

4 Assessment and recommendations

This chapter presents an assessment of the subjects covered in chapters 1 and 2, and delivers recommendations for improvement. Recommendations mainly come from OECD principles and international experiences.

The assessment and recommendations are divided among the following sections: 1) General policy topics; 2) Impacts on health and the environment; 3) Stakeholder engagement; 4) International co-operation; 5) Registration and post-registration; 6) Responsible use of pesticides.

Mexico has an extensive pesticides regulatory framework¹ that involves a number of different authorities. COFEPRIS, SEMARNAT and SENASICA are the three leading authorities as far as pesticide registration is concerned. However, the following authorities also have a role in pesticide regulation design and implementation: Secretary of Economy, the Tax Administration System, the Secretary of Communications and Transportation, the Health Secretary, the National Water Commission, the National Commission for Regulatory Improvement. There are also key international regulatory co-operation considerations, since the Mexican agrochemical industry is highly dependent on international trade.

Having a clear, efficient, and modern regulatory framework is essential to address pesticide impacts on human health and the environment, and to support a life-cycle approach to their management, while ensuring crop protection and a sustainable agricultural industry. The goal of this chapter is to provide an assessment of key aspects surrounding the pesticide regulatory framework in Mexico. This includes the existing state of the regulatory framework, as well as the design and implementation of regulation.

Based on the assessment, the chapter also provides a set of recommendations to support the on-going reforms in the area of pesticides management in Mexico. Some of these recommendations are practical applications of OECD best practice principles on regulatory policy, including on enforcement and inspections (OECD, 2018^[1]), Regulatory Impact Assessment (RIA) (OECD, 2020^[2]), reviewing the stock of regulation (OECD, 2020^[3]), and governance of regulators (OECD, 2014^[4]).

These recommendations do not intend to cover the complete range of possible reforms and changes. Instead, they should be considered as topics for consideration by the Mexican authorities and other stakeholders about possible areas for future improvements. While the order of the sections and issues in this chapter do not necessarily suggest a prioritisation, it should be noted that addressing the overarching recommendations included in the General Policy Issues section would support addressing several other issues described in the report.

General policy topics

Assessment

Mexico lacks a unifying and overarching policy statement that sets priorities for pesticide management

A clear description of the key objectives of the pesticide management system is essential for authorities, stakeholders and the public, as it enables understanding what the system is aiming to achieve. A unifying policy statement also enables prioritising objectives to support decision-making, particularly if there are two or more competing or conflicting objectives.

As described in Chapter 1, Mexico has no unifying policy statement that prioritizes goals of a pesticide management system. There is no specific overarching national policy on pesticides. Main policy documents such as the National Development Plan, the Agriculture and Rural Development Sectorial Plan 2020-2024, the Health Sectorial Plan 2020-2024 or the Environmental and Natural Resources Sectorial Plan 2020-2024 cover pesticides in a limited or fragmented manner. Goals and objectives are included in various policy and regulatory instruments dealing with these substances. This creates a situation where competing goals, for instance related to the protection of human health or the environment and crop protection, can have an impact on the co-operation between ministries or regulators and the implementation of the system in general.

Historically, reforms on pesticide regulation have focused on partial “patches” rather than a system-wide comprehensive reform. If the fragmented management of the pesticide regulatory framework persists, it could continue to be an obstacle for system-wide improvement.

This raises concerns on the overall functioning of the pesticide management system. The lack of clear objectives, and their prioritisation, makes a national dialogue on pesticide policy difficult, for instance where there is a need to address competing goals. This creates implications for regulatory decisions¹, such as the prohibition and restriction of hazardous substances. The lack of explicit policy objectives also complicates the design, assessment and funding of a rounded pesticide management strategy that includes evaluation of pesticide products and active constituents, monitoring of impacts on human health and the environment, regulatory enforcement and technology infrastructure to sustain the system, among others.

Mexico also has sectorial development plans that address specific portfolios of the different Secretaries. The Agriculture and Rural Development Sectorial Plan 2020-2024 has three main objectives. The third objective states the following: Increase sustainable production practices in the agricultural and fishing aquaculture sector in the face of agro-climatic risks. This objective informs the basis of several action plans including the following: Promote regulatory standards for the use of pesticides and the coordination of local and territorial actions to protect the survival, biodiversity and abundance of pollinators. The Health Sectorial Plan 2020-2024 does not directly address the effects of pesticides in relation to human health. The Environmental and Natural Resources Sectorial Plan 2020-2024 addresses pesticides as part of an assessment of water contamination, but does not specifically address them in concrete action plans.

The existing pesticide regulatory framework in Mexico is comprehensive but scattered between various regulatory instruments and administered by several authorities

Mexico has a comprehensive pesticide regulatory framework in place, addressing issues throughout its value chain. The protection of health and the environment (linked to the sound management of pesticides) is reflected in several articles of the Mexican Federal Constitution. Three federal laws (General Health Law, General Law of Ecological Balance and Environmental Protection and Federal Plant Health Law) constitute key legislative tools to manage pesticides in Mexico, and are supplemented with legislation dealing with additional policy issues surrounding pesticides, for instance waste management or occupational health. The PLAFEST Regulation is the most relevant by-law in relation to pesticides, as it addresses their registrations and import and export authorisations. Nevertheless, there are several other regulations (by-laws) on pesticides. Moreover, there are more than 20 obligatory Official Technical Standards (NOMs) in place addressing technical aspects of pesticide management, such as biological efficacy, maximum residues limits (MRLs), labelling, pesticides establishments and aerial spraying.²

The current regulatory framework has a broad scope. Beyond pesticides, it covers vegetal nutrition inputs, fertilisers, as well as other hazardous materials. This creates challenges in allocation and prioritisation of scarce resources. This makes the regulatory environment in Mexico overly complex and difficult to implement, including maintaining and keeping technical requirements up to-date. In addition, pesticides management is shared across multiple ministries and agencies, posing an additional co-ordination challenge.

The three most relevant authorities in Mexico are the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), a decentralised body within the Undersecretary of Health Prevention and Promotion; the Secretary for Environment and Natural Resources (SEMARNAT) and the National Service of Agrifood Health, Safety and Quality (SENASICA), a decentralised body of the Secretary for Agriculture (SADER). However, the Secretaries of Finance and Public Credit, Communication and Transport, Labour and Social Security and Economy are also involved, to some extent, in pesticides management in Mexico. Different regulators implement the pesticide regulatory framework in the context of their own overarching legal framework and therefore have varying priorities and policy goals in relation to pesticides. This, in turn, affects the processes, timelines and co-ordination mechanisms in place.

Mexican regulatory framework would benefit from updated definitions and better accommodation of new technologies and new bio-pesticide products

The current regulatory framework for pesticides in Mexico does not easily accommodate new, lower risk technologies, making it harder manufacturers to gain approval and for users to adopt them. In particular, existing definitions and data requirements, as embedded in the applicable laws and regulations, create challenges for regulators. Not only when they need to apply them to the evaluation and registration of new technologies or products, but also for industry providing information that would allow the authorities to make a decision. In particular cases, for instance for the application of pesticides by drones, there are no procedures or standards in place.

Strengthening a life-cycle approach to pesticides is essential

Mexico does not have a fully-fledged integrated life-cycle regulatory approach³ to pesticides management. In the last decades, Mexico has “patched” different issues instead of focusing on designing a regulatory system that effectively and efficiently covers the whole life-cycle of pesticides. As highlighted in the Regulatory Compliance and Enforcement section, enforcement efforts need to be strengthened to control the use of pesticides. The outcomes of enforcement activities and undertaken studies indicate, for instance, that the use of not registered, expired or even prohibited pesticides continues to take place, including unintended poisonings. There are additional challenges in ensuring a proper use of these substances at the national level, including the geographical size of Mexico, the number of stakeholders involved in the application of pesticides, as well as differing social conditions and agricultural practices.

There is an increasing need to enhance efforts on compliance assurance, with wide-reaching compliance promotion activities directed to farmers as the top priority. Farmers and other users of pesticides need easily accessible and comprehensible education and training on the safe management of pesticides, as well as information on the applicable norms and regulations in this area. This requires continuous co-ordination and joint efforts from all stakeholders involved, and while authorities are best suited to provide information on regulatory requirements, the industry has knowledge and experience in providing advice and training on the safe use of pesticides.

The current regulatory framework in Mexico does not differentiate between the professional uses of pesticides and the amateur use by general public and, consequently, there are no restrictions on access to pesticides including the ones for which there are additional conditions with respect to either limitations on use or qualifications of the persons who are authorised to use such products. Moreover, there is no national certification scheme for the professional users of pesticides.

The Mexican NOM (NOM-003-STPS-2016) is currently under preparation to update the existing provisions in the area of occupational health and safety of the use of pesticides. It should also introduce updated and new obligations in this field. Linked for instance to the obligatory verification that all pesticide containers include the original label, only certified personnel use pesticides in aerial spraying and obligatory signalling containers and areas of storage of pesticides is ensured. Unfortunately, the project of this NOM is stalled in the consultation process since 2016.

Recommendations

The Mexican authorities would benefit from adopting a comprehensive, mutually agreed policy strategy for pesticides, encompassing a vision, goals and mission statements, and recognising that pesticide management is a shared responsibility across national and local governments, the pesticide industry, pesticide users as well as the general public. It would be essential to establish a foundation for a hierarchy of goals and objectives, as well as an effective and efficient division of responsibilities, including co-ordination of obligations. Non-governmental stakeholders should be involved in the preparation and implementation of the strategy.

An on-going comprehensive review of the legal and regulatory framework for pesticides management in Mexico could include as one of its objectives streamlining, simplifying and consolidating the existing frameworks. The Mexican authorities could consider, for instance, the adoption of a specific federal law focused on pesticides. A pesticides law would allow to address the full cycle of pesticides management, better reflect the need for environmental protection goals take equal weight compared to human health protection goals, and to better reflect international developments (see specific issues on this topic below). Moreover, streamlining the institutional framework, with empowering a single “leading” authority with a more decision-making power could be considered as one of the options. It could allow addressing the recurring issue of varying timelines, as well as boosting the enforcement of the regulation in benefit of the public policy objectives.

There are different regulatory improvement strategies that Mexico can use to keep definitions updated and better accommodate new technologies and new bio-pesticide products. For instance, Mexico could introduce revision clauses/criteria mandating the pesticide regulators to review existing definitions every certain number of years. If feasible under its regulatory system, Mexico could also consider introducing a regular review and/or development of technology-specific data requirements guidelines aligning, where possible, with international developments, as these are often easier to amend or update than the primary regulatory framework. This is an area where regulators would also benefit from international working groups and periodical consultation with Mexican stakeholders.

Mexico should consider restricting the sale of certain pesticides (including these for which there are additional conditions with respect to either limitations on use or qualifications of the persons who are authorised to use such products). Only persons who are trained or certified in their proper use and reintroduce national certification in this field. It would also support risk assessments to better take into account the risks for both occupational handlers and the public. It should also consider enhancing its life-cycle approach with elements of co-operation on international monitoring and incident reporting in relation to pesticides.

Impacts on health and the environment

Assessment

There is room for improving pesticide data collection and availability to support their life cycle management and addressing illegal trade of pesticides

The Mexican authorities have data on pesticide sales and their import and export. Domestic pesticide production and sales data are available from the Monthly Survey of the Manufacturing Industry conducted by INEGI. This monthly data is obtained from in-person and virtual surveys carried out by INEGI with manufacturing establishments. The Secretary of Economy manages data on international trade in the Commercial Information System via Internet (SIAVI) platform. Collection of certain data on pesticides by industry (e.g. records of aerial spraying, records of sales and production of certain pesticides) is required by the Mexican NOMs, but there is no general obligation in the regulatory framework to keep the sale register of pesticides.

However, as indicated in Chapter 1, information on pesticides sales in Mexico is presented only in terms of a total volume, not a volume of active ingredient, which limits the possibility to compare the situation in Mexico with other OECD countries. There is also limited information available on the uses of pesticides, their commercialisation and application, including information coming from environmental and health monitoring, as it is not required in the post-registration stage, for instance during the renewal of the pesticide registration.

Lack of systematic environmental monitoring of pesticides, in part due to limited resources available, is a challenge

Collecting and monitoring data in food and environment over a prolonged period is essential to sound decision-making on pesticides, but also to build public confidence about the use of pesticides and to have effective compliance and monitoring in place. Many of Mexico's trading partners, such as Canada, the European Union and the United States, have comprehensive environmental monitoring programmes in place and release regular reports summarising the findings of these programs.

Mexico has conducted certain monitoring activities in different parts of the country, covering some pesticides (for instance studies undertaken by the National Water Commission, CONAGUA). Studies have been elaborated on water and soil contamination by pesticides. A residue-monitoring programme, with a focus on export of food products, is in place. However, the country does not perform a systematic environmental monitoring of pesticides and their residues. It has been partly linked to the lack of resources to perform such monitoring. Moreover, Mexico does not have binding national reference/limit values for the contamination of water and soil by pesticides. Monitoring of the intoxication caused by pesticide poisoning could be improved to provide reliable information to decision-makers.

Mexico has recently updated its regulatory framework on Maximum Residue Limits (MRLs) and should focus efforts to ensure its full implementation

Pesticide Maximum Residue Limits (MRLs) are based on field trials and toxicological data and are essential in ensuring safe consumer exposure to and protecting vulnerable groups from products containing pesticide residues. MRLs play a role in determining if the pesticide was misapplied. MRLs are also relevant in the context of international trade in food. COFEPRIS and SENASICA share responsibility of developing and implementing MRLs in Mexico. In 2017, Mexico adopted the Official Mexican Standard for Maximum Residue Limits, Technical Guidelines and Authorisation and Review Process (NOM-082-FITO/SSA1-2017). Prior to this, Mexico applied MRLs from Codex Alimentarius or the US EPA.

The adoption of the NOM is an important step for Mexico, as it introduced the possibility of granting authorisation also for national MRLs generated during field studies conducted in Mexico. The NOM also regulates the process of revision of MRLs, for instance based on dietary risk analysis conducted by COFEPRIS. NOM-082-FITO/SSA1-2017 is currently being implemented, which does not allow Mexico to fully benefit from the NOM, which resulted in no national MRLs established since 2017.

Recommendations

Mexico would benefit from better collecting, analysing and co-ordinating data on sales and uses as required under existing regulatory framework. Mexico would also benefit from comprehensive information on sales and additional information such as how the pesticides have been used, any adverse experiences, any issues with the compliance with directions for use as well as any observed impacts on the environment. Additional information would not only support the improvement of evidence-based decision-making on pesticides in their lifecycle, but would also help in countering the illegal trade of pesticides.

The process of collecting, managing and analysing this data must ensure respecting of confidentiality business information. It could be noted that certain complexities with collecting data can be expected in Mexico, taking into account the size of the country and the number and variation of the affected stakeholders (e.g. small farm enterprises). Therefore, it could be considered that additional data could focus on high risk areas and for instance be linked to training/licensing requirements when seeking access to certain chemicals, as discussed in General Policy Topics section.

Mexico can also benefit from implementing an incident reporting system similar to those of other national pesticide regulators from some OECD countries. Such a system would identify areas of risk in need of a regulatory response (for example, implementing specific restrictions and/or labelling) and support the comparison of incidents across a number of countries.

There is a need for Mexico to establish a systematic national environmental monitoring programme for pesticides, building on existing measures and initiatives (such as expanding the residue-monitoring programme to domestic food). It would support a timely identification and response to the misuse of pesticides, strengthen the work on pesticide resistance in Mexico and assure the public that the use of agricultural chemicals is conducted according to safety regulations. Such a programme would also provide valuable information that could be used to better target compliance and enforcement activities to those areas identified via the monitoring programme. Adopting a risk-based approach can improve the efficiency, as monitoring can focus on monitoring higher-risk pesticides and/or targeted agricultural areas. In this context, pesticides prohibited and or restricted by multilateral environmental agreements and those identified as imported in large quantities to Mexico could be the starting point for the scope of monitoring. Recommendation 82 of 2018 of the Mexican National Human Rights Commission should support the activities in this regard, as it called for adopting the National Programme of Monitoring Pesticides Residues and making the monitoring, contamination and poisoning information publically available. The Mexican authorities should also consider adopting binding national reference/limit values for the contamination of water and soil by selected pesticides.

Mexican authorities should focus efforts on the preparation of relevant regulatory procedures and guidelines to ensure the complete implementation of NOM-082-FITO/SSA1-2017. For instance, to allow accrediting laboratories that could undertake field studies in Mexico necessary to establish national MRLs and to provide clear guidelines to the industry on the MRLs evaluation criteria and approval. Mexico could also consider addressing import MRLs, not covered by NOM-082-FITO/SSA1-2017, in its regulatory framework, taking into account the need to provide an equal level of health and the environment protection for imported food products and ensuring a level-playing field for farmers in Mexico. The Mexican authorities should consider strengthening efforts to ensure that information on allowed MRLs in public available databases is up-to-date and systematically updated

Stakeholder engagement

Assessment

Formal channels to conduct public consultation when modifying existing or issuing new regulatory projects can be improved in practice

The Secretary of Economy heads the National Standardisation Programme that annually publishes the projects that will issue or revise technical regulation. This programme has several thematic subcommittees, for example the Subcommittee on Phyto-sanitary Protection. Each subcommittee includes members of the regulation addressed. Regulatory projects on these subcommittees are further divided in those listed for public consultation and those not listed. In 2019, there were three regulatory projects related to pesticides, all of them not listed for public consultation. In the 2020 programme, there are six regulatory projects related to pesticides, and only one has been listed for public consultation. Once the projects move forward to their respective committees, they are expected to be included for public consultation.

The National Commission for Regulatory Improvement (CONAMER) manages a Regulatory Impact Assessment (RIA) platform for regulatory emission and modifications. The RIA system directs the central government to assess costs and benefits in order to justify new regulation or modifying existent regulation.

Part of the RIA process includes a public consultation stage, where both the RIA and regulatory project are published in the CONAMER website to collect comments from the public.

However, Mexico has yet to fully reap the benefits of the RIA and public consultation systems in the pesticide sector, as some important changes to the regulatory framework have been introduced through the modification of legal instruments on Tax policy, which are exempted from RIA, and therefore have not undergone the process of public consultation.

Pesticide regulators can improve engagement with stakeholders about regulatory aspects, procedures, industry programs and environmental and health impacts

The pesticide industry is moving fast with new technologies and products entering the market constantly. Moreover, there are also regular updates on scientific evidence about the impacts of pesticides. A large number of stakeholders in different regions use pesticides, so having enhanced engagement and a closer communication with all of them can be very informative to develop sound policies. Having up to-date information on registered, prohibited and reduced risk pesticide products is also of great importance.

Recommendations

The standardisation process may benefit from introducing early consultation and increased transparency in how inputs from public consultation are taken into account. Early consultation is a practice adopted by some OECD country members, which involves practices such as research commissioned by the government or periodical discussions with stakeholders, before having a regulatory proposal. The standardisation committees subject the regulatory projects to public consultation once they are fully drafted, and approved by the relevant subcommittee. This, by mere design, limits the ability of the regulators to transform regulatory projects from public consultation inputs. Moreover, it may limit the scope of regulatory innovation, as it limits interaction with research centres, academia, international entities and industry experience.

By increasing the use of Regulatory Impact Assessment (RIA) and public consultation in the pesticide sector in Mexico, regulators can guarantee beneficial policymaking and regulatory certainty for all stakeholders. The use of RIA and public consultation are effective tool to ensure the net-benefits of regulatory reform. If the pesticide framework is to be updated, even if it is done through the modification of Tax related legal instruments, the use of RIA and public consultation will be a key regulatory improvement tool in the process.

Mexican regulators may benefit from having more dynamic and periodical engagement with stakeholders including industry, NGOs, academics, etc. This may come in the form of early consultations, periodical thematic discussions on key issues, from registration to environmental impacts. These communications have to be transparent and the government has to ensure consistency, so that all stakeholders are treated equally. As enhanced engagement can be resource intensive, the focus should be on a mechanism that can be implemented in the Mexican context.

International co-operation

Assessment

Mexico could further benefit from its international co-operation on pesticides management, notably from the co-operation under T-MEC (formerly NAFTA) and OECD umbrellas

Mexico co-operates on pesticides management directly with its trade partners, like with Canada and the United States under the T-MEC Agreement that replaced in 2018 the former NAFTA Agreement. Mexico is participating in the work of the OECD. Mexico also co-operates in other multilateral context. Some

examples include the implementation of the FAO/WHO Codex Alimentarius, relevant Multilateral Environmental Agreements, like the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (where FAO has recently supported Mexico in its pesticides management efforts), or the Stockholm Convention, which aims to protect human health and the environment from so-called Persistent Organic Pollutants.

In 2019, OECD adopted the Recommendation on Countering the Illegal Trade of Pesticides along with the Best Practice Guidance (OECD, 2019^[5]). This helps to support adherents in establishing or strengthening national procedures aimed at countering the illegal trade of agricultural pesticides and to boost co-operation in this area.

Mexico would benefit from increasing harmonisation with other countries

Mexico accepts studies and methodologies developed in line with the OECD Test Guidelines, FAO guidelines, the US EPA Testing Guidelines and the Analytical Methods developed by the Collaborative International Pesticides Analytical Council. In line with recommendations from the Mexican authorities, studies submitted should be conducted according to the OECD Principles of GLP.

The General Law of Ecological Balance and Environmental Protection already includes a provision that pesticides prohibited in other jurisdictions cannot be legally authorised in Mexico.

However, further efforts could be considered by Mexico to align its regulatory provisions with other countries, in particular countries which Mexico has trade agreements. It would support securing that Mexican farmers have access to similar products as farmers in other countries and it would have a positive impact on trade. Mexico could for instance reconsider, if the current regulatory deadlines allow undertaking evaluation of pesticides in a similar way as in its main trade partners and if the evaluation process itself allows for the full harmonisation of approach to pesticides evaluation, the alignment of processes and timelines in all three T-MEC partners.

Recommendations

International co-operation could be further strengthened to allow Mexico to fully benefit from opportunities it creates and to support addressing challenges that Mexico is facing in the area of pesticides management. For instance, while Mexico co-operates with Canada and the United States in the Technical Working Group on Pesticides (TWG) under the T-MEC Agreement, it could be enhanced to cover also the performance of joint evaluations of pesticides, where up to now Mexico could only participate as an observer. The 2014 modification of the PLAFEST Regulation enabled Mexico to undertake such joint evaluations, but this possibility has not been applied in practice until now. Mexico should consider to be actively involved in the OECD Rapid Alert System that supports the exchange of reports on suspicious or rejected shipments of pesticides between Adherents.

The Mexican authorities could also consider systematically requesting information on known restrictions or prohibitions of pesticides in other countries to support their decision-making on pesticides. In this context, the Mexican authorities could consider including a specific requirement to provide such information during the registration, modification and extension of a registration, as well as when requesting an import permit for pesticides.

Mexican regulators are independent in their decision making on pesticides, but would benefit from a better use of the pesticide evaluations undertaken by other countries and international organisations, as well as greater use of tools such as OECD dossier guidelines, harmonised data requirements, and electronic submissions.

Registration and post-registration processes

Assessment

There are areas of opportunity in the co-ordination between regulators to ensure an efficient registration process

The PLAFEST Regulation sets out the roles and responsibilities of COFEPRIS, SEMARNAT and SENASICA in the joint process of pesticides registration. Pesticides registration starts with the submission of the registration application to COFEPRIS. COFEPRIS then provides SEMARNAT and SENASICA with part of application that contains relevant information for their technical evaluation. Both authorities can ask COFEPRIS to request additional information from the applicant. After receiving this information (or if there is no information request) COFEPRIS requests technical opinions from SEMARNAT and SENASICA. COFEPRIS issues a resolution that could either be positive, which results in granting the registration, or negative, which results in rejecting the registration application. The PLAFEST regulation describes the data and information requirements and the timelines or respective registration activities.

Mexico has had co-ordination mechanisms for regulators dealing with pesticides management for many years, with the establishment of the first formal inter-institutional body in 1987.

Nevertheless, the actual co-operation between the authorities has not always been very effective. Several reasons could explain this situation. The main authorities may face competing policy objectives, goals and priorities impacting the extent of the co-operation between them. The very construction of the shared responsibilities under the PLAFEST Regulation could also be a hampering factor. While COFEPRIS is in theory ultimately responsible for granting the registration, in practice it is bound by the veto power of SEMARNAT and SENASICA. If any of these institutions uses its veto power, it has to be respected, and cannot be overruled by COFEPRIS. This limits the drive to work together to identify solutions and reach a consensus among all three regulators and highlights the need for all three regulators to harmonise approaches (e.g. risk management vs. hazard based) so that they can effectively work together. To improve the current situation, an Inter-Secretary Working Group on Pesticides Regulation, was established in 2019.

There is an additional challenge on the registration process timeline. Once the registration process initiates, COFEPRIS cannot place an application on hold pending the receipt of the information requested, beyond a maximum of 60 days, as regulated in the PLAFEST Regulation. If companies take a long time, the registration lag will be noted as the regulator's fault.

The pesticides registration process in Mexico requires significant human resources and time. For example, Mexico requires information to be provided by applicants in the traditional, "paper" format. Registration information is also shared between the authorities in the same way. Therefore, making the processing time slow and lengthier. As the resources available are limited and the co-ordination mechanisms do not always work, this has generated two types of problems. First, significantly longer processing times affecting the feasibility to respect the regulatory timelines for registration enshrined in the PLAFEST Regulation. Second, the possibility of sending conflicting information requests to the applicant.

There are benefits of revising the existing requirements for pesticides data requested at the registration stage

Each country is independent in determining the scope of data required for pesticides registration, reflecting its national circumstances, but the FAO/WHO (FAO & WHO, 2013^[6]) and OECD guidelines recommend certain types of data that can be required for this purpose, including guidelines specifically developed for bio-pesticides. The PLAFEST Regulation establishes data requirements in Mexico. It includes technical

data required for chemical pesticides (active ingredients and formulated products), for biochemical pesticides, microbial pesticides, botanical pesticides and miscellaneous pesticides for agricultural use.

Regulators in Mexico do not fully benefit from the use of Information and Communication Technologies to enhance the efficiency of the pesticides registration process

The PLAFEST Regulation describes the data and information a pesticide registrant must submit to COFEPRIS. In general, all the relevant documentation in the dossier has to be provided in a traditional, paper format. COFEPRIS shares with SENASICA and SEMARNAT only the information relevant to their responsibilities under PLAFEST, also in paper format. If SEMARNAT and SENASICA request COFEPRIS to access additional information from the registration dossier, the same process applies.

The current system affects the efficiency of the co-operation among the regulators on pesticides registration, which could be affecting regulatory timeliness defined by the PLAFEST regulation, as well as the communication between the regulators and the regulated entities. It also creates unnecessary burden for registrants. The digitalisation of the pesticides registration process has already happened in many OECD countries, for instance in Canada and the EU. An example is the work undertaken under the OECD Pesticides Programme on the Globally Harmonised Submission Transport Standard (GHSTS), a standardised set of technical specifications used to assemble electronic files for any pesticide package in a predefined manner (OECD^[7]).

The current pesticide regulatory framework lacks well-established criteria to justify registration decisions, there is room to improve uniformity and coherence on evaluation criteria, as well as for issuing relevant guideline material”.

Mexico has a pesticide classification (the Official Technical Standard NOM-232-SSA1-2009) that classifies toxicity based on the WHO pesticide toxicity criteria. The Mexican General Health Law states that the use of persistent and bio accumulative pesticides can only be authorised if they are not dangerous for human health and it is not possible to replace them with less hazardous ones. However, Mexico does not have a clear definition and criteria for registration decisions (i.e. it does not refer, in principle, to unacceptable risk nor define it), e.g. NOM-232-SSA1-2009 does not specify when the risk is considered unacceptable and a registration should not be granted or be granted with restrictions. The lack of clear definitions and decision criteria make the system less transparent and it can lead to inconsistencies in decision-making.

The PLAFEST Regulation contains detailed information on the information required by the authorities to evaluate a pesticide registration dossier. It also stipulates the regulatory timelines of the registration process. The Mexican authorities reach their decision solely based on the text of the PLAFEST Regulation.

However, apart from the text of the PLAFEST Regulation, stakeholders in Mexico do not have at their disposal additional information that would allow them to better understand how the Mexican authorities reach their decision. In fact, they signal the lack of consistency of conclusions for similar registration requests. To address this, pesticide regulators in other countries prepare guidance documents that include scientific or technical criteria supporting relevant decision-making. Development and adoption of international guidelines would also benefit international work-sharing and potentially faster access to new pesticides.

There is a room for improvement in addressing post-registration phase in the Mexican regulatory framework on pesticides

The General Law of Health stipulates that a pesticide registration is valid for five years. Registrants have to request a registration renewal before the five-year period expires. The renewal procedure, regulated by the PLAFEST Regulation, is simplified and short, only limited information is requested from the registrant at the renewal stage. According to the regulatory framework, a lack of response from the authorities is

considered as favourable for the applicant's request (*afirmativa ficta*), although this is not implemented automatically.

The renewal provisions apply only to pesticides registered after 2005. All pesticides registered before this date, estimated to be the majority on the market, benefit from indefinite registrations. Unlimited registration periods for existing pesticides could potentially create a disincentive to develop new and more environmentally friendly pesticides, as those new pesticides would have to undergo an evaluation.

Pesticide registration in Mexico can be revoked, if it becomes known that authorised products constitute a risk to human health. However, this power has not been applied very often in the past. One of the reasons is that as the registration is considered an acquired right, it cannot be revoked without the registrant consent. Moreover, a potential risk presented by a pesticide is not enough at the moment to cancel registration. Further risk assessment is needed to evaluate potential risks. If renewal is not requested, or the registrant changes or modifies the product or raw material without authorisation, registration is cancelled. Effective monitoring and compliance enforcement of these provisions requires adequate resources.

Mexico currently does not have a systematic process of re-evaluation of pesticides in place. During the registration renewal process, registrants do not provide updated information on the safety of the registered pesticides, its use and impact. Such information would support the Mexican efforts to timely address human and environmental pressures from pesticides. It could also support improving the current registration cancellation process.

Under the current regulatory framework, obtaining an import/export permit on a yearly basis is necessary for all registered pesticides. This adds a layer of complexity to the system. Having in place a systematic review programme for pesticides might permit Mexico to consider streamlining the registration and import permits provisions.

There is a need to strengthen the Mexican institutions involved in pesticides management.

The on-going process of a comprehensive review of the legal and regulatory framework for pesticides management in Mexico can potentially lead to the introduction of further activities for the authorities in order to address existing gaps and improving the system. They could for instance relate to the post-registration phase, addressing new technologies and products or strengthening compliance and enforcement of the regulations. This suggests that additional resources will be needed to allow the authorities to discharge their duties, including monitoring, effectively.

At the same time, the available policy documents, including the Recommendation 82 of 2018 of the Mexican National Human Rights Commission, as well as feedback from the Mexican stakeholders, indicate that the insufficient availability of resources is an ongoing issue. Some of the authorities indicate that they do not have the necessary human or technical resources to verify the quality of pesticides or to address new pesticide technologies or products, such as biopesticides or pesticide application by drones. Rotation of qualified technical staff affects learning curve and institutional memory.

Recommendations

Mexico would benefit from enhancing the co-ordination between the regulators on registration, such as streamlining the responsibility for granting registration (that could be linked to the potential streamlining of the institutional framework discussed in the General Policy Topics section) or establishing a cross-agency mechanisms for communication and the management of submissions. The regulatory timelines pressure could be eased by enhancing a “stop-the-clock mechanism” when requesting additional information from the applicants that would allow reflecting the time needed to prepare such information. Introducing an optional pre-screening mechanism in the registration process to ensure the completeness of submitted information (that it includes all required elements) and with a goal to improve the quality of applications

entering the regulatory process to follow and making it more efficient, could also be considered. This tool can be useful in signalling at an early stage (before the formal registration process starts and therefore without affecting regulatory timelines) that some required information is missing. To ensure that such a mechanism fits for purpose and does not become an additional burden, it needs to be transparent, well documented, have clear requirements and be time-limited.

The digitalisation of the registration process would support the efficient and resource-wise use of an optional pre-screening mechanism. Digitalisation can also allow cross-agency mechanisms for communication on relevant ministries policies and priorities and on the cross-agency management of submissions so that these submissions could navigate through the registration process in a more co-ordinated manner could be beneficial for the ongoing efforts. Mexico should consider moving away from a paper registration process to a secure on-line registration and exchange of information system. It would ensure that regulatory work can continue in every condition and it would allow for a fast and secure access to and sharing of registration information among the involved authorities. It would facilitate not only regulatory work, but also the information submission process for industry and the access to updated information for the public, for instance by providing timely information on the status of registrations. Greater use of ICT would also benefit international work sharing and potentially faster access to new pesticides.

Mexico could consider undertaking an in-depth analysis of their registration data requirements versus data requirements in FAO/WHO's Guidelines on data requirements, the OECD Dossier Guidance (OECD^[8]) and in its main trade partners, to verify to what extent Mexico's requirements (including those for bio-pesticides) are aligned with these data requirements and where further harmonisation could be achieved. This would support authorities in receiving, under the pesticides registration process, comparable information as it is required in other jurisdictions. It should also provide the Mexican authorities with information that would help them to perform risk evaluation of pesticides. It could be noted that where authorities accept data packages submitted to other regulators (e.g. using the OECD numbering system) this would benefit international work sharing and potentially faster access to new pesticides.

Mexico could also consider how to better reflect a risk proportionate approach under the registration process, for instance in relation to flexibility of data requirements for specific types of lower risk pesticides (e.g. bio pesticides) to support their greater uptake. In particular, it could consider taking a tiered approach to the request for data/studies, which would result in lower risk pesticides not needing to submit a large amount of data to be reviewed by the regulator. The tiered approach to the assessment of exposure and hazard involves a framework where each tier is more refined than the previous tier. As the tiers of assessment increase, because the effort to perform the assessment generally increases, the data required to support the refinements also increases.

Mexico should consider defining more clearly the criteria used for registration decision-making in its regulatory framework, for instance define what is considered an unacceptable risk. In its review Mexico could take into account its resources in terms of evaluation and enforcement, as well as its approach to decision-making for registration (hazard-based vs risk-based). The FAO Registration Toolkit, in particular the module on registration criteria, is a useful resource for such considerations. It could also consider introducing specific provisions for pesticides subject to international agreements, allowing for their simplified adoption in the national regulatory framework, therefore supporting their phasing out and avoiding duplication of effort and resources at national level (FAO, n.d.^[9]). This would help Mexico to concentrate its efforts and available resources on the pre-market assessment of pesticides, as well as in the post-market compliance and enforcement. Moreover, it could also support Mexico in ensuring that only pesticides with risks to human health and environment found to be acceptable (and/or subject to adequate conditions for use) are registered, in line with Recommendation 82 of 2018 of the Mexican National Human Rights Commission (NHRC) on non-compliance with the obligation to restrict the use of highly hazardous pesticides.

In this respect, Mexico would benefit from more clarity on the approach and scope of the evaluation done by each agency and to support consistency of their decisions. To enhance the transparency of the decision-making process on pesticides, Mexico should provide more information on scientific or technical criteria to support relevant decision-making in relation to the registration of pesticides. It should consider preparing guidelines in this respect.

Where it might be difficult to provide general guidance, as some types of products (e.g. bio-pesticides) might need to be regulated more on a case-by-case basis, the Mexican authorities could consider establishing a routine pre-submission process/consultation between the authorities and the registrant.

It is important that Mexico consider the establishment of a systematic review programme for pesticides, that would ideally take into account information from monitoring activities, adverse experiences, international developments and include clearly defined triggers for when a full review and regulatory action is needed. Such a review programme should also address pesticides with an unlimited registration period, as no updated safety information is requested for them now. Establishing this systematic review would contribute to the life-cycle management of pesticides. The programme should be functional within the context of the existing challenges the Mexican system is looking to address and build on the experience of similar programmes in other jurisdictions to ensure that challenges faced there are not recreated. For instance, it could consider risk-proportionate approach to registration renewal timeframes. It is worth noting in this context that the EU applies different renewal timeframes depending on the risk of pesticides (European Parliament, n.d.^[10]). Such approach allows for better prioritisation and allocation of resources. The regulatory streamlining effort in Mexico should also include an evaluation of the registration and import permits provisions.

Mexico should consider increasing efforts to ensure that authorities have better infrastructure and there are adequate skills, expertise and capacity within each of the regulatory authorities involved. The existing annual training programmes for employees should be enhanced to enable regulators to better address the current and future needs, for instance linked to the introduction of new technologies and new products. Moreover, Mexico could consider performing an assessment of the implementation costs of its regulatory framework on pesticides to equip policy makers with appropriate information on the needs in the area of human, financial and technical resources. In this context, Mexico could also consider further efforts to better leverage international co-operation (e.g. via T-MEC Agreement) and the work of other organisations such as the OECD, as well as to look for ways to leverage the decisions of other like-minded regulatory authorities.

Regulatory compliance and enforcement

Assessment

Mexican regulators do not have a common enforcement strategy and a transparent, multi-annual plan with goals to have an adequate monitoring of regulatory enforcement

Effective compliance and enforcement strategies are essential to monitor the adequate implementation of the pesticides regulatory framework, and to address consumer safety, detect misuse of pesticides and address the illegal trade of pesticides. While implementing a whole-life cycle approach to pesticide regulation, evidence-based enforcement is key to achieve health and environmental objectives. However, there are areas of opportunities on regulatory enforcement that can be hindering the fulfilment of pesticide policy's objectives.

A challenge in regulatory compliance and enforcement in the area of pesticides management in Mexico is that roles and responsibilities are fragmented and scope to be covered is wide, creating competing priorities and complexity. There is no common enforcement strategy in Mexico, as enforcement activities

are decided by each of the authorities separately. Recommendation 82 of 2018 of the Mexican National Human Rights Commission pointed out the need to adopt such a common strategic action plan, addressing clearly responsibilities on monitoring, control and compliance with the regulatory framework. There is limited evidence of risk-based inspection plans to reduce highest risks while being resource efficient.

Increased uptake of the Information and Communication Tools (ICTs) in preparing, conducting and reporting from the inspections might bring efficiency gains. Moreover, it might also be feasible to evaluate the effectiveness of the inspection efforts, which is currently challenging for the Mexican authorities. An improved data collection and risk-based analysis strategy might help pesticide regulators understand patterns of pesticide misuse. Additional compliance promotion strategies might reduce the use of unregistered, unregulated and illegal products.

Enforcement need to be strengthened to effectively stop the use of unregistered, unregulated and illegal pesticides

The General Law of Health prohibits the use of illegal and unregistered pesticides, and includes both a criminal sanction of up to 8 years of prison and a monetary fine of up to two thousand days of minimum salary equivalent. The Federal Plant Health Law obliges federal authorities to establish co-ordination mechanisms to implement pesticide regulatory framework. There is co-operation on enforcement between the main authorities for pesticides, for instance in relation to the notification of infringements.

However, many Mexican stakeholders underline the urgent need to address ever-growing issues with the use of unregistered, unregulated and illegal pesticides, as well as with the quality of registered pesticide products used. At the same time, as in many places in the world, the compliance and enforcement activities in Mexico are negatively impacted by decreasing available resources. There is a critical shortage of technical staff conducting inspections and supervising tasks for the pesticide regulations.

Mexico has a broad range of technical regulations (NOMs) on pesticides and a well-developed and inclusive process for their development, however their consolidation and improvement of their implementation could be beneficial

As highlighted in the 2020 OECD “Implementing Technical Regulations in Mexico”, the country has put in place a strong framework around technical regulations, known as NOMs, with numerous actors involved in their implementation, including public sector bodies, technical entities and businesses. Mexico has more than twenty NOMs regulating various aspects of pesticides management.

Recommendations

Mexico could benefit from adopting the OECD best practice principles on regulatory enforcement and inspections (OECD, 2018^[1]) and from the OECD Pesticides Programme work on compliance and enforcement (OECD^[11]). Regulators can improve enforcement efforts by adopting a common, integrated compliance and enforcement strategy. This includes enhancing co-ordination mechanisms by digitalising and sharing information records between agencies, with all necessary privacy and risk precautions.

Moreover, the preparation of publicly available multi-annual inspection plans with clearly set enforcement goals and objectives should help to improve regulatory compliance and enforcement in the medium- and long-term and send transparent signals to the regulated entities. The formulation of these plans can take into account key improvements such as risk proportionality, and professionalism of inspectors.

Mexico should consider performing the analysis of the human, financial and technical resources needed to effectively implement its existing pesticides management framework and reflecting the on-going comprehensive review of the legal and regulatory framework on pesticides in Mexico.

Increased co-ordination efforts might lead to staff and budget benefits for the authorities involved, but they might require formalisation of co-operation, for instance via Memorandum of Understandings between the regulators. Scheduled joint inspections could allow for a comprehensive and co-ordinated approach to the regulated entities, at the same time reducing their administrative burden.

Mexico could consider undertaking a comprehensive review of the pesticides-related procedures regulated by NOMs to consolidate the binding provisions in a more limited number of NOMs and therefore support the overall regulatory clarity and its understanding by stakeholders. This would also allow Mexico to standardise the provisions and to better reflect the developments in the area of pesticides application, for instance the increasing use of drones. Addressing this issue is of great importance in the context of the expected transition to lower risk technologies and giving priority to products with lower risk. As part of this process, authorities should complete work on the unpublished Mexican NOM (NOM-003-STPS-2016) regulating occupational health and safety of the use of pesticides.

Moreover, the lack of cohesive and coherent vision affects the implementation and promotion of compliance of NOMs. As an example, a NOM on pesticide MRLs adopted in 2017 is not fully operational yet. Developing a coherent, risk and evidence-based approach to regulatory inspections that focuses on managing and targeting resources and improving co-ordination and data sharing among agencies involved, can strengthen regulatory delivery of NOMs.

Responsible use of pesticides

Assessment

There are commendable efforts on training on Good Agricultural Practices (GAP) and Personal Protective Equipment (PPE), however there is a need to make these efforts more systematic and wide-reaching

This is an area of shared responsibility among all stakeholders (government, pesticide industry, suppliers and users). Industry-led awareness campaigns on the correct and safe use of pesticides have a long tradition in Mexico, for instance through the Good Use and Management of Agrochemicals (CUIDAGRO-BUMA) programme. Its activities are co-ordinated with local and federal authorities (in particular SENASICA), as well as with other stakeholders, including academia. The Mexican authorities also disseminate information and guidance material on good practices and the safe use of pesticides. For instance, in 2019, SENASICA published a Manual of Good Use and Management of Pesticides in the Field (SENASICA, 2019^[12]), describing the concept of the Integrated Pesticides Management (IPM) and addressing several relevant topics of Good Use and Management of Pesticides. The use of Personal Protective Equipment is regulated by the Mexican Official Standard dealing with work and safety conditions in the workplace.

However, there seems to exist a significant regional disparity on the efficacy and prudential use of pesticide technologies throughout Mexico. Export-oriented large-scale farmers seem also to have the best pesticide practices in place. Moreover, available monitoring and enforcement data suggests that more efforts are needed to control the use of pesticides throughout Mexico.

The strategy to address empty pesticide containers has not been fully effective and Mexico needs further efforts in this area

Empty pesticide containers should be properly managed in order to avoid negative consequences to human health and the environment. In line with the General Law on Prevention and Integral Management of Waste, Mexico considers them as hazardous waste. It is required that information on the triple rinsing

of the empty containers should be included on the product label. Mexico has a system of primary and temporary collection centres and authorised recycling centres. The formal Management and Collection of Empty Containers Plans are being adopted at state level. As in many OECD countries, industry co-operates with the authorities by disseminating information on triple rinsing, collection of empty containers and their final disposition among the Mexican stakeholders, for instance through its “Campo Limpio” programme, co-managed with SENASICA.

Nevertheless, further efforts are needed, as it is estimated that each year in Mexico some 50 million empty pesticide containers (SAGARPA, 2015^[13]) are being disposed and many of them are abandoned in the fields. Additional financial and human resources are needed to increase the promotion, coverage and enforcement of actions dedicated to empty pesticide containers. It is estimated that only 10% of the amount needed to cover the yearly costs of the collection of empty containers is available for the Mexican authorities. While Mexico has in place an inventory of obsolete pesticides, it has only limited information on the holders of small amounts of obsolete pesticides.

Recommendations

Mexico could consider enhancing joint stakeholders’ efforts to increase the amount, scope and reach of the training provided to the farmers, in particular in relation to Good Agricultural Practices (GAP) and Personal Protective Equipment (PPE), as well as good practice in relation to bio-pesticides.

Further incentives, led by government with co-operation of stakeholders, to increase the scope of participation (currently not obligatory) of Mexican companies in the management and collection of empty pesticide containers should be considered, in order to establish a level-playing field. Moreover, the Mexican authorities should analyse the feasibility of including bio-pesticides in the collection of empty pesticide containers scheme.

Mexico could also consider developing a more comprehensive inventory of obsolete pesticides to support its actions in the area of empty pesticide containers.

Notes

¹ See Chapter 1 for an extensive review of the pesticide regulatory framework in Mexico.

² Chapter 1 provides further information on the evolution of the Mexican legal and regulatory framework on pesticides.

³ The life-cycle regulatory approach in this report in principle includes manufacturing, distribution, storage use, and container recycling and disposal (OECD, 2012^[14]).

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