oversee the enforcement of consumer-related technical regulations and NOMs issued by the Ministry of Economy when no specific sectoral regulator is tasked with their oversight (LFPC, article 3). In addition, PROFECO is also occasionally engaged in conformity assessment procedures such as the certification of scales and verification of gas stations.

Customs officials at entry points are responsible for checking compliance of imported goods with NOMs (LCE, article 26). In order to demonstrate compliance with the standards set in a NOM, the importer must exhibit a certificate of compliance. Thorough consideration of the system of controls at the border was beyond the scope of this review, but interviews conducted nonetheless allowed to identify a number of critical issues that touch upon the implementation of NOMs. These deserve to be investigated further, because effective border controls and good co-ordination between border and in-country supervision on technical conformity issues are essential to the proper functioning of the technical regulation system. Mexico's performance in terms of trade facilitation is solid, as evidenced by the OECD Trade Facilitation index (OECD, 2017[4]) – ensuring that the system is also effective in terms of technical safety is an important next step. This involves a reliable certification system; the existence of technical resources at border control points to assess conformity of shipments which present a significant risk; and a system to assess the risk-level of shipments from a technical regulation perspective (distinct from the system that exists for customs valuation).

Recent and ongoing reforms in Mexico affecting technical regulations

In recent years, Mexico's efforts to strengthen its regulatory policy framework have gone beyond the early stages of the regulatory policy "lifecycle" and extended to the enforcement and *ex post* review of regulations, including NOMs. This is illustrated by a number of past and ongoing reform initiatives that target or have an impact over the Mexico's Metrology, Standardisation and Technical Regulation System. This is the case of the 2018 reform to the General Law of Regulatory Improvement that focused on reinforcing good regulatory practices such as RIA, including for NOMs. Also in 2018, the consumer protection watchdog (PROFECO) was granted new powers to impose sanctions and fines for breaches of the Federal Consumer Protection Law. In January 2020, Congress passed a new Law to Promote Citizens' Trust (*Ley de Fomento a la Confianza Ciudadana*) that creates a simplified inspection regime for certain individuals and entities.

In addition to these reforms, Congress is currently discussing a reform to the LFMN. Furthermore, the current administration recently announced a project to roll out a new Law on National Quality Infrastructure (*Ley de Infraestructura de la Calidad*). The following section briefly discusses these past and ongoing reform initiatives.

Table 1.4. Summary of recent and ongoing reform initiatives impacting technical regulations

Reform	Status	Impact on technical regulations (NOMs)
Reform to the General Law of Regulatory Improvement	Passed in 2018	• Creation of a National Registry of Inspections • Regulatory offsetting rule applicable to NOMs
Reform to the Consumer Protection Law	Passed in 2018	• Strengthens PROFECO's powers to impose sanctions including for non-compliance with NOMs
Law to Promote Citizens' Trust	Passed in 2020	• Creation of a voluntary simplified regulatory inspection regime for special entities or individuals • Consideration of businesses track-record
Law on Quality Infrastructure	Drafting by the Executive and discussion ongoing	• Complete overhaul of Mexico's Metrology, Standardisation and Technical Regulation System

Source: Author's own elaboration.

Roll-out of the General Law of Regulatory Improvement

The General Law of Regulatory Improvement establishes the scope and the basis for the development of regulatory policy in Mexico. The 2018 reform created the National System on Regulatory Improvement, revamped the role of CONAMER and defined new obligations for subnational entities and autonomous institutions. The reform put in place a number of measures that impact a range of instruments including technical regulations, notably regulatory offsetting and the creation of a National Registry for Inspections (Box 1.2). In addition, it banned regulatory proposals not included in the Regulatory Agenda, which is updated every six months, from being published in the Official Gazette.

Box 1.2. The National Registry of Inspections

The 2018 reform to the General Law of Regulatory Improvement creates a National Registry of Visits (*Registro Nacional de Visitas Domiciliarias*), a repository aimed to increase publicly available information on the details of inspection processes.

The registry includes a list of inspection activities that can be carried out by public institutions and the civil servants authorised to perform them, as well as other relevant information identified by the National Council of Regulatory Improvement.

CONAMER is responsible for managing the Registry with information provided by the relevant sectoral regulator or agency leading the inspection and verifications activities — including statistics.

While the complete dataset that the Registry will contain is yet to be defined in the National Strategy of Regulatory Improvement, some minimum information requirements set forth in the law include the contact numbers for the internal compliance office in each institution responsible for inspections and civil servants authorising the activity.

The implementation of the Registry is still pending.

Source: Regulatory Improvement Law (*Ley de Mejora Regulatoria*).

New Law to Promote Citizens' Trust

In January 2020, the Law to Promote Citizens' Trust (*Ley de Fomento a la Confianza Ciudadana*) was approved by Congress with the objective of creating a simplified inspection regime for certain individuals and entities. The rationale behind the law is that those societies with higher levels of trust between the government and the private sector achieve stronger economic growth and are subject to fewer corruption issues.

The initiative creates a special registry (*Padrón Único de Confianza*) managed by CONAMER where individuals and entities can enrol voluntarily to benefit from a reduced burden of inspections and other administrative simplification advantages. Individuals and entities included in the registry will be subject to special inspection system managed by CONAMER.

The simplified inspection regime will not be applicable to inspections and verifications undertaken in matters related to food safety, human and animal health, tax, customs, labour, social security, foreign trade, financial sector, fire arms and explosives, money laundering regulations, and certain activities related to petroleum products.

CONAMER will determine the target and frequency of inspection visits based on a strategic analysis. The law introduces the foundations for a risk-based system, in particular varying inspections frequency based on risk, and assessing risk by combining intrinsic risk and business' track record. CONAMER is also working to develop an information system to support such an approach. While these are very positive developments, they will nevertheless require a robust, well-structured and thorough implementation programme – possibly focusing first on specific regulatory functions and pilot implementation in some selected states or cities. Experience suggests that the implementation of such changes requires good planning, resources and time.

Reform to the LFMN

Congress is discussing a proposal to reform the LFMN first presented in 2017 to address weaknesses in Mexico's LFMN. The main elements of the reform proposal are the following:

- Simplification of the processes for NOM design and review;
- Establishment of the process, elaboration, consultation and publication of Mutual Recognition Agreements;
- Providing guidelines to strengthen oversight and operation of conformity assessment bodies, as well as the sanctions applicable to them; and

- Strengthening the sanction system by increasing the fines for breaches of the LFMN.

The reform also intends to overhaul the System of Norms and Conformity Assessment (*Sistema Integral de Normas y Evaluación de la Conformidad*). The system, managed by the Ministry of Economy, would work as a repository that gathers all the information related to standardisation and conformity assessment. It would include the list of products, services and systems that have been evaluated, the accreditation entities in the country, the inventory of NOMs and all relevant documents. At the time of preparation of this report, the reform proposal is still awaiting discussion in Congress.

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OECD (2018), *Standard setting and competition in Mexico 2018*, OECD, http://www.oecd.org/daf/competition/WEB-Standard-setting-Mexico-2018.pdf. [1]

OECD (2017), *OECD Trade Facilitation Index*, http://www.oecd.org/trade/topics/trade-facilitation/. [4]

Notes

[1] LFTR, articles 7, 15, 289 and 291.

[2] Public consultation on the “Proposed Draft Technical Provision IFT-011-2017, Part 2. Mobile Terminal Equipment operating in the 700 MHz, 800 MHz, 1900 MHz, 2100 MHz and / or 2500 MHz bands”. http://www.ift.org.mx/industria/consultas-publicas/consulta-publica-sobre-el-anteproyecto-de-disposicion-tecnica-ift-011-2017-parte-2-equipos.

[3] Article 17.

2 Conformity assessment in Mexico

This chapter provides an overview of the conformity assessment and accreditation frameworks applicable in the country and the actors involved in these activities. It also presents specific illustrations of conformity assessment techniques used by sectoral regulators in the health and agricultural markets.

In order to reap the full benefits of technical regulations and voluntary standards, and ensure that the specifications set out within them are met, countries require a well-functioning national quality infrastructure (NQI) framework. Quality infrastructure is the "the system comprising the organisations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes, relying on metrology, standardisation, accreditation, conformity assessment, and market surveillance".[1] A sound NQI relies on metrology, standardisation, accreditation, conformity assessment, and market surveillance.

Conformity assessment and accreditation are key building blocks of a country's quality infrastructure. Conformity assessment connects the requirements set in technical regulations with the products and services available to the public. ISO/IEC 17000:2004 defines conformity assessment as the demonstration that the specific requirements applicable to a product, process, system, person or body are met before they enter the market. Accreditation provides an additional layer of assurance by verifying and attesting that conformity assessment bodies (CABs) have the competences and impartiality to perform their functions.

A well-designed NQI system is key for the effective operation of domestic and international markets. Strong conformity assessment and accreditation frameworks allow countries to reap the benefits from technical regulations and voluntary standards, and have a range of positive spillovers. They enable governments to effectively implement policies to promote public health and safety, as well as environmental and consumer protection, *inter alia*. NQI also plays a key role in supporting global trade. By strengthening the quality and effectiveness of technical regulations and conformity assessment procedures, countries can strengthen the credibility of their quality infrastructure for foreign partners.

This chapter provides an overview of the conformity assessment techniques used in Mexico and the actors involved in conformity assessment and accreditation. It then discusses the implementation of conformity assessment procedures (CAPs) in specific sectors.

Conformity assessment in Mexico

The legal framework for conformity assessment in Mexico is set out in the Federal Law on Metrology and Standardisation (*Ley General sobre Metrología y Normalización*, LFMN) and its regulation. These instruments provide the process for development and implementation of CAPs and rules for the organisation of conformity assessment bodies. From the range of approaches to conformity assessment (Box 2.4), Mexico's favours a range of third-party techniques recognising four main types of activities: certification, verification, calibration, and testing. These techniques are supplemented by other assessment forms established in some sectoral regulations or NOMs. This is the case of NOM-005-SCFI-2017 on Supply and Measurement Systems for Petrol and Liquid Fuels that recognises prototype testing of fuel meters as a form of conformity assessment.[2]

In addition, certain sectoral regulations establish special CAPs that depart from the accreditation and approval framework set under the LFMN. This is for instance the case of the General Health Law that provides a separate conformity assessment regime for health-related NOMs.

In Mexico, first-party CAPs remain rather underutilised. While this approach to conformity assessment relies on the manufacturer or supplier taking on the responsibility for demonstrating compliance with the requirements set in a NOM rather than a third party, it does not necessarily mean absence of conformity assessment as they need to be accompanied by the relevant technical examinations and documentation. More recently, CAPs for some NOMs have introduced the use of forms of self-certification. For example, the conformity assessment process for NOM-199-SCFI-2017 on Alcoholic Beverages[3] combines two types of approaches: a Suppliers Declaration of Conformity (SDoC) to attest the conformity of fermented

alcoholic beverages and third-party certification for assessment of other types of alcoholic drinks considered to be of higher risk.

Once conformity of a product or service has been assessed in accordance with a NOM, the LFMN enables the attachment of an indication to it as a certificate or mark of conformity. However, the use of these types of statements in Mexico remains limited and little guidance is provided by regulators on how to indicate conformity with NOMs. The use of these marks can help consumers identify products that comply with technical regulations. They are common in countries with strong conformity evaluation cultures. This is for instance the case of the European Union "CE" marking that demonstrates that a product sold in the European Economic Area has been evaluated to meet the corresponding safety, health and environmental protection requirements (Box 2.1). In Chile, the electricity and fuels regulator has set in place a special labelling system for a wide range of electrical and fuel products that require certification (Box 2.2).

Box 2.1. CE Marking in the EU

In the EU, products for which EU specifications exist require a CE (*Conformité Européenne* or European Conformity) marking before they can be sold in the EEA. CE marking proves that a product has been positively assessed to meet EU safety, health and environmental protection requirements. The marking is valid for products manufactured both inside and outside the EEA, that are then marketed inside the area.

In cases when there is minimal risk to the public, importers, distributors and manufacturers may often self-certify their compliance with EU directives. Nevertheless, the process requires a technical dossier to support the claims of compliance with the necessary directive that proves the product meets all EU-wide requirements.

Source: EU (2019), EU Product Market Requirements - CE Marking, https://europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm (accessed October 2019).

Box 2.2. Certification labelling by the Electricity and Fuels Superintendence of Chile

Chile's electricity and fuels regulator, the Superintendence of Electricity and Fuels (*Superintendencia de Electricidad y Combustibles*, SEC) sets mandatory requirements to guarantee the safety and energy efficiency through testing and certification of a wide range of electrical products, including for instance domestic appliances, lighting, power tools, motors, and IT devices.

Since 2013, the SEC provides that products for which a certification requirement exists need to obtain an approval certificate and display a special label issued by the SEC (*Sello SEC*) that includes a QR Code, approval number and when applicable, energy efficiency information.

The SEC labelling system is intended to promote the purchase of products that comply with certain quality and safety standards, strengthen the market of certified products and facilitate consumer purchases. For certain types of products, the label is mandatory and any breach thereof is subject to sanctions.

Source: SEC, Exempt Resolution No. 2142/2012.

Conformity assessment bodies (CABs)

CABs are independent and impartial persons or entities responsible for performing conformity assessment activities. The organisation of CABs varies across countries; they can be public agencies, industry bodies or private organisations or companies. In many countries, a diversity of actors intervene in conformity assessment. While at times these bodies are organised as non-profit entities, they generally charge a fee for their services creating competitive markets. The services of CABs may be localised in a specific country or cover a sector or region. A number of international standards guide the operation of conformity assessment bodies involved in certification, testing and inspection.

In Mexico, CAPs can be carried out by the sectoral regulator responsible for a NOM or by CABs that act as third-party providers of assessment techniques. CABs are entities accredited by EMA and approved by the relevant sectoral regulator. These entities are subject to certain structural requirements to secure their impartiality and independence and the confidentiality of their operations. The LFMN also allows PROFECO and CENAM to perform specific conformity assessment activities as required under specific NOMs.

The activities of CABs are overseen by the DGN, as co-ordinator of technical regulations and standardisation system, and the EMA, responsible for surveilling compliance with the conditions under which CABs were accredited. The EMA is allowed sanction CABs with the total or partial suspension or cancellation of their accreditation. Finally, the CENAM oversees specific operations of CABs related to calibration.

The landscape of CABs in Mexico has increased in number and in the range of sectors covered. Yet, in certain regulated sectors, access to some conformity assessment activities prescribed under NOMs is hindered due to the inexistence or insufficiency of CABs or lack of technical capabilities to perform certain procedures. As of February 2019, only 34% of 786 NOMs in force requiring conformity assessment by an accredited body had an accredited CAB competent for evaluating their implementation.

In addition to their conformity assessment functions, CABs are occasionally invited to participate in certain sessions of CCNNs discussing the drafting of a proposed NOM or NMX.

Conformity assessment procedures in the LFMN

The LFMN defines conformity assessment procedures as the “Determination of degree of compliance with NOMs or conformity with NMXs, international standards or other specifications, dispositions or characteristics. It includes, among others, the procedures of sampling, testing, calibration, certification and verification.”

In Mexico, the relationship between NOMs and conformity assessment procedures is not linear. The LFMN recognises that not all NOMs require conformity assessment. When they do, the specific procedures required by a NOM may be designed as part of it or at a later stage after a NOM has been issued. In this case, CAPs are subject to a separate process including a 60-day public consultation period and publication in the Official Gazette. Furthermore, CAPs may cover a specific NOM or provide the assessment requirements applicable to a set of technical regulations.

As a result, a number of NOMs currently in force lack the relevant assessment techniques to evaluate that the prescribed requirements are fulfilled. Without this, these NOMs become *de facto* unenforceable. In practice, the absence of CAPs for a specific NOM has at times resulted in the postponement of their effects. While the DGN has taken steps to ensure that new NOMs are developed simultaneously with their corresponding CAP, looking forward Mexico could take steps to reduce the existing stock of technical regulations for which a CAP is needed but has not been developed.

When designing a technical regulation, regulators can select from a variety of approaches to conformity assessment, from self-declarations issued by the supplier (Box 2.4) to third-party evaluations such as auditing, calibration, evaluation, and testing, *inter alia*. Mexico favours a range of third-party conformity

assessment procedures. The LFMN regulates the main techniques, including calibration, laboratory testing, certification and verification activities.

While the LFMN provides for the process for developing CAPs, it does not provide a rationale or specify the minimum requirements that a CAP needs to observe other than noting that it should be designed according to the nature of the risk addressed through a NOM. Currently, in Mexico there is no common methodology for developing CAPs or selecting procedures. As a result, the development and use of CAPs vary greatly across sectors.

International examples on guidance for designing and issuing CAPs may serve as inspiration to advance towards a more coherent and consistent use of this tool. For instance, the EU framework lays down a system for selecting a CAP based on modules from which legislators can select, similarly in the United States the National Institute of Standards and Technology (NIST) provides Federal Agencies with considerations on conformity assessment options (Box 2.3). The ISO/CASCO toolbox includes guidance on the steps that may be followed for using conformity assessment in regulations including considerations on risk and availability of resources, among others. Finally, APEC's Information Notes on Good Regulatory Practice guide regulators to select conformity assessment approaches based on risk considerations while also balancing the regulatory burden that these procedures may represent (APEC, 2000[1]).

The LFMN defines certification as the "procedure through which it is ensured that a product, process, system or service adjusts to the rules, guidelines or recommendations or national or international standardisation bodies". In Mexico, certification activities include the following: an evaluation of the object of conformity through inspection, sampling, testing, field review or evaluation of quality programmes; and a follow-up review of compliance. Additional requirements for certification can be established by the relevant sectoral authority, the NOM or international standards. Certification bodies must have national coverage and need to be accredited by the EMA and approved by the relevant sectoral regulator. As of April 2019, there were 120 certification bodies accredited in Mexico.

The LFMN recognises conformity assessment through testing and calibration performed by laboratories accredited by EMA and authorised by sectoral regulators. As of April 2019, 1,609 laboratories had been accredited in Mexico. In addition to laboratories, CENAM and PROFECO are also allowed by law to perform specific calibration activities.

Verification activities are defined in the LFMN as "Eye inspection or verification via sampling, measurement, laboratory testing or examination of documents performed for conformity assessment at a given time". Verification units need to be accredited by the EMA and approved by the relevant sectoral regulator to undertake these activities. However, certain NOMs allow regulators to directly authorise verification units without the need for accreditation. The statement of conformity issued by a verification unit is an opinion (*dictamen*). As of April 2019, there were 631 verification units accredited in Mexico.

Box 2.3. International examples of guidance on conformity assessment approaches

The modular structure of conformity assessment in the EU New Legislative Framework

The EU's "New Legislative Framework" (NLF) adopted in 2008, consists of a set of legal documents that complete the overall EU product-related legislative framework, including conformity assessment, accreditation and market surveillance, and the control of products from outside the EU.

Conformity assessment is a key element of the NLF. It is defined as "[T]he process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled." Under this framework, a product can be subject to conformity assessment both during the design and production phase.

The framework consolidates conformity assessment procedures and the rules for their selection through modules/procedures laid down under Decision No. 768/2008/EC. Conformity assessment processes are composed of one or two modules, some modules cover both the design and production phases. In other cases, distinct modules are used for each phase.

The EU approach provides a rationale for selecting from the menu of conformity assessment modules/procedures the most appropriate ones for the concerned sector, avoiding options that are too onerous. The modules are designed to favour their selection from the lightest for simple products or products that present only limited risks, to the most comprehensive, for those which are more complex or hazardous. Annex B provides an overview of the modules.

Considerations for U.S. Federal Agencies to support the use of conformity assessment

In the United States, an Office of Management and Budget (OMB) guidance document sets the elements that Federal Agencies should consider when assessing the effectiveness of conformity assessment approaches and selecting conformity assessment options. These elements are listed in Circular A-119 (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities).

The National Institute of Standards and Technology (NIST) gives additional non-binding guidance to Federal Agencies in using conformity assessment in an efficient and cost-effective manner for both the agency and stakeholders. This publication includes elements to approach and manage conformity assessment schemes balancing the risk of non-conformity and the resources necessary to demonstrate conformity. There are four major elements to a government conformity assessment program: 1) objectives and goals; 2) conformity assessment scheme and oversight; 3) requirements for object of conformity; and 4) programme management. This guidance provides a framework for defining a conformity assessment scheme building on the elements set forth in OMB Circular A-119. These elements include:

- Defining the conformity assessment programme goal;
- Defining clear and unambiguous technical requirements and specifications or other requirements and standards for the object of conformity;
- Defining a clear and unambiguous method for determining conformity;
- Understanding the confidence point and the information derived from its analysis;
- Selecting conformity assessment activities based on the requirements and confidence point. These activities include testing, inspection, audit, attestation, and surveillance.
- Determining the role of the agency as the programme manager and programme oversight authority, and approval authority if needed;
- Determining whether first-, second- or third-party organisations perform the respective conformity assessment activities;
- Determining whether existing conformity assessment programs or activities, in both the private sector and public sector, can be leveraged to achieve conformity assessment goals, meet requirements and satisfy the confidence point;
- Determining the mechanism for indicating conformity or approval; and
- Developing the conformity assessment scheme and determining that when implemented, it helps to manage the risk of non-conformity, meets agency objectives, and contributes to the confidence of purchasers and users that requirements have been fulfilled.

Source: European Commission (2016), *The 'Blue Guide' on the implementation of EU products rules 2016* (2016/C 272/01), https://eur-lex.europa.eu/legal-content/en/txt/pdf/?uri=celex:52016xc0726(02)&from=bg, United States (2016), *OMB Circular A-119, Revised: Federal Participation in the Development and Use of* Voluntary *Consensus Standards and in Conformity Assessment Activities*, Washington, D.C.,

Executive Office of the President, Office of Management and Budget, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A119/revised_circular_a-119_as_of_1_22.pdf, and Carnahan, L. and A. Phelps (2018), *Conformity Assessment Considerations for Federal Agencies*, National Institute of Standards and Technology (NIST), Washington, http://dx.doi.org/doi.org/10.6028/NIST.SP.2000-02.

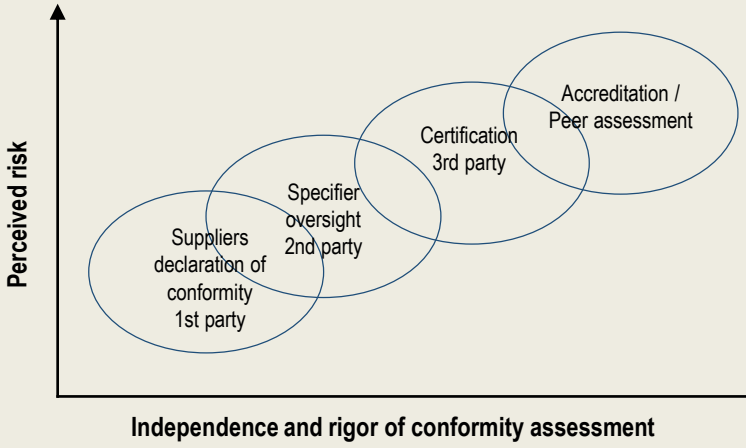
Box 2.4. The variety of approaches to conformity assessment

There are three main approaches to conformity assessment depending on who performs the evaluation:

- First-party assessment: when evaluations activities are performed by manufacturers or suppliers themselves using their own staff and equipment. This is typically the case of self-declarations such as Supplier's or Manufacturer's Declaration of Conformity.
- Second-party assessment: when the evaluation is carried out by the purchaser that will use the product or service; and
- Third-party assessment: when the evaluation of conformity is performed by a person or entity that is independent from the manufacturer or supplier of the object of conformity assessment and from its end users. This is the case of CAPs performed by certification bodies, testing laboratories, or inspection bodies. Certification is the result from a third-party assessment.

Technical regulations can target products, processes, services, management systems, persons or organisation: this is deemed the "object of conformity assessment". The selection of approaches for conformity assessment should be based on the level of risks involved in the object of conformity assessment (Figure 2.1). When a failure of the object of conformity assessment involves a low risks of negative effects, the most appropriate approach may be a self-declarations by the supplier or manufacturer. On the contrary, when there is a high risk of harmful effects following failure of the product or service subject to conformity assessment the preferred approach may involve action by a third party to independently evaluate that the specifications set in a technical standard are met. In these cases, accreditation can provide an additional guarantee for the quality of the products or services.

Figure 2.1. Conformity assessment approaches and levels of risk



Source: Guasch, J. et al. (2007), Quality Systems and Standards for a Competitive Edge, The International Bank for Reconstruction and Development/The World Bank, http://dx.doi.org/10.1596/978-0-8213-6894-7; and Using ISO/CASCO standards in regulation, ISO, https://www.iso.org/sites/cascoregulators/documents/casco-regulators-fulltext.pdf.

The Mexican accreditation system

Accreditation is the main approach used to verify the impartiality of CABs and their capabilities to perform their functions. It enables the attestation that a CAB has the competences to evaluate the conformity of a specific product or service according to a mandatory technical regulation or a voluntary standard. The key value of accreditation lies in the fact that it provides an authoritative third-party statement of the technical competences of CABs. The International Organization for Standardization (ISO) together with the International Electrotechnical Commission (IEC) have developed standards dealing with accreditation bodies and their activities (Box 2.5).

Accreditation is a key pillar of the Technical Regulations, Standardisation and Metrology System set up in the LFMN. Article 3 defines accreditation as the "Act through which an accreditation entity recognises the technical competence and reliability of certification bodies, testing laboratories, calibration laboratories and verification units for the purposes of conformity assessment." The LFMN and its regulation set forth a number of requirements for the governance and operations of accreditation entities. While the law formally allows any private entity authorised by the Ministry of Economy to provide a statement over the competences of conformity assessment bodies, to date the Mexican Accreditation Entity (*Entidad Mexicana de Acreditación*, EMA) is the only accreditation body authorised to operate in the country. As such, Mexico is part of a majority of countries where a single national body performs accreditation activities (Box 2.6).

Box 2.5. The requirements of ISO and the IEC for accreditation entities and the accreditation process

ISO has a number of standards related to conformity assessment and accreditation that are developed and published by its Committee on Conformity Assessment (CASCO) (OECD/ISO, 2016[2]). In the development of these standards, ISO works closely with a number of international organisations including the International Electrotechnical Commission (IEC), the International Accreditation Forum (IAF) and the International Laboratory Accreditation Co-operation (ILAC).

According to the ISO/IEC Standard 17000:2004 on Conformity Assessment – vocabulary and general principles, accreditation is a "third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out a specific conformity assessment task".

The ISO/IEC Standard 17011:2017 sets out a range of requirements for accreditation entities and the process of accreditation. These include:

- Governance requirements – including legal responsibility, structure of the accreditation entity, impartiality, confidentiality, liability and financing and accreditation activity.
- Management requirements – including requirements for the management system of the accreditation body, document control, records, nonconformities and corrective actions, preventive actions, internal audits, management reviews and complaints.
- Human resource requirements – dealing with the staff associated with the accreditation body, staff involved in the accreditation process, monitoring and personnel records.
- Accreditation process requirements – addressing accreditation criteria and information, application for accreditation, resource review, subcontracting the assessment, preparation for assessment, document and record review, on-site assessment, analysis of findings and assessment report, decision-making and granting accreditation, appeals, reassessment and surveillance, extending accreditation, suspending, withdrawing or reducing accreditation, records on CABs, and proficiency testing and other comparisons for laboratories.

- Requirements on the responsibilities of accreditation entity and conformity assessment bodies. Dealing with the obligations of CAB and accreditation bodies as well as the reference to accreditation and use of symbols.

The activities covered under this standard include testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification.

Source: Using ISO/CASCO standards in regulation, ISO, https://www.iso.org/sites/cascoregulators/documents/casco-regulators-fulltext.pdf.

Box 2.6. The organisation of accreditation across countries

The institutional set up and legal status of accreditation entities varies across countries, although a majority of them have a single national accreditation body (Table 2.1 and Table 2.2). This is the case of EU Member countries as they are required under EU Regulation (EC) 765/2008 to maintain a single national accreditation entity that provides authoritative statements of the competence bodies to perform conformity assessment activities (European Parliament and European Council, 2008[16]). In Latin America, all signatories of the ILAC/IAF MLAs have a single accreditation body organised as either a private or public entity (IAF, 2019[3]) (ILAC, 2019[4]).

In a few countries, a number of accreditation entities coexist performing accreditations in different sectors. This is the case for instance in Korea, where three separate accreditation entities are responsible for assessing the competences of laboratories and certification institutions: the Korea Accreditation Board (KAB), the Korea Accreditation System (KAS), and the National Institute of Environmental Research (NIER). In the United States, five private bodies operate simultaneously across sectors of the accreditation market.

In addition, some countries have established common accreditation systems that allow them to share accreditation institutions. This is for instance the case of the Joint Accreditation System of Australia and New Zealand (JAS-ANZ), an independent accreditation body established in 1991 through an agreement that creates a bilateral governing board responsible for overseeing accreditation activities. Following this example, in 2013 Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates, and Yemen created a similar system named the Gulf Accreditation Centre (GAC).

Table 2.1. Number of accreditation bodies per economy of ILAC Full Members (MRA Signatories)

Number of ILAC Full Member (MRA Signatory) accreditation bodies per economy	Number of economies
1	78
2	4 (Australia, India, Russia and United Arab Emirates)
3	3 (Canada, Japan and Thailand)
5	1 (United States)

Notes: ILAC is the international organisation for accreditation entities involved in the accreditation of laboratories and inspections. Figures relate to ILAC's current 101 Full Members (signatories to the ILAC MRA). The ILAC MRA currently covers five separate scopes of activity for accreditation bodies, namely: testing, calibration, medical testing, inspection, and proficiency testing providers.

Table 2.2. Number of national accreditation bodies in IAF member's economies

Number of accreditation entities	IAF member's economies
1	85
2	3 (India, Russia and United Arab Emirates)
3	2 (Japan and Korea)
5	1 (United States)

Notes: IAF is the international organisation for accreditation entities involved in the accreditation of management systems, products, services, personnel and other similar programmes of conformity assessment.
Source: IAF and ILAC.

The organisation of accreditation in Mexico

The current Mexican set up for accreditation was established in 1992 with the LFMN. It allows private non-profit organisations especially created for these effects to operate as accreditation entities. Before a 1997 reform, the DGN was responsible for accreditation in Mexico.

Accreditation bodies are authorised by the Ministry of Economy with the previous approval of a majority of relevant Ministries. To obtain this authorisation, interested third parties must certify their legal, technical, administrative and financial suitability to act as accreditation entities. The request for authorisation to the Ministry of Economy also needs to indicate the maximum fees that the accreditation body will charge for their operations. The Ministry of Economy may revoke or suspend an authorisation of an accreditation entity if the requirements set in the LFMN are breached (LFMN, article 103 and 104). In these cases, the Ministry is allowed to take over the accreditation activities for a specific sector or market.

The LFMN and RLFMN include a set of provisions dealing with the governance structure of accreditation bodies. They must be established as single purpose entities and secure a balanced representation of different stakeholders[4] in their governing bodies, including business and academic representatives. Individuals who participate in an accreditation body are banned from joining other similar entities. There are no express rules promoting the independent operation of accreditation bodies from commercial conformity assessment activities, such as separating the ownership of accreditation bodies from CABs or other participants in the standardisation system for example. However, the Ministry of Economy can establish specific obligations on the fees and service conditions of accreditation entities or conformity assessment bodies with relevant market power (LFMN, article 70-C).[5]

Mexican accreditation entities must meet the requirements set in the LFMN and RLFMN to safeguard the integrity, impartiality and confidentiality of their functions. These include, inter alia, allowing public officials to oversee their activities, maintaining an updated public record of accredited entities, and addressing complains submitted by stakeholders. Accreditation entities are also required to periodically review that CABs continue to meet the conditions under which they were accredited. Finally, accreditation entities are encouraged to participate in regional or international accreditation organisms to agree on common guidelines and mutual recognition of accreditations.

The Mexican Accreditation Entity

The EMA is a private non-profit organisation established in 1999, authorised by the Ministry of Economy and approved by the CNN to grant formal recognition to CABs in Mexico through accreditation. To date, the EMA remains the only accreditation entity for conformity assessment bodies in Mexico, which comprise testing laboratories, calibration laboratories, medical laboratories, inspection bodies and certification bodies, proficiency testing providers, greenhouse gas emissions verification/validation bodies, and reference materials producers.

The Ministry of Economy, through DGN, leads the relationship between the Mexican administration and the EMA. While the LFMN and other instruments lay down the obligations of the EMA towards the Ministry of Economy, anecdotal evidence from interviews shows opportunities to enhance the strategic relationship between the two entities to strengthen Mexico's quality infrastructure around accredited bodies. The model of the United Kingdom Accreditation Service (UKAS) engagement with the UK Government based on a Memorandum of Understanding (MoU) may provide a useful reference in this regard (Box 2.7).

The governance structure of the EMA includes a number of bodies formed by public and private sector representatives. The General Associates Assembly (*Asamblea General de Asociados*) is the uppermost body of the EMA and gathers 165 associates (including some accredited conformity assessment bodies). The Board of Directors (*Consejo Directivo*) is responsible for management and is formed by 36 members that represent the federal government holding 9 votes; business sectors holding 9 votes; participants of the accreditation market (including conformity assessment bodies) holding 9 votes; and representatives from academia holding 9 votes. Business sector representatives are appointed by the chambers of industry and commerce, while conformity assessment bodies are appointed by laboratories, inspection bodies, calibration laboratories, and certification entities.

EMA bases its accreditation requirements on international standards and is recognised by the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC), the main international organisations of accreditation bodies. EMA is also a member of the regional pillars of the international accreditation system and its accreditation services have received recognition from a number of bodies: the Inter-american Accreditation Cooperation (*Cooperación Interamericana de Acreditación,* IAAC); and the Asia Pacific Accreditation Cooperation (APAC). Additionally, it participates in specific fora, including those related to the OECD Good Laboratory Practices and the Mutual Acceptance of Data as well as the Joint ILAC/World Anti-doping Agency (WADA).

EMA operates at the national level and is involved in a range of activities related to the Mexican Technical Regulation and Standardisation System. However, its core responsibility is accrediting conformity assessment bodies against technical regulations and voluntary standards (Table 2.3). Accreditations are voluntary and led by evaluation committees that are formed and operate according to General Guidelines issued by the Ministry of Economy.[6] These evaluation committees are formed by up to 6 technical experts, a representative of producers, a representative of consumers, a technician from EMA, a public sector official and up to two representatives from academia or research centres. The work of these evaluations committees follows the procedures established by the EMA and the monthly and annual programmes of work of the entity.

Once a CAB issues an accreditation request, the evaluation committee sets up a special team to assess the accreditation according to procedures established per sector. To date, the EMA has 10 evaluation committees that assess 29 accreditation procedures. On average, the accreditation process takes 4 months.

Table 2.3. Activities performed by the EMA

Participation in the development of technical regulations and standards	Occasionally
Accreditation against technical regulations (NOMs)	Yes
Accreditation against voluntary standards (NMXs)	Yes
Metrology functions	No
Conformity Assessment Procedures	No
Regulatory Inspection and/or market surveillance	Yes

Source: Author's own elaboration.

In addition, EMA is occasionally invited to participate in certain sessions of CCNNs discussing the drafting of a proposed NOM or NMX. EMA is also responsible for surveilling CABs compliance with the requirements under which their accreditation was issued and maintains a list of CABs with suspended or cancelled accreditations.

Box 2.7. The Memorandum of Understanding between UKAS and BEIS

The United Kingdom Accreditation Service (UKAS) was established in 1995 and is the single national body responsible for the accreditation of conformity assessment bodies in the United Kingdom.

In March 2019, the Secretary of State for Business, Energy and Industrial Strategy (BEIS) and UKAS entered into a Memorandum of Understanding (MoU) that provides the way in which both entities work together to maintain and promote a strong national accreditation service and clarifies the roles and responsibilities of each institution.

The MoU is an operational and voluntary document that establishes the details of the scope of activities, governance and accountability of UKAS and the forms of support across institutions. An Appendix sets out the basis for this BEIS monitoring of UKAS through delivery of documentation on a periodic basis and upon request, regular meetings, participation of BEIS as a member in certain UKAS activities and sharing of independent reviews.

Source: (BEIS/UKAS, 2019[5]).

CAPs in Mexico: Experience from specific sectors

In Mexico, certain laws governing specific sectors establish special conformity assessment procedures that diverge from the regime set under the LFMN. This section presents specific conformity assessment techniques, taking place in the health and agricultural sector.

COFEPRIS

The Federal Commission for the Protection of Sanitary Risks (*Comisión Federal para la Protección Contra Riesgos Sanitarios,* COFEPRIS) is Mexico's health authority. COFEPRIS is a decentralised and autonomous body that oversees the enforcement of four regulations on medical devices, health control of products and services, environmental health and pesticides. In total, COFEPRIS has 81 NOMs under its authority.

The LFMN recognises that the procedures for verification and testing of products, activities and services regulated in the General Health Law (*Ley General de Salud,* LGS) part from the default regulatory delivery regime and are specially governed by this sectoral law.[7] This regime differs from the framework set under the LFMN on a number of fronts. Certain health-related NOMs, for example, do not embed a specific CAP since their assessment is carried out by sanitary inspection and testing activities set forth in the LGS. In addition, the organisation of CABs in this sector is led by COFEPRIS and does not rely on Mexico's accreditation infrastructure. Finally, the LGS also provides for specific pre-market and post-market regulatory delivery mechanisms as well as sanctions for non-compliance. In fact, NOMs are only used in health for medical labelling (NOM137 – Labelling of medical devices) and the post-market surveillance (NOM240 – Installation and Operation of Technosurveillance).

As part of its activities, COFEPRIS supervises health facilities, control of advertising activities, and monitors the manufacturing, import and export of health products. Although it does not follow the CAP process under the LFMN, COFEPRIS requires that most medical devices, pharmaceuticals and other

health products are registered before they are placed on the market, after they have been demonstrated to be safe through a combination of testing, inspection and certification.

Authorised Third Parties

In Mexico's health sector, conformity assessment activities are carried out directly by COFEPRIS or by specially authorised third parties (*Terceros Autorizados*, ATPs). Authorised third parties support health control and inspection activities through testing, verification or by performing bioequivalence and/or bio comparability studies. The authorisation can fall on four types of bodies: testing laboratories; verification units; biocomparability and interchangeability testing units. As of June 2019, there were 212 third parties authorised by COFEPRIS (115 testing laboratories, 28 verifications units, and 69 biocomparability and interchangeability testing units) (COFEPRIS, 2019[6]). The statement of conformity issued by an ATP is an opinion (*dictamen*).

ATPs must meet the requirements set in the LGS and Regulation of Health Supplies (*Reglamento para Insumos de la Salud*) to secure their technical competences and the integrity, impartiality and confidentiality of their activities. Authorisations are voluntary and once a request is submitted a technical evaluation committee assesses the application. These evaluations are carried out according to guidelines issued by COFEPRIS for each type of authorised body. COFEPRIS periodically publishes calls for expressions of interest to be authorised to act as an ATP for a specific regulation or NOMs.

COFEPRIS is responsible for overseeing the activities of ATPs, including through inspections aiming to ensure that they continue to meet the conditions under which they were authorised. The authorisation may be revoked or suspended if an ATP fails to meet the requirements set in the LGS or regulations. COFEPRIS publishes a record of authorised ATPs as well as revoked or cancelled authorisations.

Registration of Medical Devices

Distributors or manufacturers are required to prove the device's safety and efficacy before sale. There are two paths to this registration of compliance with Mexican requirements for medical devices. Through the standard path, the distributor shows approval of the device in the manufacturer's home market and proof of a certified quality management system (e.g. ISO 13485 certificate). A second path involves the use of a Third Party Reviewer. TPRs are public or private entities authorised by COFEPRIS to provide a technical report on the medical device's efficacy, based on the dossier sent by the manufacturer or Mexican distributor for the medical device. Once reviewed by a TPR, the information is submitted to COFEPRIS for a final registration certificate. If necessary, COFEPRIS may request additional information. However, the use of a TFR normally speeds up the registration certificate process.

In addition, COFEPRIS recognises the certificates of a number of other jurisdictions, often unilaterally. Medical devices approved by the US FDA and Health Canada can apply for registration without an extensive technical review. Additionally, the USMCA further strengthens the mutual recognition of pre-market health product approval processes. The Pharmaceutical Annex of the USMCA states that:

> *Each Party shall ensure that for a measure it applies to ensure the safety, effectiveness, or quality of pharmaceutical products, including marketing authorizations, notification procedures, and elements of either, products imported from the territory of another Party be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country, in a comparable situation. (Article 12.F.5 of the Annex to the USMCA)*

The Annex further states that the three countries will share information on pharmaceuticals upon certification by a competent authority.

SENASICA Federal Inspections Type (TIF) Certification

The National Service of Health, Food Safety and Agri-food Quality (*Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria,* SENASICA) is a deconcentrated body of the Ministry of Agriculture and Rural Development (*Secretaría de Agricultura y Desarrollo Rural*, SADER). SENASICA is responsible for the prevention of epidemics and diseases that affect agriculture, aquaculture and animal husbandry. In addition, it regulates and promotes the application of mechanisms to reduce the risk of food contamination.

In 2014, SENASICA published the requirements and specifications for the authorisation of third parties that carry out conformity assessment procedures in the sector. These third parties (*órganos coadyuvantes*) are private entities or individuals authorised to verify, certify, diagnose and confirm that regulated subjects comply with their regulatory requirements—particularly NOMs. Although third parties perform most of the conformity assessment procedures, if deemed necessary SENASICA can inspect and audit its regulated subjects directly.

For NOMs and regulations related to meat products and by-products, SENASICA created the Federal Inspections Type Certification (*Tipo Inspección Federal*, TIF). A TIF certified establishment is a slaughter facility for animals, refrigerators and industries of beef, poultry, eggs, dairy, honey, sausages and cold meats that is subject to permanent sanitary inspections to verify that the place and the processes comply with the regulations indicated by the SADER.

Establishments that wish to receive the TIF certification are required to have an authorised veterinarian—who is in charge of carrying out the conformity assessment procedures—on the premises. Furthermore, in export-oriented establishments the authority appoints an additional independent veterinarian. SENASICA determines the requirements and criteria that the veterinarians must follow for assessing regulatory compliance in the slaughter facilities. It also provides online guides and manuals—including instructions for animal welfare, inspections, and maintaining sanitary conditions—to meet the stringent criteria. According to information from SENASICA, by August 2019 there were two accreditation bodies of TIF establishments in Mexico and 471 certified premises, which produce more than 60% of the beef available in the market.

Anecdotal evidence shows that compliance with NOMs is generally better in industries that are strongly export-oriented. As TIF establishments are the only ones eligible to export, this certification has helped reduce the risk of diseases, improved national supply of meat and its by-products, and benefited the national economy. Moreover, as discussed in greater detail in Chapter 3, SENASICA appears to have developed a more robust risk-based approach to enforcement that helps to maintain the integrity of this sector.

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[2] NOM-005-SCFI-2017 on Supply and Measurement Systems and Instruments for Petrol and Liquid Fuels – Specifications, and testing and verification methods (*NOM-005-SCFI-2017 Instrumentos de medición-Sistema para medición y despacho de gasolina y otros combustibles líquidos-Especificaciones, métodos de prueba y de verificación"*).

[3] Conformity Assessment Procedure for *NOM-199-SCFI-2017* on Alcoholic Beverages – Denomination, Physico-chemical Specifications, Comercial Information and Testing Methods (*Proyecto de Procedimiento para la Evaluación de la Conformidad de la Norma Oficial Mexicana NOM-199-SCFI-2017, Bebidas Alcohólicas- Denominación, Especificaciones Fisicoquímicas, Información Comercial y Métodos de Prueba*) published in the Official Gazette on 4 September 2019.

[4] The LFMN defines interested parties as all accredited entities, users of accreditation services, professional associations or academics, industrial and trade chambers, higher education institutions, research centres and public entities involved in the activities subject to accreditation.

[5] In November 2017, COFECE launched an investigation over possible barriers to entry and competition in the normalisation, accreditation and evaluation sectors.

[6] Ministry of Economy Guidelines on the composition, organisation and co-ordination of Evaluation Committees (*Lineamientos para la integración, organización y coordinación de los Comités de Evaluación, dictados por la Secretaría de Comercio y Fomento Industrial*).

[7] LFMN, Article 108.

3 Regulatory inspections and market surveillance

This chapter provides an overview of the different regulatory inspections used to supervise, promote and enforce compliance with NOMs. These include market surveillance activities (control of consumer products on the market), as well as a range of other inspection types and fields such as medicines safety, food safety, occupational safety and health, inter alia. The chapter gives an overview of the resources and approaches that regulatory authorities use to plan and conduct inspections and enforcement activities.

Introduction

Regulatory inspections are the key instrument for the government to control compliance with regulations and enforce them. Market surveillance involves checking products or services directly, either at the retail stage or, in some cases, at import or wholesale stage. Other types of inspections look at compliance during the production stage – to ensure safety for workers, neighbours, the environment, and to achieve effective food safety throughout the food chain. At times, regulatory authorities can also verify the work of CABs – usually this would happen if a certified product has been found to be non-compliant by market surveillance inspectors.

In Mexico, as a general rule the government authority in charge of a NOM is also responsible for its supervision, including developing an inspections programme. Both the Federal Law on Metrology and Standardisation (*Ley Federal sobre Metrología y Normalización,* LFMN) and the Federal Law of Administrative Procedure (*Ley Federal de Procedimiento Administrativo*, LFPA), which define the requirements for inspection visits, regulate the inspections of compliance with NOMs. However, the level and types of sanctions are often set in sectoral laws.[1]

Mexico has had some successes in building trust, particularly in export markets for agricultural products, automotive products and others. Yet, in the domestic market trust in government institutions and in product compliance remains a challenge. In interviews conducted as part of this review, PROFECO reported to have found that roughly 20% of products sold in Mexico were not compliant with technical regulations, while industry representatives reported that it could be as high as 50% in certain product areas.

This chapter provides an overview of regulatory inspection practices (including market surveillance) for some regulatory fields in Mexico, looking at a few key sectors and at some of the main challenges.

Overview of regulatory inspections in Mexico

The LFPA and the LFMN are the two central laws that govern the post-market inspection and enforcement of technical, safety and consumer market regulations in Mexico.

To supervise the correct implementation of conformity assessment, the LFMN allows sectoral regulators or authorised parties to perform inspection visits ("*visitas de verificación*") targeting:

- Accreditation entities to verify their compliance with the LFMN, the RLFMN and NOMs (Art. 71); and
- Conformity assessment bodies to verify their compliance with NOMs (Art. 91) and specifically that CABs are implementing their functions with due diligence and without fraud.

The LFMN likewise empowers (under Art. 94) sectoral regulators to perform:

- Legal metrology inspections (verification of measuring instruments);
- Market surveillance activities (control of conformity of consumer products and services on the market) – including verifying the composition and content of products through sampling and laboratory testing; and
- Facilities – which may cover a very broad range of safety and technical controls.

The LFMN also establishes that when two sectoral regulators have powers to inspect a single NOM, as a result of shared responsibility, then they must co-ordinate with each other. Still, the law does not specify *how* they must co-ordinate and it is somewhat unclear whether this co-ordination actually takes place and how frequently.

In practice, discussions with competent authorities and stakeholders showed that the use of different terms ("inspection", "verification", "supervision", "monitoring", among others) is not necessarily consistent domestically or with the terminology used for instance by APEC for conformity assessment procedures (APEC, 2000[1]) or by the European Union for market surveillance inspections (PROSAFE, 2008[2]). This may create confusion as to the exact definition and application of each term, and as to the activities that correspond to a regulatory function (using this review's terminology: "regulatory inspections") or to a delegated function that can be exercised by accredited and authorised third-parties ("conformity assessment", which can include a variety of methods including on-site visits).

The LFMN also refers to how inspectors should collect and manage samples and the actions they may take in case of inaccurate labelling.

The LFPA sets specific requirements that must be observed by inspectors. It grants administrative authorities the powers to check compliance with laws and regulations. They may carry out verification visits in which the verified party is provided with a written order issued by the competent authority that specifies the place or area to be checked, the purpose of the visit, and the scope and the laws upon which it draws, among others. At the beginning of each visit, inspectors must present an ID badge with photo, issued by the competent authority, confirming authorisation to perform this function as well as the express order. Other articles in the LFPA also refer to the specific procedures to be followed during the visit.

Article 70 of the LFPA sets out the administrative sanctions that may apply, which range from a warning, through fines and arrest for 36 hours, to temporary or permanent closure. In cases of repeated non-compliance, fines may be doubled. The LFPA also provides the administrative procedures for appeal of a sanction. Giving advice or other support for compliance is not specifically foreseen by the law.

Still, each sectoral regulator has its own strategy or framework for implementing inspections and enforcement activities, beyond the legal frameworks provided by the LFMN and LFPA. The use of fines and warnings varies substantially between different government authorities. In addition, most government authorities provide some form of guidance or checklists for implementing applicable regulations. A number of sectoral regulators frequently use warnings to encourage compliance with regulations among non-compliant firms.

Regulatory inspections in practice: examples from specific regulatory domains and economic sectors

It would be impossible to describe inspection practices for every ministry or agency in Mexico that is responsible for some of the 702 NOMs currently in force. Even grouping NOMs by economic sectors covered or regulatory domain (food safety, environment, technical safety, inter alia), international experience suggests there can be dozens of different bodies, if not more. Rather, this section highlights some practices from key sectors and domains that were assessed through interviews with stakeholders and desk-research. Specifically, it highlights the case of PROFECO, which has a special role in the application of Mexico's technical and market regulations and in its overall NQI, as well as two special regime programmes under the Energy Regulatory Commission (*Comisión Reguladora de Energía*, CRE) and the Federal Commission for the Protection of Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*, COFEPRIS), and an example from the Ministry of Labour and Social Protection (*Secretaría de Trabajo y Protección Social,* STPS).

For certain regulators, rather than the LFMN, their own sectoral law gives them inspections and market surveillance powers. Although the agencies are themselves regulated under laws separate from the LFMN, when they enforce NOMs or their own technical, safety etc. regulations, they must follow the administrative rules for inspections and enforcement found in the LFPA. This is for instance the case for COFEPRIS, the

federal agency that deals with the importation of medical devices and advertising permits for medical products, described below.

Furthermore, some administrative authorities are empowered under sectoral laws to issue instruments similar to technical regulations but not subject to the LFMN. This is for instance the case of the Federal Law on Plant Health that allows SAGARPA to regulate phyto-sanitary issues through a number of instruments similar to technical regulations, effectively a system distinct from that of the LFMN.

Regulatory enforcement and inspections by PROFECO

PROFECO has a special role in Mexico as the main inspectorate responsible for consumer protection. Its mandate covers a broad range of areas, including product safety, labelling, consumer contracts, and in some cases work safety equipment and energy efficiency. In total, PROFECO has responsibility for 163 NOMs pertaining to five ministries: Ministry of Economy (109 NOMs), Ministry of Tourism[2] (7 NOMs), Secretary of Energy (26 NOMs), Ministry of Labour and Social Security (8 NOMs) and Ministry of Health (16 NOMs).

The Federal Consumer Protection Law (*Ley Federal de Protección del Consumidor*, LFPC) gives PROFECO the authority to supervise and verify compliance with the provisions set forth in the law and, within the scope of its jurisdiction, the observance of the LFMN, as well as the Mexican Official Standards (NOMs) and other applicable provisions and, if applicable, to establish the criteria to verify their observance.

In addition to these functions, PROFECO conducts some information activities to promote the awareness and exercise of consumer rights. In interviews, Mexican businesses suggested that PROFECO inspections tended to focus more on prices and “quality” (a concept that is often difficult to describe, and that – in good practice – is mostly not covered in technical regulations, except insofar as it relates to truthful consumer information) rather than on product safety.

PROFECO has approximately 350 inspectors for the 163 NOMs under its jurisdiction. In practice, the agency mostly focuses proactive inspections on only three NOMs (covering gasoline, scales and weights), and on labelling. For other NOMs, inspections are conducted only or mostly based on complaints. This means that PROFECO is, in practice, mostly conducting legal metrology and consumer protection / consumer information inspections. Moreover, in these areas (gasoline, scales/weights), third parties may be accredited by EMA to perform conformity assessment, but PROFECO also performs fee-based conformity assessment services. This may create a conflict of interest within PROFECO which acts both as conformity assessment provider *and* as regulatory power conducting market surveillance. It is also likely to bias competition in favour of PROFECO against third party CAPs. Fraud in conformity assessment (which was reported by PROFECO to be a problem) would be better addressed by a robust programme of second-tier supervision (regulatory inspections), not by PROFECO providing competing paid-for services.

Fines for breaking NOMs under the purview of PROFECO may reach up to MXN 5.4 million (about EUR 250 000) in cases when one fact or omission has resulted in several infringements of the LFPC.

PROFECO faces a challenging compliance environment in consumer markets. Mexico has a large shadow economy. A number of interlocutors during interviews with the OECD also mentioned that price is the key concern of most consumers in Mexico. Income per capita in Mexico is among the lowest in the OECD. Turkey has a similar issue, but benefits from its close trading relationship with the EU (Box 3.1). Industry groups reported that Mexican consumers are extremely cost-conscious, so they may be less likely to be ready to pay a premium for products that meet high technical standards, and more willing to take the chance to buy cheaper non-conforming products. PROFECO and the Ministry of Economy have nevertheless attempted to inform Mexican consumers about technical standards. For instance, PROFECO produces the General Coordination of Education and Dissemination programme, which promotes the awareness and exercise of consumer rights and better purchasing decisions.

Box 3.1. Market Surveillance challenges in lower-income markets in Turkey

Turkey is another OECD member where limited household income, particularly in some parts of the country, mean many consumers will buy lower-cost products regardless of safety or reliability considerations. The domestic market in Turkey is also regionally very different – modern and sophisticated in Istanbul and south-western coastal regions, far poorer in the eastern part of the country. Challenges have been compounded by devaluation and the refugee influx.

Since the 1995 Customs Union between Turkey and the EU, Turkey has gradually transformed its technical regulations system to approximate the EU model and legislation. This means the country has moved away from a system previously based on very widespread mandatory certification *ex ante* and strict import controls to a regime relying more on producer/importer declaration, third-party conformity assessment etc., and more open to international trade. This means that the importance of market surveillance is also far higher.

Creating additional challenges, not unlike in Mexico, different institutions are in charge of checking compliance of products at import stage (the Ministry of Economy in Turkey) and in-country – and, on the internal market, several institutions are in charge of different types of goods (10 ministries in Turkey), while co-ordination and information sharing are still insufficiently developed.

The Ministry of Science, Industry and Technology, which is in charge of market surveillance for electrical and gas appliances, has been facing an uphill struggle in improving compliance levels on the market. In fact, the gradual reinforcement of its activities has led to higher levels of detected non-compliance, because there are more inspectors and checks. As indicated in discussions with its management and specialists, low-income consumers (particularly in eastern Turkey) are simply unable to pay more for the goods they need – so, if the Ministry becomes more effective at removing non-compliant goods from the market, new informal operators simply take the place of previous ones and import new non-compliant (but cheap) goods. By contrast, Istanbul shoppers primarily buy from formal stores, and are far more likely to prefer reliable, reputable brands and products, because they have enough disposable income to afford them.

This situation shows the importance of gradually developing differentiated, segmented regulatory delivery approaches. Whereas “classical” market surveillance, with risk-based inspections and a combination of information and enforcement, is appropriate for the higher-income regions, and can lead gradually to improved compliance and safety levels, it is less applicable to poorer areas. There, by contrast, imposing sanctions and confiscation of non-compliant goods does not drive them sustainably out of the market (they are quickly replaced by new shipments, because demand persists), but may further impoverish local consumers by increasing costs for traders, and thus prices. In this case, reinforcing education and information campaigns, and supporting industry to set-up a voluntary compliance scheme to allow customers to more easily recognise reliable traders and goods, may help gradually develop the market.

Source: Turkey 2017 Annual Market Surveillance Programme, http://ec.europa.eu/DocsRoom/documents/21490/attachments/1/translations/en/renditions/pdf; Technical Barriers to Trade: The case of Turkey and the European Union by Sübidey Togan, www.jstor.org/stable/43264532; notes from meetings with Market Surveillance officials in Turkey.

PROFECO reports having an annual programme focused on complaints and key holidays when many consumers and businesses are buying and selling many goods. For example, PROFECO has tested the quality of fabrics during holidays. This practice may create costs for businesses as they face higher pressures during busier times of the year. Managing inspection processes is more difficult and costly for

businesses during such times, particularly if inspections are frequent and repeated. In many countries, this has been found to generate opportunities for corruption, as hard-pressed businesses try and get the inspectors away as fast as possible.

In addition, such an approach is not risk-based. It targets a type of product (fabrics) that creates generally little hazard, and on which there typically are very few substantive requirements. It is likely that such a focus is linked to the ease in finding minor (formal) non-compliances, rather than on a data-driven approach (as it is unlikely that major harm for consumers is recorded). In addition to the heavy burden on businesses and probable higher costs for consumers, this approach is prone to result in an inefficient allocation of resources. A similar problem of excessive controls following minor consumer complaints, for goods on which no substantive technical regulations exist, was found by the OECD in Lithuania, and likewise produced increased burdens and decreased efficiency.

It means the inspectorate wastes around half of its already scarce resources on conflicts of a purely private nature, where there is no safety issue involved and no reason for the state to act. The lack of good statistics on product safety and injuries or deaths caused by unsafe products in Lithuania means that the negative impact of this misallocation of resources is difficult to estimate, but the serious situation with fire safety (see above) suggests that it may in fact be significant (OECD, 2015[3]).

In total, PROFECO tested 10.1 million products in 2018 and found that around 20% or nearly 2 million did not comply with Mexican NOMs (PROFECO, 2018[4]). PROFECO also manages more than 100 000 complaints a year and reports that over 80% are resolved in favour of the consumer. This does not mean that these complaints were actually grounded, or that they corresponded to significant issues from a risk-based perspective (see Box 3.2 on Ukraine's experience). Rather, complaints have been consistently found to be a poor basis for planning inspections. While they may be cost-efficient (obviating the need to collect and analyse data to plan interventions), they inherently mean that the inspection comes "too late". In addition, a complained-based inspection system may often be misled by consumer bias, as propensity to complain may be driven by many factors unrelated to the gravity of the issue, or by ill-intentioned complaints made by competitors of a given business (Blanc, 2018, pp. 84-86[5]).

Box 3.2. Formal vs. substantial non-conformities in Ukraine

High levels of identified cases of non-compliance does not always mean that substantial regulations, particularly relating to safety, are violated. It may simply mean that there are some "paperwork" issues, particularly in countries with a procedurally complex system. In its 2008 report on Technical Regulations in Ukraine, the World Bank Group noted the following:

- According to data obtained in the course of inspections conducted by the State Standardisation Committee in the first half of 2007, between 44% and 72% of goods were found to be non-compliant with the appropriate regulations. Yet only between 4% and 14% (depending on the type of goods) the cases of industrial goods were due to nonconformity with standards. All other violations were of formal norms. Inspections of food products did not reveal any nonconformity at all, the only exception being fat and oil products. The lion's share of all documented cases of non-compliance were due to a lack of appropriate documentation (29-62%) and/or product information (20-62%).

Source: *Derzhstandart* press releases of 13 March 2007; 1 June 2007; 4 May 2007; and Technical Regulations in Ukraine 2008, World Bank Group.

Effectively, PROFECO's market surveillance and inspections are either complaint-based or random. While random inspections suffer from less bias than complaint-based ones, they are inefficient, spreading resources and burdens equally without regard to the probability of violations or the potential harm. As such, they also offer no incentive for improvement, since businesses face the same chance of inspection regardless of their efforts to improve their practices. Box 3.3 presents an explanation of good risk-based inspection practices.

In the United Kingdom, market surveillance activities target products that create the highest risks for consumers. The Office for Product Safety and Standards (OPSS) was specifically created in January 2018 (through the merger of several previous structures covering metrology, regulatory delivery improvement, and some areas of market surveillance) to improve the system countrywide, through increased consistency between local authorities, better methods for risk management, increased consolidation of information, nationwide action on hazardous goods etc.

Box 3.3. Risk-based inspections – key concepts and approaches

Risk should be understood here as the combination of the likelihood of an adverse event (hazard, harm) occurring, and of the potential magnitude of the damage caused (itself combining number of people affected, and severity of the damage for each).

It is important that risk is not wrongly understood as only the probability of some violation or problem taking place – indeed, in some types of establishment, certain violations may be frequent (highly likely), but have very little (if any) adverse effects. On the other hand, risk is also not identical to the level of hazard, that is, the potential severity of the consequences only: if an event is very unlikely, even if potential consequences are dire, the overall risk level may not be considered extremely high.

An adequate understanding of risk is to define it, in line with best practice and research findings, as the product of "magnitude" (which itself is the combination of the severity of the effect and of the numbers potentially affected) and "likelihood":

Risk level = Magnitude x Probability.

The term "risk assessment" in the regulatory sense means the assessment of:

- Strategic risk: i.e. consideration of the purpose of the regulatory organisation, the key regulatory risks that the primary legislation and regulatory authority is designed to control, and definition of objectives to address those risks;
- Operational risk: i.e. the design of risk-based interventions taking into account the concerns and priorities of citizens, the business environment – its mode of operation and incentives, and wider market conditions;
- Risk assessment of individual businesses; and
- Sanctioning according to risk: i.e. the use of risk-based sanctioning decisions as part of a proportionate response to non-compliance.

The term "risk-based targeting" refers to:

- The selection of the most appropriate intervention to drive better regulatory outcomes, which may be education, provision of information, inspections, among others.
- The allocation of resources to various interventions;
- The criteria against which businesses are targeted for those interventions.

Risk assessment in the context of this document refers to the various schemes used to assess the level of risk associated with a particular business, activity, premises or product, which feed into (and in some cases determine) the nature of the subsequent regulatory response and its priority.

Risk assessments (or risk "ratings") of businesses should ideally be based not only on what is found at the time of an inspection or other intervention, but should also take account of other relevant, available intelligence to inform the judgement about regulatory responses. Risk assessment is therefore key to better regulation and plays a crucial part in all of its principles: accountability, transparency, proportionality, targeting and consistency.

Source: World Bank Group (2013), Introducing a risk-based approach to regulate businesses; and UK Better Regulation Delivery Office, (2012), Proposals for Developing a Common Approach to Risk Assessment.

PROFECO's remit covers a large number of sectors and areas of consumer protection, particularly because it includes not only consumer product safety but also metrology and general consumer protection provisions. PROFECO is also responsible for a number of NOMs related to tourism, for example the NOMs related to dive instructors and tour operators and the hygiene of resorts. As a next step in assessing the system for technical, safety and market regulations in Mexico, a benchmarking of PROFECO's functions against international good practices could be undertaken – which would also involve benchmarking the reach of technical regulations in Mexico in terms of sectors and products to determine which ones do (or do not) fit with a risk-based approach.

Finally, PROFECO has been affected at different points in time by inspector corruption cases as well as political interference in inspection activities. Several times, PROFECO has fired many inspectors at once. To try to address this, in 2015, PROFECO introduced a Code of Conduct to avoid conflicts of interest, but it is unclear at this stage how effective this has been.

International experience suggests that the lack of a risk-based approach, emphasis on formal requirements, excessive use of complaints-based inspections, and increased inspection activities during holidays, *inter alia*, are all factors that tend to increase corruption. Doing "less, but better", and ensuring staff are well-qualified and adequately compensated are important steps toward a more professional and ethical inspectorate.

Moreover, technical regulations of non-food products typically feature highly specific and well-developed requirements and specifications (which many stakeholders report as among the best examples internationally, e.g. for safety of electrical devices). By contrast, their regulatory inspections rest with PROFECO, a non-specialised body, with a very broad mandate and a professional profile that is primarily on 'law enforcement' rather than technical.

Regulatory enforcement and inspections by the CRE

Mexico's Energy Regulatory Commission (CRE) is in charge of regulating significant parts of the hydrocarbon market in Mexico, including mid-stream and downstream markets, as well as the entire electricity value chain. Although primarily an economic regulator, the CRE is responsible for supervising compliance of numerous NOMs. The CRE is responsible for the following NOMs:

- NOM-001-SECRE-2010 - Specifications of natural gas;
- NOM-014-CRE-2016 - Specifications of the quality of petrochemicals; and
- NOM-016-CRE-2016 - Specifications of the quality of petroleum products.

The mission of the CRE is to regulate and supervise in a reliable and co-ordinated manner the activities of the energy sector to promote productive investment and its efficient and sustainable performance for the benefit of Mexico. Its stated aim is to create a system of independent and specialised regulators, capable of guaranteeing a safe, reliable, competitive and sustainable energy sector.

The CRE has adopted an official policy document for inspections based on the OECD Best Practice Principles on Regulatory Enforcement and Inspections. The policy is specifically designed to target inspections on businesses most likely to be in non-compliance and which create the most significant risks. Inspections from the CRE are based on:

- The availability of human and financial resources;
- The degree of fulfilment of obligations by the permit holders;
- The number of complaints that the permit holders have;
- The number of operational emergencies and fortuitous cases or force majeure in the systems permissible; and
- Other factors, for example, market and systemic conditions.

In general, as noted above, excessive reliance on complaints to target inspections results in a purely responsive, non-risk-based approach. To the extent that the number and types of complaints are used only to improve the risk-based targeting, and provided that targeting is based on other elements (for instance, characteristics of the operation and findings from previous inspections), this could prove to be good practice. Further information would be needed to assess the CRE's approach in this respect.

The CRE's inspection policy aims to selectively target firms most likely to be in non-compliance, but not necessarily to target NOMs or parts of NOMs of greatest risk to society. Again, to what extent CRE effectively does this, or whether for now its risk-based targeting is really primarily compliance-based, would have to be further ascertained through additional research.

Unlike other technical inspections authorities, the CRE has created three-tiered system of inspection levels (reduced, normal, and rigorous) based on the risk of the non-compliance profile of business and market conditions for inspections that it performs on certain regulations but not on NOMs. This is a model that could be further imitated and replicated.

The CRE also has an explicit policy to encourage compliance by duty-holders, rather than a strong focus on sanctions. The fourteenth paragraph of the policy document asserts that to encourage voluntary compliance, it is necessary that regulated businesses know:

- The regulations and the obligations to which the permitted activities are subject;
- What the consequences are for not complying with the regulation and with permit obligations, as well as the types of sanctions which can apply.

The CRE has also adopted a new Code of Conduct of the Energy Regulatory Commission, aligned with the Code of Ethics of Servants of the Federal Government, to promote an environment of responsibility, commitment and respect for the labour and human rights of the personnel of CRE (Box 3.4).

Box 3.4. The eleven values of the CRE Employee Code of Conduct

1. Competition. Knowledge, skills and experience that people develop to understand and execute their daily tasks.
2. Commitment. Responsibility to meet the objectives set in a timely manner.
3. Empathy. Understand the position and circumstances of the general public, of regulated subjects and collaborators.

4. Teamwork. Collaboration of all members of the Commission, based on fluid and effective communication at all levels and in all directions.
5. Excellence. Result of constant work and with high quality standards in the individual and collective.
6. Integrity and Honesty. Act in accordance with the law and the public interest, with ethics and transparency.
7. Pragmatism. Practicality in carrying out the daily activities of the Commission, with the purpose of achieving agile and effective work.
8. Respect. Guarantee violence-free spaces where freedom of expression is guaranteed and diversity and tolerance towards others are promoted.
9. Creativity. Constant generation of new ideas for problem-solving and ongoing improvement.
10. Determination. Take responsibility proactively, with courage and perseverance.
11. Responsiveness. Make decisions and communicate risks in a timely manner, in order to anticipate problems and generate effective solutions.

Source: CRE (2018), Code of conduct of the energy regulatory commission, 14 December.

Regulatory enforcement and inspections by COFEPRIS

COFEPRIS is a decentralised, regulatory body of the Mexican government that supervises health and health-related issues, broadly defined. It is responsible for the market supervision and inspections across several sectors with an important health impact, including the safe manufacture and distribution of drugs and medical devices, medical care (hospitals, clinics), and a number of aspects of food safety. Its authority was granted under the General Health Law.

The General Health Law gives COFEPRIS the power to perform inspections that are part of a CAP itself or by a third party. The General Health Law also grants COFEPRIS powers to oversee the work of third parties that may report on the efficacy of drugs and medical products, as well as labs.

Regarding food, COFEPRIS has a competence that is shared with SENASICA (under the Ministry of Agriculture, and responsible for primary production but also for a part of transformation / processing) and with State-level authorities (responsible for most inspections of food processing, trade and service) – with the latter acting along guidelines and plans issued or validated by COFEPRIS.

Based on current findings, COFEPRIS appears to largely base its inspections on random selection or based on complaints, within broadly defined sector-level priorities. For example, COFEPRIS was reported to randomly inspect food products at point of sale to verify compliance with current food labelling regulations, and samples food products to guarantee that such products are safe for human consumption (USDA - Foreign Agriculture Service, 2018[6]). If this is a monitoring activity (aiming at establishing average levels of compliance) random selection may be appropriate, but if it is an inspections activity (leading potentially to enforcement measures) random selection is inefficient.

COFEPRIS can make two types of visits: a verification visit or health promotion visit. A verification visit is an inspection of regulatory nature to an establishment to verify compliance with the legal and regulatory requirements. A health promotion visit aims to promote better practices through counselling and training, good practice guides or brochures to inform the owner of a health facility how to act in accordance with current legislation (Tiol-Carrillo, 2017[7]). COFEPRIS did not report the use of specific risk-based methods for planning inspections (except for pharmaceutical production inspections), although the Commission for Evidence and Risk Management (CEMAR) within COFEPRIS does identify and evaluate health risks arising from drugs and medical devices.

In terms of the selection of inspection targets, interviews suggested that this was done on the basis of a rough sectoral analysis (which types of objects or sub-sectors appear to generate the most problems), with some level of consideration for the track-record of establishments (mostly in the sense of prioritising inspections toward those with previously recorded problems). Selection may be more targeted for health-care establishments, particularly major ones (which are smaller in number), and less so for food establishments (mostly controlled by State authorities on behalf of or in co-ordination with COFEPRIS).

While there appears to be a general understanding of a broad, high-level risk-based approach (selecting priority sectors, paying attention to track record), there do not seem to be any specific methods, tools (criteria, scoring methods etc.), processes or systems to target inspections in a systematically risk-based manner. Moreover, there seems to be a high level of reliance on "reactive" inspections, i.e. on inspection visits following complaints. These have generally been found to be less effective at improving outcomes, particularly if there is insufficient management of complaints to screen them and decide on a proportional response based on the specifics (reliability, issues raised, first instance or repeated cases, etc.).

Good Manufacturing Practices Inspections (Pharmaceuticals)

As the pharmaceuticals regulator, COFEPRIS performs Good Manufacturing Practices inspections and certification for medical drugs. An inspection is required prior to submission for approval. A verification visit by COFEPRIS is required to verify manufacturing processes for registration and manufacturing changes of biological, blood and biotech products. In addition, COFEPRIS inspectors perform verification for the new registration or renewal of a drug produced in a country that cannot prove high a level of sanitary surveillance. COFEPRIS, however, recognises the verifications from health authorities that are members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). As noted in the 2018 OECD Competition Assessment of Mexico, COFEPRIS does not recognise the GMP of some the largest suppliers, India and China – but this is in line with international good practices, as the European Union similarly treats producers from these countries with scrutiny.

Self-Management Program in Health and Safety at Work (PASST) by the Ministry of Labour and Social Protection (STPS)

The Ministry of Labour and Social Welfare is responsible for labour policy in Mexico. It carries out many inspection activities to ensure that workplaces comply with their obligations to maintain good general working conditions, to protect the health and safety of workers and to ensure that business are properly training employees.

The Ministry of Labour and Social Protection has a Self-Management Program in Health and Safety at Work (PASST). The programme allows businesses to assess their own compliance for all 38 relevant NOMs for workplace safety. The three objectives of the programme are to:

- Promote schemes for self-assessment of compliance with regulations, with co-responsibility of employers and workers.
- Induce continuous improvement in the prevention of accidents and occupational diseases.
- Decrease occupational accidents and diseases.

The programme also includes a computer-based tool for the identification of the relevant NOMs in health and safety at work. While both of these (programme overall, and computer tool) are potentially very useful and in line with international good practice, their effectiveness may be jeopardised by the regulatory structure – i.e. emphasising compliance with separate NOMs rather than a comprehensive management of occupational health and safety risks in the establishment. Benchmarking of practices and outcomes in different countries has shown that a regulatory approach that focuses on comprehensive risk management rather than on "box-ticking" on a number of separate precise rules is both less burdensome and considerably more effective. Research showed that the United Kingdom achieved better occupational

safety and health outcomes than France and even Germany with 3 to 5 times less frequent inspections, thanks to more risk-based inspections and a more comprehensive approach to risk-management (Blanc, 2018[5])

The Health and Safety Executive (HSE), responsible for OSH in the United Kingdom, has developed an enforcement policy that is based on risk-focus and risk-proportionality, both to target inspections, conduct verifications "on site" and decide on potential measures post-inspection (Box 3.5). These play a role in the UK having one of the lowest rates of workplace fatalities in the EU and globally. Only 10 workers die per million economically active population per year compared to an average of 38 in EU-27, EFTA/EEA, candidate and pre-accession countries. (WHO, 2019[8]) Other countries have developed similar sets of principles and approaches – a good example in another field (food safety) is that of the Danish Veterinary and Food Administration (Box 3.5).

Box 3.5. Principles of inspections and enforcement

UK Health and Safety Executive Enforcement Policy

The HSE applies the following principles to its enforcement activities:

- Proportionality in applying the law and securing compliance;
- Targeting of enforcement action;
- Consistency of approach;
- Transparency about how HSE operates and what businesses, workers and the public can expect; and
- Accountability for its actions.

These principles apply both to enforcement in particular cases and to the management of enforcement activities as a whole. They are not applied in isolation, but are informed by an understanding of the business environment. They allow for effective enforcement without stifling economic growth, by requiring inspectors to be proportionate in their decision-making and mindful in keeping the burden on business productivity to a minimum.

The HSE adopts a proportionate approach to enforcing the law across different industries and sectors, recognising the importance of supporting businesses to comply and grow. In its dealings with duty holders, it seeks to ensure that enforcement action is proportionate to the health and safety risks and to the seriousness of any breach of the law. This includes any actual or potential harm arising from any breach, and the economic impact of the action taken. The HSE expects that duty holders, in turn, will adopt a sensible and proportionate approach to managing health and safety, focussing on significant risks i.e. those with the potential to cause real harm. Applying the principle of proportionality means that inspectors should take particular account of how far duty holders have fallen short of what the law requires and the extent of the risks created.

The HSE uses a risk-based approach when deciding which duty holders to proactively inspect, taking into account factors such as size, type of activities, industry sector, and the associated death, injury and ill-health rates. The HSE also uses proportionate and outcome-based criteria when deciding which incidents, diseases and dangerous occurrences have to be investigated. This means that the HSE targets inspection and investigation resources primarily on those activities, industries and sectors giving rise to the most serious risks, where and when the hazards are least well-controlled, or where competence to manage health and safety is in doubt. Low risk activities will not, in general, be subject to enforcement unless actual harm has occurred.

Source: Health and Safety Executive (2015), Enforcement Policy Statement, pp. 2-4, https://www.gov.gg/CHttpHandler.ashx?id=106727&p=0 (accessed 10 September 2019).

Danish Veterinary and Food Administration

Inspections in the Danish Veterinary and Food Administration follow certain key principles for official control of products:

Control must be preventive

An important element in the control process is the provision of information to establishments and primary producers to ensure that they understand the reasoning behind the regulations and are motivated to follow them.

Analytical control

Analytical control ought to be a verification of whether the establishment or primary producer can manage the handling of foodstuffs or primary production.

Need-oriented inspection

Inspections should be both need-oriented and regular. It should also be dynamic, and most intensively applied where the need is greatest. Once a problem has been solved, the inspection effort should be moved elsewhere. The results of the inspection and the new knowledge acquired from, for example, surveillance and charting studies, should be used to keep the control process goal-oriented and to improve regulations.

Seek the source of the problem

Inspections should seek out the source of the problem. The inspection efforts should be concentrated as close as possible to the relevant links from which problems are emanating in the chain from "stable to table". If problems are discovered further down the chain, the responsible party should be contacted with regard to carrying out an inspection of the establishment or primary producer concerned, which is where the problem should be solved.

Reaction

The control process should avail of whatever sanctions are necessary to ensure that the regulations are observed. On the one hand, the reaction should not be more radical than necessary, while on the other hand, sanctions must have sufficient impact to ensure that the regulations are respected. If the establishment or primary producer concerned fails to comply with the control authority's sanctions, the sanctions should be escalated.

Uniform effects

The effects of inspections must be uniform, both geographically and within the various branches of the food industry. This means, for example, that import and production must be subject to the same requirements, and that regulations must be uniformly enforced throughout the entire country.

Document its own reliability

The inspection process must be able to document its own reliability and effectiveness, and must be made available to the public. Inspection results must be visible at places where consumers purchase foodstuffs, and on the Internet, so as to make it easier for consumers to evaluate the establishments involved and the official control process.

Source: Danish Food and Veterinary Authority, *Inspection Principles* (October 2015) – available at: https://www.foedevarestyrelsen.dk/english/Inspection/Inspection_principles/Pages/default.aspx

Regulatory inspections and market surveillance in practice: major challenges

This section identifies the most significant challenges facing Mexico's regulatory inspections of NOMs against the OECD Best Practice Principles on Regulatory Inspections and Enforcement. Practices for risk management, information sharing, among others, vary significantly between different ministries and federal agencies. Despite this variation, however, there are some general trends in the challenges facing inspections and enforcement of technical, safety and market regulations in Mexico.

Resources

- Related Best Practice Principles: Professionalism; Selectivity; Risk Focus and Proportionality

Market surveillance and inspections require sufficient expertly-trained inspectors that understand the NOMs and nature of the regulated businesses. In addition, inspectorates must target resources to regulation or portions of a technical regulations that present real risks to citizens. The Mexican government faces a particular challenge in using government resources effectively. Mexico has the lowest government spending per capita in the OECD, so inspection resources should be very carefully targeted to those regulatory issues (NOMs) that have the greatest impact on citizens, and to the businesses, products, etc. that create/present the most risks.

Similar to the issue of a lack of CABs, in interviews, Mexican regulators mentioned that there may be some areas or NOMs that may be significantly under-inspected. For example, SENER focuses on inspections of large power plants and, though smaller power plants might pose a significant risk, SENER lacks the resources to monitor power plants below a certain size.

In other key areas, like consumer protection, market surveillance in Mexico sometimes focuses on the most easily "visible" regulations, rather than targeting resources to areas of the greatest risk to the public. For example, PROFECO has previously targeted clothing quality. As indicated above, this is quite far from good practice, in that it specifically directs most resources to the lowest-impact areas. In addition, experience suggests that (because of the low number of safety rules applying to clothing) such inspections can be quite market-distorting, with inspectors focusing on price or labelling issues in ways that can show clearly excessive use of discretion.

As briefly outlined above, PROFECO is responsible for a large number of NOMs, many of which have significant technical content (which, in many cases, appears to be of high quality). The staffing of PROFECO, however, does not correspond to this mandate. The institution has a strong "legal" profile, rather than a technical one. There do not appear to be specialised technical units or teams to deal with goods presenting a higher level of complexity or risk. The limited number of staff combined with the very large size of the market means that PROFECO would need to have a very strong risk-based approach so as to focus its limited resources on the most critical risks. However, this is currently not the case.

Many authors have pointed out, in this respect, that it may be necessary to pay an efficiency wage to inspectors – a wage set above market rates – to discourage corruption. If inspectors are paid more than fairly for the role, they are much less likely to accept bribes that may have legal or financial consequences. At the very least, inspectors should be paid *at market rates* and not less. Countries where inspectors are seriously underpaid are known for major corruption problems in inspections, which no official reform manages to curtail. Cuts in the size of the public service, both in wages and employment, will likely further reduce the number of inspectors and their pay. While fewer, better paid staff could be an adequate approach, cutting wages will almost certainly have adverse consequences on the quality of the staff who enforce the NOMs.

Targeting and responsive regulation

- Related Best Practice Principles: Professionalism; Selectivity; Risk Focus and Proportionality

Inspections should be targeted towards those businesses, products, infractions that (can) have the gravest consequences for the health, safety, and well-being of citizens. Governments can ensure this by allowing inspectors to target specific areas for enforcement and to leave other areas up to market forces.

In Mexico, we also heard that inspectors are often obliged to check the entire contents of a given NOM during inspections. This may not be the best use of resources, because not all parts of a NOM create the same amount of risk to Mexican citizens. Inspections themselves should pass a cost-benefit analysis; the inspection system should improve the functioning of markets and reduce risks through enhanced compliance rates more than it costs businesses and governments to pay for inspections. As Blanc notes, there is a growing body of research on the harmful effects of bad (excessive, non-targeted, or arbitrary) regulation and inspections (Blanc, 2018[5]). It is, therefore critical that resources (both from the government and the costs of businesses compliance) are carefully targeted to high-risk regulations, products, establishments etc.

Targeting should also be part of an overall strategic framework of inspectorates. In Mexico, some inspectorates have started using the Matrix of Indicators for Results (MIR), which is reported to the Ministry of Finance and Public Credit through its application portal. SENER, for example, uses the MIR and reports on quality indicators and goals.

It is not sufficient to target inspections to the right parts of a technical regulation. Governments should be following the principles of responsive regulation or, as phrased by Baldwin and Black, governments must decide “when to punish; and when to persuade” (Baldwin and Black, 2007[9]). In the case of Mexico, we heard that, in part because of the structure of the FLPA and sectoral, inspectors often warn and then sanction. Essentially, businesses are told to “comply or else”. As (Hawkins, 2002[10]) showed, Britain’s HSE approach on the opposite emphasises the use of “law as a last resort” – i.e. co-operation and advice are the primary tools. As shown above, this co-operative and responsive approach has shown far superior outcomes.

Nevertheless, market surveillance authorities often produce some guidance, toolkits, or self-checklists to help promote compliance with NOMs. However, it is not clear if inspectors can offer advice on compliance, even after giving a warning – and it has not been assessed to what extent the existing guidance tools are convenient, clear, well-known etc. PROFECO reported that, among the different types of visits it could conduct, some were advisory and others led to enforcement measures but there does not seem to be as yet a clearly established system and methods for a compliance-promoting approach.

The new Law to Promote Citizens’ Trust could be used as a foundation to make inspections more focused on compliance-promotion, reducing inspections pressure on compliant businesses, make targeting more proportional to risk, among other potential uses. Article 11.IX, in particular, can be used as a basis for risk-proportional inspections and enforcement of those enterprises that opt to register under the Law.

Fractionalisation and co-ordination

- Related Best Practice Principles: Co-ordination and Consolidation; Responsive Regulation; Information Integration

Co-ordination is a key aspect of inspections and enforcement. First, co-ordination helps reduce administrative costs for businesses, because they need to manage fewer inspections per year. Secondly, a co-ordinated framework for inspections and enforcement allows authorities to more effectively identify and target riskier businesses. For example, a business that is not compliant with a set of standards in occupational safety may be more likely to be non-compliant with environmental standards, or at the very least such non-compliance may be a “flag” for verification – whereas a business that has been found

consistently and constantly compliant by others may be visited less frequently. Visits by other inspectorates can also contribute to updated information about the type of activities, their volume etc. – because there are typically many variations compared to the initial business registration data.

According to the LFMN, sectoral regulators are required to co-ordinate when there are overlapping NOMs and jurisdictions. However, it is currently unclear how this is enforced, even when they have overlapping duties, e.g. product labelling. Suboptimal inter-agency sharing of information may make it harder to target riskier CABs, businesses, and products and services.

In Mexico, inspection and surveillance are organised in reference to each NOM. Through interviews, very few inspectorates or agencies mentioned that they co-ordinate inspections when a business might be subject to multiple NOMs from different supporting agencies. Furthermore, interviewees did not mention any information or data-sharing practices. Even within individual agencies, such as SEMARNAT, there seemed to be minimal co-ordination between different units working on similar areas of technical regulation.

Each inspection creates a burden on businesses who must manage or support every inspection of their business. In many cases, they are subject to inspection from a number of different regulators. As a result, when they must manage many different inspections, they face high burdens, uncertainty and even contradictory requirements. A fragmented system also hampers information sharing, which makes it more difficult for regulators to identify high-risk businesses. Finally, multiple related inspections mean additional uncertainty for businesses in terms of which rules will be applied or how they will be interpreted, and this may act as a serious deterrent for investment and growth.

Whereas in the non-food products field PROFECO has very broad responsibilities (making co-ordination less of an issue), food safety supervision is divided between SENASICA, COFEPRIS and state-level authorities. While responsibilities in the food safety sphere may on paper be relatively clear, experience suggests that such divisions rarely function seamlessly in practice, and certain stages e.g. of processing could be subject to multiple competence. There did not appear to be a formalised co-ordination system for food safety inspections between SENASICA and COFEPRIS. A useful example of co-ordination could be that of the United Kingdom's MSNetwork – or the guidelines adopted in Italy to foster co-ordination between inspectorates, which are then implemented at the regional level (Box 3.6).

Box 3.6. Inspections Co-ordination – UK and Italy examples

UK Market Surveillance Co-ordination through the MSNetwork

In the United Kingdom, market surveillance refers to the suite of activities carried out by regulators that protect consumers from unsafe and non-compliant goods, by ensuring effective interventions (regulatory inspections) with businesses before they place goods on the market, when in the supply chain and when corrective action is needed.

The Department for Business, Energy and Industrial Strategy (BEIS) has responsibility for the subject matter of most technical regulations. Responsibility for co-ordinating market surveillance activity in the UK is held by the Office for Product Safety and Standards (OPSS) that is part of BEIS. Market surveillance in the UK is carried out by a range of both national bodies and local authorities. To ensure effective co-ordination of activity, these authorities come together through a Market Surveillance Network (MSNetwork).

The MSNetwork meets four times a year, providing a forum to exchange information, share best practices and review joint programmes and projects that are undertaken alongside the forum's meetings.

Current work programmes of the network are:

- Preparation of the UK National Market Surveillance Programme;
- User insights into the development of the UK Product Safety database;
- Re-alignment of the Single Point of Contact between market surveillance authorities and HM Revenue and Customs to share data on imports to target checks on risky products and economic operators; and
- Agreeing arrangements to pass cases between authorities.

Members of the MS Network include OPSS (consumer products, eco-design and environmental product regulation); Health and Safety Executive (products used in the workplace and pyrotechnics); Driver and Vehicle Standards Agency (automotive vehicles); Maritime and Coastguard Agency (products used in the maritime environment); Medicines and Healthcare Products Regulatory Agency (medical devices); and Office of Communications (communications equipment).

Source: UK Office for Product Safety and Standards.

Italy: National Guidelines for Inspections

Co-ordination of inspection activities

To reduce or eliminate disproportionate or unnecessary duplications, administrations should adopt co-ordination instruments between the different areas that exercise control activities. They should first identify the optimal level at which to conduct the co-ordination activity to obtain the best synergies between all actors.

The principle of co-ordination is then pursued through different instruments, such as:

a) Annual control plans co-ordinated between different administrations;
b) Shared databases between administrations that work in the same sector or in connected sectors;
c) Agreements between administrations in charge of inspections to conduct, where possible, co-ordinated or planned inspections; and
d) Harmonised documentation and forms that can be agreed jointly by all the administrations conducting inspections (e.g. official conclusions of inspections).

Source: Italy, Civil Service Department, Linee Guida in Materia di Controlli – adopted in 2013 by the Interregional Coordination Roundtable, http://www.funzionepubblica.gov.it/sites/funzionepubblica.gov.it/files/documenti/Semplificazione/Precedenti%20semplificazioni/Linee%20guida%20Controlli_24-01-2013.pdf .

Nevertheless, there are positive examples of co-ordination in Mexico. In 2018, ASEA, CRE and CNH created offices for co-ordination to assist stakeholders in processes requiring the intervention of more than one of the three regulators. Co-ordination between Mexico regulatory agencies in general was one key recommendation of the OECD report Driving Performance at Mexico's ASEA, CNH and CRE, which advocated for the creation of an Energy Regulatory Group to catalyse information sharing and facilitate co-ordination among the different regulators (OECD, 2018[11]). The ERG was inaugurated in 2018 (Box 3.7).

Box 3.7. The Energy Regulators Group in Mexico: CRE, CNH and ASEA

The ERG is an institutional approach to improving co-ordination. It is a permanent forum for exchange and implementation of joint work, whose mission is to "regulate and supervise in a reliable and co-ordinated manner the activities of the energy sector, to encourage productive investment and its efficient and sustainable performance in Mexico".

The group has also developed a Strategic Plan from 2018-2022, which lays out five key objectives to: facilitate the development of the energy sector; offer long-term regulatory certainty to the energy sector; meet the needs of the sector in a co-ordinated manner through systematic operations; promote cutting-edge financial and technical capacity permitting the operation of the system; and be recognised as a benchmark by society as well as national and international markets.

Source: OECD (2018), Impact Update: Driving Performance of Mexico's Energy Regulators, OECD, Paris, http://www.oecd.org/gov/regulatory-policy/Mexico-Impact-Update-web.pdf.

Generally, however, other ministries and regulators did not mention any explicit programs for information sharing or co-ordination between them and another agency. No inspections information-sharing platform, like Safety Gate in the EU or the Company Dossier system in the Netherlands (Blanc, 2012[12]), or like the "*fascicolo d'impresa*" in Lombardy[3] (Italy), exists in Mexico.

To support SMEs, the authors of the 2019 Economic Survey of Mexico suggested that "greater co-ordination between tax and labour inspections would also help, for example, by obliging tax inspectors to report suspected breaches of labour regulations and establishing stronger co-ordination mechanisms." (OECD, 2019[13]). Labour regulations include 36 NOMs, enforced by the STPS.

The UK's Office for Product Safety and Standards was established precisely to try to overhaul a system seen as too fragmented and insufficiently effective in terms of inspections and enforcement. Improved co-ordination, efficiency and effectiveness can also be achieved by creating shared information management systems (Box 3.8).

Box 3.8. Shared information systems for inspections

Risk-based planning cannot be done without each agency having data on all objects under supervision, which is costly and difficult to update – while, at the same time, because many of the risk dimensions are correlated, and because a non-compliant business tends to be thus in several areas, inspectorates would be able to improve their risk analysis if they also had data from other inspectorates. In addition, many inspectorates (even in OECD countries) have been found not to have proper information systems in the sense of systems allowing them to plan their activities based on risk, and to record the inspections results – setting up a system for each of these separately, and "populating" each with data on all objects, is far more costly than setting up a joint system. All these points speak strongly for setting up, as much as possible, joint information systems shared by most or all inspectorates. The information system should be built on a database that includes the following data:

- List of all business entities and of all establishments (not only all companies/businesses, but also all separate premises) in the country.

- For each establishment, have data on a set of relevant parameters corresponding to different risk factors, some "general" risk parameters generally relevant to all or most types of inspections (e.g. size, volumes handled, type of technology or process, etc.), and other more specific ones grouped by risk dimensions (e.g. food safety, workplace safety etc.).
- List all inspections and their results.
- Automatically generate risk ratings for each business and establishment.
- Automatically generate inspections selection and schedule.
- Filter and analyse data reporting.

More advanced systems can also incorporate functions to plan activities inside the inspectorate and manage processes, have online checklists, etc.

Source: Abridged from OECD (2015), Regulatory Policy in Lithuania: Focusing on the Delivery Side, OECD Reviews of Regulatory Reform, Annex A, Paris, https://doi.org/10.1787/9789264239340-en.

Under the proposed update to the LFMN, the Integral System of Regulations and Conformity Assessment (SINEC) as the virtual interactive platform will integrate, monitor and evaluate all the activities of the actors that participate in the Mexican System of Technical Regulations and Conformity Assessment. This would make information of all CABs available to all regulators and could reduce the resources in monitoring CABs after accreditation.

Risk analysis and proportionality

- Related Best Practice Principles: Evidence-based Enforcement; Risk Focus and Proportionality; Information Integration

Inspectors cannot monitor all businesses for violations at all times. It is absolutely critical that inspections are targeted at products and businesses that are most likely to create significant risks, both because they are more likely to be in violation and because these violations can create more serious hazards. This requires a system for government to make some appraisal about a business's risk level before the inspector makes a visit. Targeting the most significant risks avoids misuse of both the inspectors' and the businesses' time through follow-up on complaints that may not have a real impact on the well-being of citizens.

Ideally, government bodies with inspection powers would use a risk-based framework to target inspections. Targeting practices at present appear rather far from this objective. Many government bodies and sectoral regulators report increasing inspections at key times of the year, e.g. increasing product market inspections during peak, holiday buying periods, which is very different from a risk-based approach (though it may be relevant in terms of the potential volume of violations). Other such as the Ministry of Energy (*Secretaría de Energía* or SENER), plan some inspections randomly among verified suppliers. Special inspections are scheduled for facilities for which breaches have been reported or sanctioned, which speaks to the "probability" aspect of risk-assessment, but not to the "potential magnitude of hazard".

PROFECO did not mention explicit risk-based approaches; rather they increased sampling of goods during key times of the year. Often their inspections did not necessarily aim at taking dangerous products off the market, but rather focused on the quality of products, e.g. testing the material content of clothing textiles. It is not clear how this supported public welfare or was at least more relevant than other products. It is likewise unclear how PROFECO balances its role as body that promotes the "quality" of products (and how this is defined) versus its role to protect Mexican consumers from potential harms. In the UK, the Office for Product Safety and Standards (OPSS) prioritises inspections and market surveillance based on the potential hazards of non-compliance and the likelihood of non-compliance – other inspectorates, such as

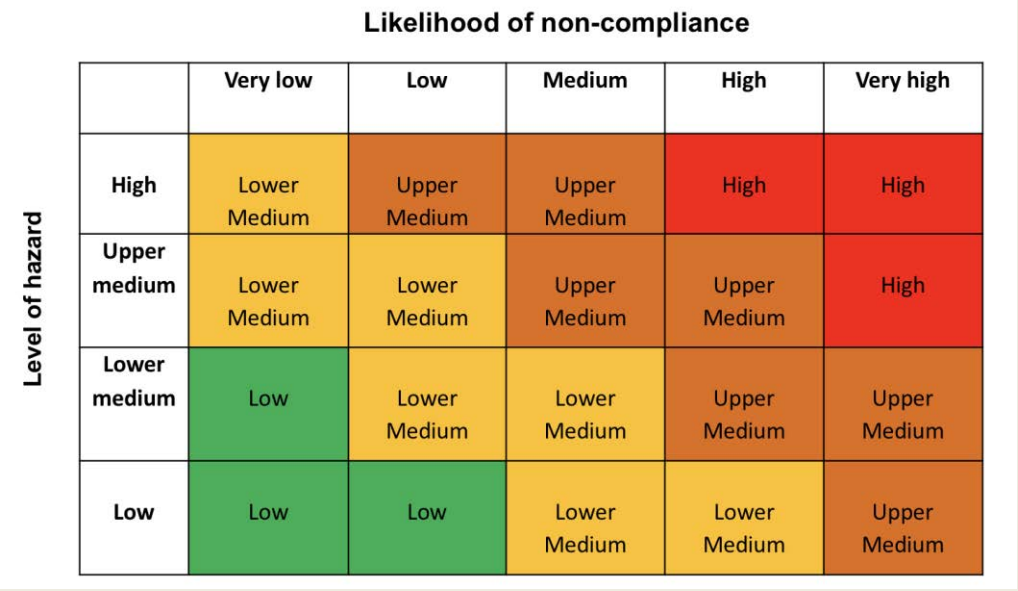
the Netherlands' *Inspectie SZW* (Inspectorate for Social Issues and Labour) use an "intervention toolbox" to select the intervention instruments that are most appropriate not just to the risk level, but to the drivers and factors, and characteristics of the target groups (Box 3.9).

Box 3.9. The UK OPSS's Risk-Based Approach and the Netherlands' "Intervention Toolbox" (*Inspectie SZW*)

UK OPSS Risk Based Approach

In the UK OPSS, inspectors use a matrix to determine which areas should be the most closely monitored and inspected. Essentially, this risk-based targeting framework ensures that inspectors prioritise technical regulations that have both a high-risk of non-compliance and create a high level of hazard.

Figure 3.1. OPSS – Risk-based targeting: generic approach



Source: Presentation by Graham Russell, CEO of the Office for Product Safety and Standards, 2018.

Netherlands' "Intervention Toolbox"

In the Netherlands, the *Inspectie SZW* (Inspectorate for Social Affairs and Labour) uses the following approach to select the most suitable intervention instrument, and not do inspections and enforcement as a "one size fits all":

1. Selecting the target group and/or specific risk. The Toolbox offers a set of choices, depending on current knowledge of the risk, the economic sector or the viewpoints of stakeholders. Each tool comes with additional information, explanations, and best practices;
2. Understanding the target groups and their motives to potentially engage in undeclared work. The Toolbox supports project managers and inspectors to understand the motives of the target group. What may explain noncompliance? Is there a lack of knowledge, or do groups consciously refuse to comply? Tools differ in terms of the number of target groups they address, the internal and external stakeholders involved, work style, time investment, degree of information required, and results;

3. The Toolbox can identify a selection of certain interventions based on the available information. For each target group, it offers information on the intervention and possible results it may generate;
4. The programme manager sets up a plan of action that includes a mix of suitable interventions. For example, the fast-food industry is at-risk of hiring cleaning companies that employ undocumented workers. An appropriate intervention would be not only to inspect companies in the three cleaning sectors, but also to speak with companies in the fast-food sector. The inspectorate may give fast-food companies the message that they should only do business with bona fide cleaning companies. This helps to increase compliance.

Source: December 2019 summary to the European Platform tackling undeclared work.

Most regulators had established annual plans for what to inspect, but it was not necessarily clear how priorities had been identified. Many regulators do not seem to adopt risk-based strategies. In part, most regulators limited data tracking to the number of inspections or administrative actions. However, both are relatively weak indicators of performance. First, the number of inspections is only related to the volume of work and does not allow the regulator to assess whether the work was effective (Blanc, 2018[5])). A focus on the number of violations is also imperfect.

As indicate above, while COFEPRIS appears to have a general understanding of what a risk-based approach could be, and to use some very broad, high-level risk-related priorities, it does not appear to use a formalised, systematised, establishment-level risk-based targeting approach. Discussions with SENASICA suggested that, in addition to an understanding of risk-based approaches overall, at least some departments of the agency were using a more formalised, developed risk-based approach for targeting of inspections. These departments report to target establishments for inspections considering not only the sector overall, but specific sub-sectors and activities, size of operations, track record, among others. For instance, regulatory inspections of TIF establishments are carried out by SENASICA staff according to a schedule, following complaints or special requests by supervisors tasked with overseeing these facilities on a regular basis. Further research would be needed to assess these issues, but they may constitute a good basis to inspire further work in other departments, institutions and regulatory fields.

The number of violations could remain the same, but the risks those violations present may be changing. In addition, a higher number of violations found might mean that a) inspections are more effective; b) compliance is significantly lower; or c) inspectors are simply finding minor or less risky violations. Full compliance may also not be a socially acceptable goal, because the costs to comply with and enforce parts of a NOM may exceed the benefits.

Many regulators indicated that when they inspect compliance with NOMs, they check the entire NOM and not necessarily those parts of the NOM with the greatest risk to the health, safety and well-being of citizens. The EU on the other hand operates on a risk management basis for market surveillance and makes a determination if a product is indeed dangerous before taking action.

Inspector Training and Codes of Conduct

- Related Best Practice Principles: Professionalism, Transparency

According to the Best Practice Principles on Regulatory Enforcement and Inspections, inspectors should be trained and managed to ensure professionalism, integrity, consistency and transparency. Nearly all the inspectorates interviewed mentioned training for inspectors in the area of technical expertise of the NOMs. Civil servants in Mexico are also subject to the Code of Ethics and related Integrity Rules of the government. However, few inspectorates mentioned specific training or a code of ethics (other than CRE

detailed above). A strong example to follow for further development of professional skills and competences would be the UK's (Box 3.10).

The surveillance of NOMs often requires significant training and education in a specific field. For example, SENER hires mostly engineers as inspectors. ASEA has also introduced a programme to keep new hires with special expertise. However, Mexico in general does not have an overarching HR policy for inspectors. Despite Codes of Conduct, it is not clear if inspectors also receive training in the non-technical aspects of the job.

As indicated above, wage levels may be a significant obstacle to attracting and retaining adequately qualified staff, and to motivating ethical behaviour. This problem may worsen if wages are lowered.

Box 3.10. UK Core Regulatory Competencies and the Regulatory Compliance Officer Apprenticeship

Planning risk-based and effective regulatory interventions (including inspections) requires the officer to have specific competencies, knowledge and skills. Many training programmes for regulators focus solely on technical and legal knowledge. In the UK, a suite of competencies has been identified that are required for all regulatory delivery roles, based on the Core Regulatory Competency Framework for Regulators. These have been developed and refined over several years by the Office for Product Safety and Standards in consultation with local and national regulators, professional bodies (including the Chartered Trading Standards Institute) and businesses.

A training programme is now available; the Regulatory Compliance Officer Apprenticeship is a standard leading to entry routes across the entire spectrum of regulatory delivery roles in both the public and private sectors. Apprentices learn the core skills, knowledge and behaviours required to be an effective Regulatory Compliance Officer. These include:

- Understanding the regulatory context in which they operate;
- Assessing the regulatory risks in the context they are working in, using and analysing data and intelligence to conduct risk assessments;
- Understanding the business environment and how the way that regulation is enforced can impact on business;
- Working effectively with other organisations, such as partner regulators, business groups and representatives of citizens to deliver regulatory outcomes such as prosperity and protection;
- Conducting audits, inspections, and checking compliance to assess performance against regulatory and other standards;
- Supporting and promoting business compliance; providing expert advice, information and guidance to help businesses comply and support compliance;
- Communicating effectively with business for example providing a range of mechanisms to engage with business in a way which best meets their needs;
- Responding to non-compliance in a proportionate way;
- Supporting those adversely impacted by non-compliance, including dealing with vulnerable victims;
- Evaluating their own personal regulatory activities and reporting against personal regulatory objectives and departmental priorities.

Source: http://www.instituteforapprenticeships.org/apprenticeship-standards/regulatory-compliance-officer/.

Trust, fraud and corruption

- Related Best Practice Principles: Transparent Governance; Compliance Promotion; Professionalism; Clear and Fair Process

Inspections and enforcement of technical regulations exist to create trust between market actors. Blanc (Blanc, 2018[5]) notes that trust in weights and measurements was one of the first uses of inspections to build trust between merchants and customers. (Monk, 2012[14]) points out that inspections support SMEs, because they allow new market entrants to be trusted in a market.

Illicit enforcement activities may threaten the credibility of the whole compliance system. Mexico scores the lowest out of any OECD country on the World Governance Indicator on control of corruption and rule of law (Worldwide Governance Indicators, 2018[15]). A number of scandals, including the corruption of inspectors of gas volume measurement and building inspectors, have rocked trust in the government in Mexico.

A number of sectoral regulators reported facing challenges with fake certificates. In addition, false import certificates are perceived as a serious problem by Mexican importers. For example, a number of importers avoided energy efficiency technical regulations for lightbulbs by falsely claiming that they bulbs were for personal use.

Weak rule of law will also hampers effectiveness of inspections in Mexico. If it is difficult or nearly impossible to effectively impose sanctions on businesses or individuals due to their social, political or economic connections, higher sanctions or more inspections will have little impact.

A report on a building collapse in Bangladesh highlighted how weak rule of law leads to less effective inspections.

> *"Indeed, inspectors had in fact responded to calls by workers that warned about the building being structurally unsafe, and ordered its closing, but their orders were simply disregarded by the owners. Thus, the disaster (and its causes) pointed to far more structural issues: weak rule of law (particularly for certain categories of powerful people), deep social inequality in terms of enforcement of legal rights, prevailing social norms among factory owners etc. Better targeted in sections and stronger powers for inspectors may be part of the solution, but they were (and are) far from certain to be sufficient." (Blanc, 2018[5])*

Cuts to inspector wages – particularly as drastically as suggested by current public administration salary reforms - could also increase the level of corruption in inspections. Low wages may encourage inspectors to accept bribed from regulates to avoid complaints or financial penalties. Researchers have demonstrated this effect both theoretically and empirically in emerging economies. For example, Besley and McLaren developed a model that suggests that tax inspectors should be paid above their reservation wage to reduce corruption (Besley and McLaren, 1993[16]). (Benito et al., 2018[17]) found significant links between corruption cases and the wages of local politicians in charge of approving building developments.

Addressing the corruption and abuse issues requires a number of steps, none of which can really work in isolation, and all of which will require time and sustained efforts to product results. They include:

1. Improvements in training and qualification
2. Introduction of proper risk-based approaches and phasing-out of inspections on "non-risky" issues
3. Improved co-ordination and consistency between inspections to avoid conflicting requirements
4. Stronger efforts at providing guidance and compliance support for businesses
5. Adequate budgeting and wages
6. Outcomes-focused performance measurement and regular review of inspectorates' activities and results.

It is important to link the ethical rules for an agency to the purpose of its work – so that they are understood not as a possibly "burdensome" add-on, but as a core element of fulfilling the agency's mission. The Canadian Food Inspection Agency's ethical framework is a good example of this (Box 3.11).

Box 3.11. The Canadian Food Inspection Agency ethical framework for employees

The Canadian Food Inspection Agency (CFIA) is the largest science-based regulatory agency in Canada with over 6 000 employees across the country. The agency has developed an ethical framework for its employees that builds on a Statement of Values and includes Code of Conduct and a Conflict of Interest and Post-Employment Code.

The Code of Conduct defines conflict of interest and includes guidelines on gifts for CFIA employees. The Statement of Values reads:

> *"As employees of the Canadian Food Inspection Agency:*
>
> *We value scientific rigour and professional and technical competence. These play a crucial role in our decision making. We do not manipulate science to achieve a desired outcome, but acknowledge that other factors must be taken into account in this decision making.*
>
> *The reputation and credibility of the Agency are vital to our ability to deliver our mandate. As such, we behave, internally and externally, in a way that trust is preserved.*
>
> *We are proud of the contributions we make to the quality of life of Canadians. We value dedication and responsiveness from all employees day to day and particularly during an emergency.*
>
> *We value competent, qualified and motivated personnel, whose efforts drive the results of the Agency.*
>
> *To develop effective policies and strategies, we value the perspectives of the stakeholders who are affected by our decisions.*
>
> *We maintain our regulatory independence from all external stakeholders. We have the courage to make difficult and potentially unpopular decisions and recommendations, free from personal bias.*
>
> *We are committed to our physical and psychological well-being."*
>
> *This set of values helps scientific employees determine what should and should not be done as they fulfill their daily responsibilities. We expect that you and your employees will respect these values in business decisions or interactions that directly affect the CFIA."*

Source: CFIA website, www.inspection.gc.ca/about-the-cfia/organizational-information/vision-and-mission/relationship/eng/1319480989283/1319481252700.

Compliance culture

- Related Best Practice Principles: *Compliance promotion*

A successful compliance culture requires consumers to demand high quality products. However, if consumers do not demand compliant goods and services businesses have little incentive to abide with laws and regulations. This may be due to lack of information, but is often primarily due to the lack of disposable income. As a result, in some markets, there are too few CABs or they are absent entirely. The Ministry of Economy has recently launched a series of initiatives to raise public awareness of the Mexican standardisation system, including a website and social media pages. The situation for the enforcement of NOMs has improved in markets where export demand is growing.

It may be appropriate to review which NOMs have the most potential to be successfully implemented given their salience in terms of risks, the possibility of market growth etc. – and which ones may simply be unrealistic or excessively stringent in current conditions. The Netherlands have developed a tool called the "Intervention Compass",[4] which allows to analyse a given issue and assess to which extent the regulatory response can be realistic, appropriate, implementable etc. A similar approach could be taken to areas where compliance with NOMs is particularly low, to more precisely identify the root causes of such non-compliance, and take decisions accordingly.

In certain cases, a lack of understanding of the risks of certain unregulated activities can pose a grave risk to health and safety. Recently, scores of people were killed in a pipeline explosion as people went to gather gasoline from a leaking pipeline – but this stemmed from very basic theft and gross disregard for safety. It was not an issue of the operators not complying with NOMs, but of thieves destroying the infrastructure, with terrible results. NOMs are found throughout the gasoline supply chain, including the environmental impacts of pipelines, quality of gasoline, and the measurement at point-of-sale. Nevertheless, there is a very large market for illegally obtained gasoline. Stolen gasoline sells for a significant discount. Beyond the lower price, consumers may also be motivated by the fact that gasoline station measuring equipment is often found to be selling short litres, according to PROFECO. This shows how much an integrated analysis of the problem and potential responses is needed – because stricter enforcement of NOMs on legal, formal operators, will not eliminate hazards due to thieves (and might even make their market position stronger, because it might increase the cost of legal gasoline due to higher compliance costs). Properly reviewing and analysing the problem and the "intervention logic" are essential, rather than simply stating that "there is a problem, therefore we need more enforcement".

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Notes

[1] N.B. These features of the Mexican regulatory system match what is found in a large number of countries. They are simply noted for informational purposes.

[2] In interviews, an interlocutor mentioned that the Ministry of Tourism only had one inspector itself.

[3] See: https://www.regione.lombardia.it/wps/portal/istituzionale/HP/DettaglioRedazionale/servizi-e-informazioni/enti-e-operatori/sportello-unico-attivita-produttive/fascicolo-informatico-impresa.

[4] Available at https://www.interventiekompas.nl/#/.

Annex A. The process for developing NOMs in Mexico

The first step for a standard proposal is to be included in the National Standardisation Program (PNN). The PNN is composed by proposals of standards, and is integrated and enforced by the Ministry of Economy. The PNN, together with the "*Suplemento Nacional de Normalización*" is then approved by the National Standardisation Commission (CNN).

Once the PNN is approved, the public sector or the National Standardisation Bodies (ONN) that want to issue a standard are required to obtain the approval from the relevant Committee; the National Advisory Standardisation Committees (CCNNs).

Stage 1 – Drafting of the proposed standard: Once included in the PNN approved by the CNN and published in the Federal Official Gazzette (*Diario Oficial de la Federación* or DOF), the public body may draft the proposed standard which shall be sent to the reference Ministry's CCNN. When elaborating the proposal, public bodies may require producers, importers, service providers, consumer or research centres, to provide any data or information (or even samples) needed to elaborate the standard

Stage 2 – Regulatory Impact Assessment: A proposed standard and its corresponding Regulatory Impact Assessment (RIA) shall be sent to the CCNN responsible of developing the NOM. CONAMER will comment on the RIA, without approving it or not, but releasing an opinion which could take three different forms: No observations or recommendations, minor comments, or not satisfactory.

A technical feasibility analysis of the standard's compliance, with an explanation of the verification mechanisms is also required. The RIA shall additionally include the monetary aspects of its potential costs and benefits, when large impacts are expected. The Ministry of Economy has the power to request these additional aspects if it is deemed appropriate.

Stage 3 – Consultation process: Draft NOMs shall be published in the DOF and interested parties will have 60 natural days to send comments to the corresponding CCNN. Depending on the comments, the draft is updated; responses given by the CCNN to the comments have to be published also in the DOF 15 days before the publication of the final version.

Stage 4 – Decision and publication: Once a NOM is approved by a CCNN, its final version shall be published by the corresponding public body in the DOF.

Stage 5 – Review: NOMs shall be reviewed every five years after its entry into force.

Stage 6 – Expiration and cancellation: The Technical Secretariat shall be notified about the results of the review 60 natural days before this term expires. If this notification is not made, the standard will expire and its cancelation will be published in the DOF. In addition, the Ministry of Economy has the power to request an *ex post* assessment of the standard after one year of its entry into force.

The development process for NMX is very similar. However, there are three key differences between the development of an NOM and an NMX.

- There is no Regulatory Impact Assessment for an NMX;
- Answer to comments to the first draft are not published in the DOF for an NMX;
- DGN has an expanded role in the development of NOMs. It is part of working groups, meetings with stakeholders and is in general for involved with the CCTN.

Source: Abridged from OECD (2018), Standard-setting and competition in Mexico: A secretariat report, Paris.

Annex B. Overview of conformity assessment modules in the EU New Legislative Framework

Modules	Description
A **Internal production control**	Covers both design and production. The manufacturer himself ensures the conformity of the products to the legislative requirements (no EU-type examination)
A1 **Internal production control plus supervised product testing**	Covers both design and production. A + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.
A2 **Internal production control plus supervised product checks at random intervals**	Covers both design and production. A + product checks at random intervals carried out by a notified body or in-house accredited body.
B **EU-type examination**	Covers design. It is always followed by other modules by which the conformity of the products to the approved EU-type is demonstrated. A notified body examines the technical design and or the specimen of a type and verifies and attests that it meets the requirements of the legislative instrument that apply to it by issuing an EU-type examination certificate. There are 3 ways to carry out EU-type examination: 1) production type, 2) combination of production type and design type and 3) design type.
C **Conformity to EU-type based on internal production control**	Covers production and follows module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B.
C1 **Conformity to EU-type based on internal production control plus supervised product testing**	Covers production and follows module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B. C + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.
C2 **Conformity to EU-type based on internal production control plus supervised product checks at random intervals**	Covers production and follows module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B. C + product checks at random intervals tests on specific aspects of the product carried out by a notified body or in-house accredited body.
D **Conformity to EU-type based on quality assurance of the production process**	Covers production and follows module B. The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to EU-type. The notified body assesses the quality system.
D1 **Quality assurance of the production process**	Covers both design and production. The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to legislative requirements (no EU-type, used like D without module B). The notified body assesses the production (manufacturing part and inspection of final product) quality system.
E **Conformity to EU-type based on product quality assurance**	Covers production and follows module B. The manufacturer operates a product quality (=' production' quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to EU-type. A notified body assesses the quality system. The idea behind module E is similar to the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system

Modules	Description
	under module E aims to ensure the quality of the final product, while the quality system under module D (and D1 too) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E is thus similar to module D without the provisions relating to the manufacturing process.
E1 **Quality assurance of final product inspection and testing**	Covers both design and production. The manufacturer operates a product quality (=' production' quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to the legislative requirements (no module B (EU-type), used like E without module B). The notified body assesses the quality system. The idea behind module E1 is similar to the one under module D1: both are based on a quality system. Their difference is that the quality system under module E1 aims to ensure the quality of the final product, while the quality system under module D1 aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is thus similar to module D1 without the provisions relating to the manufacturing process.
F **Conformity to EU-type based on product verification**	Covers production and follows module B. The manufacturer ensures compliance of the manufactured products to approved EU-type. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to EU-type. Module F is like C2 but the notified body carries out more systematic product checks.
F1 **Conformity based on product verification**	Covers both design and production. The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to the legislative requirements (no EU-type, used like F without module B) Module F1 is like A2 but the notified body carries out more detailed product checks.
G **Conformity based on unit verification**	Covers both design and production. The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body verifies every individual product in order to ensure conformity to legislative requirements (no EU-type).
H **Conformity based on full quality assurance**	Covers both design and production. The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system.
H1 **Conformity based on full quality assurance plus design examination**	Covers both design and production. The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system and the product design and issues an EU design examination certificate. Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design. The EU-design examination certificate must not be confused with the EU-type examination certificate of module B that attests the conformity of a specimen 'representative of the production envisaged', so that the conformity of the products may be checked against this specimen. Under EU design examination certificate of module H1, there is no such specimen. EU design examination certificate attests that the conformity of the design of the product has been checked and certified by a notified body.

Implementing Technical Regulations in Mexico

Regulations are indispensable for the proper functioning of society and markets. Technical regulations, referred to as NOMs in Mexico, set specific safety and quality requirements for products across sectors. *Implementing Technical Regulations in Mexico* provides the first assessment of the challenges facing regulatory delivery of technical regulations carried out under the aegis of the OECD Regulatory Policy Committee. This report analyses the delivery of Mexican NOMs, focusing on policies and practices around conformity assessment and regulatory inspections. Based on an analysis of NOMs' framework and implementation policies and practices, the review identifies key areas for improvement and provides recommendations for Mexico to develop a whole-of-government and systemic approach to regulatory delivery of technical regulations.

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