The COVID-19 crisis has highlighted the need for trusted, evidence-based, internationally co-ordinated and well-enforced regulations. Strikingly, the crisis has underscored the critical importance of technical regulations, a specific type of normative instrument that covers a wide array of goods yet goes relatively unnoticed in normal times. Technical regulations set specific safety and quality requirements for products, services, and sometimes production processes, across different sectors. They typically govern many of the essential items needed to face the current health emergency: facemasks and personal protective equipment, disinfectants, drugs and medical products, among other. However, the mere existence of technical regulations is not enough to secure these objectives. To fully reap their benefits governments need to ensure their proper implementation.

The OECD Review on Implementing Technical Regulations in Mexico is thus a timely undertaking. It aims to support Mexico in its efforts to improve the regulatory quality and delivery of Mexican technical regulations, known as NOMs. Over time, Mexico has demonstrated a strong commitment to ensuring that its laws and regulations are of high quality, including NOMs. Yet, Mexico’s efforts have mostly centred on the early stages of the “regulatory lifecycle”, targeting mainly the design of normative instruments. Nonetheless, achieving the desired outcomes of regulations requires proper enforcement.

When it comes to NOMs, a number of challenges create a gap between their development and their subsequent application. Mexico has over 700 NOMs in force covering a range of regulated sectors. Nearly 20% of products inspected by PROFECO in 2018 were in non-compliance with NOMs. Furthermore, at times NOMs lack the relevant conformity assessment techniques or a competent body to evaluate that their requirements are fulfilled. As of February 2019, only 34% of NOMs requiring conformity assessment by an accredited body had an accredited CAB competent for evaluating their implementation. Without them, these NOMs become de facto unenforceable and the efforts that went into their development are squandered. The review provides avenues for possible solutions and suggests actions to reap the full benefits from technical regulations.

By undergoing this Review, Mexico shows its resolve to address key areas of weakness through a whole-of-government and a systemic approach to the implementation of these regulatory instruments.

The review on Implementing Technical Regulations in Mexico documents:

- the legal and institutional frameworks governing the implementation and enforcement of NOMs;
- the conformity assessment and accreditation frameworks applicable in Mexico and specific sectoral illustrations; and
- the regulatory inspection mechanisms used to supervise, promote and enforce compliance with NOMs (including market surveillance activities).

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. It 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.

Recent and ongoing legislative initiatives to reform the technical regulation system and regulatory inspections create momentum for Mexico to strengthen the implementation of NOMs. These initiatives could be accompanied by measures to promote co-ordination among relevant authorities and other 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.
Conformity assessment and regulatory inspections are complementary and necessary instruments to ensure regulatory delivery of technical regulations

The implementation of NOMs takes place through two 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. Both instruments are complementary and necessary to ensure the effective functioning of markets and the delivery of the policy goals set in each NOM.

Figure 1. Schematic of regulatory delivery of NOMs

Mexico has put in place a strong framework around NOMs, still there is no cohesive and coherent vision to secure their implementation and promote compliance

Mexico has over 700 NOMs in force covering a number of regulated sectors. They are governed by a strong framework spearheaded by the Federal Law on Metrology and Standardisation (Ley General sobre Metrología y Normalización, LFMN) and led by the Ministry of Economy through its General Bureau of Standards (DGN). Numerous additional actors are involved in the regulatory delivery of NOMs, including public sector bodies, technical entities and businesses in a range of sectors (Figure 2) (Table 1). However, the absence of unifying principles, combined with the breadth of issues covered, contribute to a fragmented and at times unclear approach to their use and implementation.

Table 1. Actors involved in the lifecycle of NOMs

<table>
<thead>
<tr>
<th>Development of NOMs</th>
<th>Metrology</th>
<th>Accreditation</th>
<th>Conformity Assessment Procedures</th>
<th>Regulatory Inspection and/or market surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>DGN</td>
<td>●</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONAMER</td>
<td>●</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sectoral Regulators</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>CENAM</td>
<td>●</td>
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<td>●</td>
<td>●</td>
</tr>
<tr>
<td>EMA</td>
<td>●</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conformity Assessment Bodies</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>PROFECO</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Civil society and business</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Customs</td>
<td></td>
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<td></td>
<td>●</td>
</tr>
</tbody>
</table>

Note: CENAM inspections powers fall over measurement equipment.
Furthermore, the compliance culture in Mexico is weak, with limited knowledge and awareness of the importance of technical regulations among the public and even some sectoral regulators. This, together with a large informal sector, are additional obstacles to reaping the full benefits of technical regulations.

The OECD recommends strengthening the framework around NOMs with a focus on implementation:

Advancing towards a whole-of-government policy and a systemic approach to the implementation of NOMs to enable their effectiveness.

This includes:

- clarifying the role of the DGN as overseer and co-ordinator of the system;
- systematically including implementation needs in the design stage of NOMs;
- promoting a continuous dialogue between authorities responsible for implementation of NOMs avoiding duplication and exchanging experiences and best practices across sectors;
- ensuring that NOMs include provisions for entry into force/applicability that take into account the time needed for different actors to secure compliance with the new requirements;
- addressing the stock of NOMs that are de facto unenforceable for lack of a corresponding conformity assessment procedure (CAP) and developing a plan to design and issue these CAPs for NOMs in key areas or sectors;
- making use of the 5-year ex post review of NOMs to address implementation challenges;
- promoting awareness of the benefits of NOMs and the importance of compliance with technical regulations across stakeholders;
- making use of Mexico’s public procurement system to promote products and services that comply with NOMs; and
- improving and strengthening the technical regulation framework for food safety.
Mexico uses a number of sector-specific approaches to conformity assessment and there is no common methodology for their development and selection

Mexico recognises a range of CAPs 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 (CABs) to perform their functions. Conformity assessment and accreditation are key building blocks of a country’s quality infrastructure.

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 CAPs that effectively account for the complexity and level of risk that a NOM is to manage, and/or ensure adequate infrastructure is in place to achieve the objectives of a NOM.

The OECD recommends strengthening the conformity assessment infrastructure:

Developing a coherent approach to conformity assessment across relevant sectors, including through guidance documents on the design of CAPs, and improving Mexico’s conformity assessment infrastructure to promote the role of CABs and the use of NOMs.

This includes:

- developing a common methodology with step-by-step guidance for designing and issuing CAPs to help build a common understanding;
- organising training courses for regulators to clarify steps for the development of CAPs and enable exchange of experience;
- promoting consistency with relevant international obligations and standards on conformity assessment;
- promoting the development of capacities in areas where CABs are currently lacking;
- ensuring absence of conflicts of interest and addressing potential risks of capture between actors around NOMs;
- recognising qualified foreign CABs in sectors and for NOMs targeting limited “niche” market where demand is insufficient to make the setup and operation of Mexican CABs viable or cost-competitive;
- exploring further the use of additional approaches including first-party assessment techniques for products with low risk of negative effects from non-compliance; and
- developing pilot programmes to test the implementation of some measures foreseen in these reforms related to implementation of NOMs.

Reliable and trustworthy inspection of NOMs in some sectors has successfully built trust but a number of significant challenges remain in enhancing the effectiveness of surveillance

Regulatory inspections, including market surveillance, are essential for making sure that products, services and, when applicable, production processes continue to meet the requirements set under technical regulations. Regulatory inspections are currently undertaken by the government authority responsible for each NOM. While Mexico has successfully built trust in export markets through the reliable surveillance and enforcement of certain NOMs, the situation varies considerably across 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. Best examples in country, for example the risk-based approach of some departments of SENASICA, can serve as basis for developing risk-based tools for other inspection fields.

The OECD recommends developing a coherent, risk and evidence-based approach to regulatory inspections:

Enhancing the effectiveness of regulatory inspections via a more coherent approach focusing on managing and targeting resources and improving co-ordination and data sharing among agencies.
This includes:

- targeting regulatory inspections of NOMs to make them more effective at reducing risks for consumers and citizens;
- developing a clear, government-wide enforcement policy with a focus on risk-based inspections that target real harms to society and focus on achieving regulatory objectives;
- strengthening professionalism of inspectors, and methods for inspection visits;
- creating a body to promote co-ordination to reduce the overlaps in inspections in the food and manufacturing areas, similar to the Energy Regulators Group in the energy sector;
- ensuring that sectoral regulators collect and share data on inspections to target businesses that are more likely to create risks for citizens and identify patterns of non-compliance with NOMs;
- building a differentiated, responsive sanction system that focuses on promoting compliance rather than punishment;
- allowing inspectors to take a clear but flexible risk-based approach during visits, relying less on sanctions and warnings that require businesses to “comply; or else”;
- develop clear and effective codes of ethics and training on conflicts of interest for inspectors;
- ensuring that in-country inspections and border inspections are linked, and that data is shared between authorities; and
- making use of the implementation of the new Law to Promote Citizens Trust as an opportunity to enable the use of key good practice principles and instruments around inspections.

The 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.
OECD Regulatory Policy Division

The Regulatory Policy Division is part of the OECD Public Governance Directorate. It serves as the Secretariat of the Regulatory Policy Committee and assists countries in implementing government-wide policies to promote regulatory policy and governance.

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