Regulatory Governance in the Pesticide Sector in Mexico

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Foreword

Laws and regulations are one of the key levers governments can use to improve the wellbeing of societies, alongside fiscal or momentary policy. But governments need to ensure that laws and regulations are fit-for purpose and effective in achieving their goals such as protecting human health and the environment. To this end, the *OECD 2012 Recommendation of the Council on Regulatory Policy and Governance* recommends that policy makers and public officials "conduct systematic programme reviews of the stock of significant regulation against clearly defined policy goals, including consideration of costs and benefits, to ensure that regulations remain up to date, cost-justified, cost-effective and consistent and delivers the intended policy objectives".

This report on *Regulatory Governance in the Pesticide Sector in Mexico* identifies the gaps, barriers, implementation flaws and inefficiencies that affect the regulatory framework of pesticides in Mexico. In particular, it takes stock of the regulatory framework and recent reforms in pesticides in Mexico and identifies the areas that pose the greatest challenges for effective regulation of these products as well as those in which the regulation – or the absence thereof – affects policy objectives and economic activity the most. These framework and practices are assessed against OECD principles in regulatory policy and pesticide regulation, and country experiences from Australia, Canada, the United Kingdom and the United States, and recommendations are provided to continue the reform efforts.

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, in collaboration with the Chemicals and Biotechnology Committee. The report was consulted for comments with an wide range of stakeholders in Mexico and internationally, including authorities, experts and private representatives in the areas of human, vegetable, animal and environmental protection, and regulatory improvement. It was reviewed by the OECD Regulatory Policy Committee in 21 April 2021 and of the OECD Chemicals Committee on 9 of June 2021, and later approved and declassified by the two committees and prepared for publication by the Secretariat.

The information used for the preparation of this report came from four main sources: desk research conducted by the OECD Secretariat, a questionnaire answered by key stakeholders information submitted by international experts to prepare the country case studies, a virtual fact-finding mission during September and October 2020 with Mexican government agencies, NGOs, academics and industry associations, and a virtual policy workshop which took place on 2 February 2021. It is to be noted that most of the work was done during the COVID-19 pandemic, which had repercussions on logistics and availability of stakeholders. Statistics and figures gathered as part of the desk research came predominantly from official sources, and from recognised international organisations.

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This study was prepared by the OECD Public Governance Directorate (GOV) under the leadership of Elsa Pilichowski, Director, and Nick Malyshev, Head of the Regulatory Policy Division; and the OECD Environment Directorate (ENV) under the leadership of Rodolfo Lacy, Director, and Bob Diderich, Head of the Environment, Health and Safety Division. This report was co-ordinated by Manuel Gerardo Flores Romero from GOV, as well as Sylvie Poret and Richard Sigman from ENV, and prepared by Alberto Morales (GOV), and Rafal Brykowski (former ENV). Inputs were provided by Erik Pérez (GOV). The report was prepared for publication by Jennifer Stein.

International peers with unique experience in pesticide regulation and regulatory policy provided instrumental advice to this review. The OECD Secretariat is very grateful for the invaluable inputs provided by Peter Brander, Executive Director, Pest Management Regulatory Agency, Health Canada; John Dale, Active Substances and Operational Policy Team Leader, Chemical Regulation Division, Health Safety Executive of the United Kingdom; Monika Ollig, Better Regulation Unit, Federal Chancellery of Germany. We also want to thank Eva Bennet, former vice chair of the OECD Working Party on Pesticides and former CEO of the Australian Pesticides and Veterinary Medicines Authority, who acted as an independent expert for this report. The Environmental Protection Agency from the United States provided valuable insights for Chapter 3 and valuable commentary on a preliminary draft.

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Critical insights were also received from Mexican authorities, as well as other stakeholders that helped inform the preparation of this review, particularly from: Federal Commission for Sanitary Risks of Mexico (COFEPRIS); National Water Commission of Mexico (CONAGUA); National Commission of Regulatory Improvement (CONAMER) of Mexico; the General Direction for Technical Regulation and the General Direction for Trade Facilitation of the Ministry of Economy of Mexico; Mexican Association of Bio Inputs Producers (AMPBIO); Food and Agriculture Organization of the United Nations (FAO); Environmental Protection Agency of the United States (EPA); Carlos Santos-Burgoa, Professor of Global Health at George Washington University; Martha Farkas, Pest Management Regulatory Agency, Canada.

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Abbreviations and acronyms

AGVET	Agriculture and veterinary chemicals – Australia
APVMA	Pesticides and Veterinary Medicines Authority – Australia
COFEPRIS	Federal Commission for Protection against Sanitary Risks – Mexico
CONAGUA	National Water Commission of Mexico
CONAMER	National Commission for Regulatory Improvement – Mexico
EPA	United States' Environmental Protection Agency
FAO	United Nations' Food and Agriculture Organization
FPHL	Federal Plant Health Law – Mexico
GLBR	General Law of Better Regulation – Mexico
GLE	General Law of Ecological Balance and Environmental Protection – Mexico
GLH	General Law of Health – Mexico
ICT	Information and Communication Technologies
INEGI	National Institute of Statistics and Geography – Mexico
MOSP	Management of Submissions Policy
MRL	Maximum Residue Limit
NHRC	National Human Rights Commission – Mexico
NOM	Mexican Official Standard
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals of
OECD	Organisation for Economic Co-operation and Development
PCPA	Pest Control Products Act – Canada
PCPR	Pest Control Products Regulations – Canada

PLAFEST	By-Law for Pesticide Registration, Import Authorisation, and
PM&C	Department of the Prime Minister and Cabinet – Australia
PMRA	Pest Management Regulatory Agency – Health Canada
RIA	Regulatory Impact Assessment
RPF	Regulatory Performance Framework
SADER	Secretary of Agriculture and Rural Development – Mexico
SALUD	Secretary of Health
SEMARNAT	Secretary of Environment and Natural Resources
SENASICA	National Service of Agrifood Health, Safety and Quality
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

Having a clear, efficient, and modern regulatory framework for pesticides is essential for addressing their impacts on human health and the environment, and to supporting a life-cycle approach to their management, while ensuring crop protection and a sustainable agricultural industry. This report conducts a broad review of the state of pesticide regulation in Mexico and provides recommendations for improvement.

Mexico has a comprehensive regulatory framework in place for addressing issues throughout the pesticide value chain. However, it is governed by a number of different laws and technical regulations, and managed by various authorities. The three most relevant authorities 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.

The lack of an integrated life-cycle regulatory approach to pesticides management in Mexico poses a major challenge. In the last few decades, Mexico has addressed various issues of the pesticide regulatory framework in an *ad* hoc way instead of designing a regulatory system that effectively and efficiently covers the whole life-cycle of pesticides. Moreover, better collection and access to data on pesticides would support the life cycle management and help address the illegal trade of pesticides.

Another challenge involves recurrent delays in the registration of pesticide products. The regulation sets out the respective roles and responsibilities of COFEPRIS, SEMARNAT and SENASICA in the joint process of pesticides registration. After receiving the information, COFEPRIS requests technical opinions from SEMARNAT and SENASICA. 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 cannot be overruled by COFEPRIS. This limits the incentive to work together to identify solutions and reach a consensus among all three regulators and highlights the need to harmonise approaches.

There are also areas for improvement around regulatory compliance and enforcement activities Mexico's pesticide sector. Effective compliance and enforcement strategies are essential to monitor the adequate implementation of the regulatory framework for pesticides and to ensure consumer safety, detect misuse and address the illegal trade of pesticides. Mexican regulators in this sector lack a common enforcement strategy and a transparent, multi-annual plan with specific goals for monitoring regulatory enforcement. Furthermore, roles and responsibilities are fragmented and the scope to be covered is wide, creating competing priorities and complexity. Other concerns include the widespread use of illegal and unregistered products, and insufficient funding for enforcement and evaluation of products.

Main recommendations to improve pesticide regulation in Mexico

- Mexican authorities would benefit from adopting a comprehensive, mutually agreed policy strategy for pesticides; 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.
- An on-going comprehensive review of the legal and regulatory framework for pesticides management in Mexico could include streamlining, simplifying and consolidating the existing frameworks as one of its objectives.
- Mexico should consider restricting the sale of certain pesticides only to persons who are trained or certified for their proper use and reintroduce national certification in this field.
- There is a need for Mexico to establish a systematic national monitoring programme for pesticides, building on existing measures and initiatives (such as expanding the residue monitoring programme to domestic food).
- The standard development process of rules may benefit from introducing early consultation and increased transparency in how inputs from public consultation are taken into account.
- International co-operation could be further strengthened to enable Mexico to fully benefit from the opportunities it creates and to support addressing the challenges that Mexico is facing in the area of pesticides management.
- 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.
- Mexico would benefit from enhancing co-ordination among regulators on registration, such as streamlining the responsibility for granting registration or establishing a cross-agency mechanism for communication and the management of submissions.
- Digitalising the registration process would support an efficient use of resources, including during an optional pre-screening mechanism to check the completeness of dossiers for pesticides products registration.
- Mexico could also consider how to better reflect a risk proportionate approach in the registration process, for instance in relation making data requirements more flexible for specific types of lower risk pesticides (e.g. bio-pesticides) to support their greater uptake.
- Mexico should consider establishing a systematic review programme for pesticides, which should also address pesticides with an unlimited registration period.
- 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, to improve evaluations of new products and to conduct inspections.
- The preparation of publicly available multi-annual inspection plans with clearly set enforcement goals and objectives should help to improve regulatory enforcement in the medium- and long-term and what is expected of the regulated entities
- Mexico could consider enhancing joint stakeholders' efforts to increase the amount, scope and reach of the training provided to farmers, in particular in relation to Good Agricultural Practices (GAP) and Personal Protective Equipment (PPE).

1 The context of regulation of pesticides in Mexico

This chapter provides an economic and regulatory overview of the pesticide sector in Mexico. The chapter starts by reviewing recent trends on production, sales and international trade of pesticide and agriculture products. The next section outlines the role that a number of agencies have on regulating the Mexican pesticide sector, and it analyses the use of regulatory improvement tools for pesticide policy.

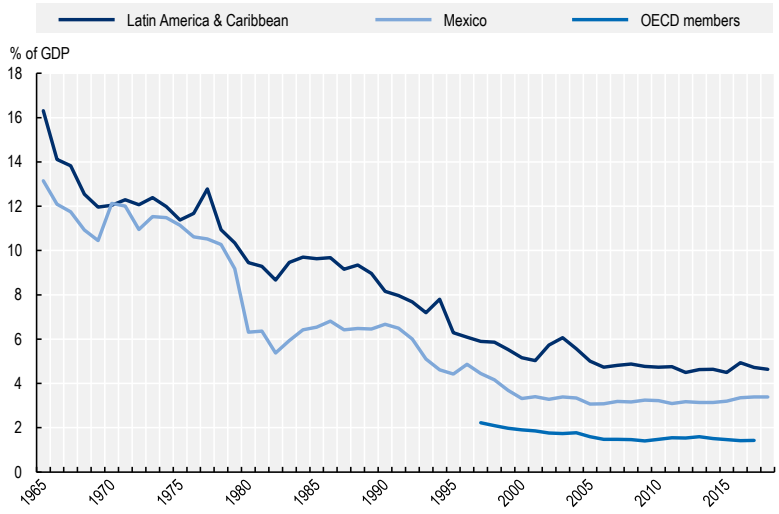
Economic activities related to pesticides in Mexico

Mexican agriculture at a glimpse

The agriculture industry in Mexico has had a small share of GDP for the past two decades

Agriculture's share of GDP declined from 4.4% in 1995 to 3.4% in 2017 (OECD, 2019[1]). The agriculture, forestry and fishery industries represent 3.39% of GDP in Mexico, lower than the Latin-America average at 4.64%, but higher than 1.4% of the OECD member countries (World Bank, n.d.[2]). Agriculture in Mexico, as a percentage of GDP, saw a sharp decrease from the 1960s to the mid-1990s and has been steady since (see Figure 1.1). This was also true of the Latin America & Caribbean (LAC) region. During this period, Mexico had a swift shift to the manufacturing industry. Despite the decreasing share of agriculture GDP, the market volume of the sector has seen a consistent growth for decades. In 2018 the GDP for the agriculture, forestry and fishery sectors in Mexico was valued at USD 41.3 billion[1] up from USD 31.7 billion in 2011.

Figure 1.1. Agriculture share of GDP



Source: Adapted from (World Bank, n.d.[2]).

Over the last two decades, the percent contribution of the agricultural sector to the workforce changed significantly, from 23% of the total workforce in 1995 to 13% in 2017 (OECD, 2019[1]). Still, over 11% of the working population in Mexico (6 million out of 52.9 million) is employed in agricultural activities, which includes small farmers and temporary workers. A further 780 000 work in livestock production and 170 000 in fishing and aquaculture. Mexico ranks 18th in the world in the total employment in these three sectors combined (SIAP, 2018[3]).

The largest agricultural products in Mexico include sugar, corn, and wheat; most of the production comes from medium and small producers.

Recent data on Mexican crops can be found in Table 1.1. In 2018 the main *annual* crops in Mexico were white corn (23 million tonnes) and yellow corn (8 million tonnes). The largest *perennial* crop was sugar cane (56 million tonnes). Regarding the industry structure, the Mexican agriculture market is not fully industrialised; in fact, most of the crops are cultivated by small and medium producers. This is especially the case for white (87%) and yellow (90%) corn, as well as for sugar cane (90%). Given the lack of

economies of scale, the agriculture sector has a relatively low rate of technology adoption and land productivity (see Table 1.2). In all categories including cereals, fruits and vegetables, Mexico has crop yields well below the United States.

Table 1.1. Main crops in Mexico (2018)

All figures in annual tonnes produced

	Annual Production	Large* Producers	Medium and Small Producers		Annual Production	Large* Producers	Medium and Small Producers
Annual crops				Perennial crops			
White corn	23 142 203	13%	87%	Sugar cane	56 354 945	10%	90%
Yellow corn	8 071 840	10%	90%	Orange	2 869 798	10%	90%
Wheat grain	3 214 047	27%	73%	Banana	2 220 400	21%	79%
Tomato	3 008 036	54%	46%	Mango	1 689 839	14%	86%
Chile	1 985 222	33%	67%	Lemon	1 110 840	23%	77%
Bean	1 308 282	8%	92%	Coffee	858 039	2%	98%
Onion	1 051 023	36%	64%	Apple	377 251	19%	81%
Zucchini	740 011	27%	73%	Grape	317 643	57%	43%
Soy	261 248	51%	49%	Strawberry	256 072	38%	62%
Rice	134 524	30%	70%	Cacao	45 377	0.3%	99.7%

* The criterion to divide large producers from small and medium is the threshold of annual sales of one million pesos (~USD 53 000). This definition comes from the 2007 Census and has only been updated in terms of the producers selling more than the threshold (not the threshold or any criteria) (INEGI, n.d.[4]).
Source: Own calculation using data from (INEGI, n.d.[4]).

Table 1.2. Crop Yields 2017

Units: hg/ha

	Cereals	Citrus fruit	Fruit primary	Roots and tubers	Vegetables
Mexico	37 997	142 034	153 007	285 105	220 053
United States	82 808	242 849	228 028	451 105	341 330
North America	74 007	242 849	217 804	316 926	332 432

Source: Adapted from (FAO, n.d.[5]).

Agricultural production in Mexico is scattered throughout the territory

Agriculture, and thus the use of pesticides, is intensive in most of Mexico, except in the north-north-eastern region. Plotting a total of 6 432 484 of land properties, INEGI categorised the amount of cropped hectares of all crops). Information is also available by specific crop. The regions with the most crops are found in Sinaloa (North West), Chihuahua (North West), Tamaulipas (North East), Zacatecas-Durango (Centre), Veracruz (Centre East), and Oaxaca and Chiapas (South).

The proportional land use for agriculture is declining in the majority of the OECD countries, and this rate of decline accelerated from 2002-14; however, Mexico is an exception, together with Chile, Estonia, Finland, Greece, Ireland, Latvia, Luxembourg and the United States (OECD, 2019[6]).

A lack of market information is a central shortcoming for both the pesticide and agriculture industries in Mexico. INEGI has carried out agricultural census (*Censo Agricola, Ganadero y Forestal*) in 1991 and 2007. At the time of the second census, it was expected that such census would be updated every ten years. However, due to a lack of funding, the census has not been updated since. The lack of microdata

is a serious obstacle for an in-depth industry analysis. Most of the data comes from the *Encuesta Nacional Agropecuaria* (ENA), which has been conducted in 2012, 2014 and 2017. This survey has limited representativeness of the Mexican market and less data indicators than the census.

The *Monthly Survey of the Manufacturing Industry* conducted by INEGI has aggregated data on trade volume and prices of pesticides. But, it does not include any further information (categorised by regions, intended use within the agriculture sector, etc.). This survey is only carried out with a limited number of establishments, which makes it difficult to examine the actual size and dynamics of the industry. Most of the foreign trade data comes from the database of the Secretary of Economy, but it's only annually aggregated.

International trade is an important driver of Mexico's economy. It represents 36% of GDP and it grew by 12 percentage points over the last 20 years. Agro-food trade is a key player in terms of total trade, both in terms of exports and imports. Mexico is the third largest agricultural and food exporter in the region (USD 32.5 billion in 2017), after Brazil and Argentina, and is among the major importers of maize, soybeans, dairy, pork and poultry. In 2016, Mexico, after almost four decades of continuous agrofood trade deficits (except during the Mexican crisis of 1985-87), became a net exporter of -agrofood- products (OECD/FAO, 2019[7]).

Organic agriculture

The existing policy framework supports developments in organic production in Mexico. For example, Mexico has a national plan to promote organic production. An integrated organic management strategy for citrus fruits was developed in Mexico in 2011. The Participatory Guarantee Systems (locally focused quality assurance systems, 7 existing and one in development) are recognised under the national legislation in Mexico (Willer and Lernoud, 2019[8]). Mexico has also in place the 2006 Law of Organic Products and implementing regulation.

In 2017, Mexico had one of the largest number of organic producers in the world – 210 000 (after India and Uganda) in 2017 – with over 27 000 certified producers. In the same year it was ranked 13th when it comes to the area of organic production – 673 968 ha which contributed to some 0.6% of the total agriculture land in Mexico. The area of production has experienced a significant growth (about 71% over ten years). Mexico is in the top ten of countries with the largest wild collection and bee keeping areas, with the largest number of organic beehives, and it has the largest area of coffee organic farming (231 000 ha, 36% share of the total area) (Willer and Lernoud, 2019[8]; SIAP, 2018[3]).

The pesticides industry in Mexico

For the past six years the Mexican pesticide industry has had a modest growth, with sales fluctuating considerably from year-to-year

According to the Monthly Survey of the Manufacturing industry, total sales of all pesticides in Mexico amounted to MXN 17 096 million in 2018 (roughly USD 908.5 million) (INEGI, 2019[9]). The average annual growth in the sales of pesticides from 2013 to 2018 was 3.08%, above the average GDP growth. However, the year-to-year growth numbers of the industry have seen considerable fluctuations. As seen in Table 1.3 all pesticide categories, once adjusted for inflation, have had negative growth rates, and large positive jumps. Insecticides account for the largest sales volume, reaching MXN 4 767 million in 2018, followed by fungicides and herbicides.

Table 1.3. Pesticide Sales Value in Mexico

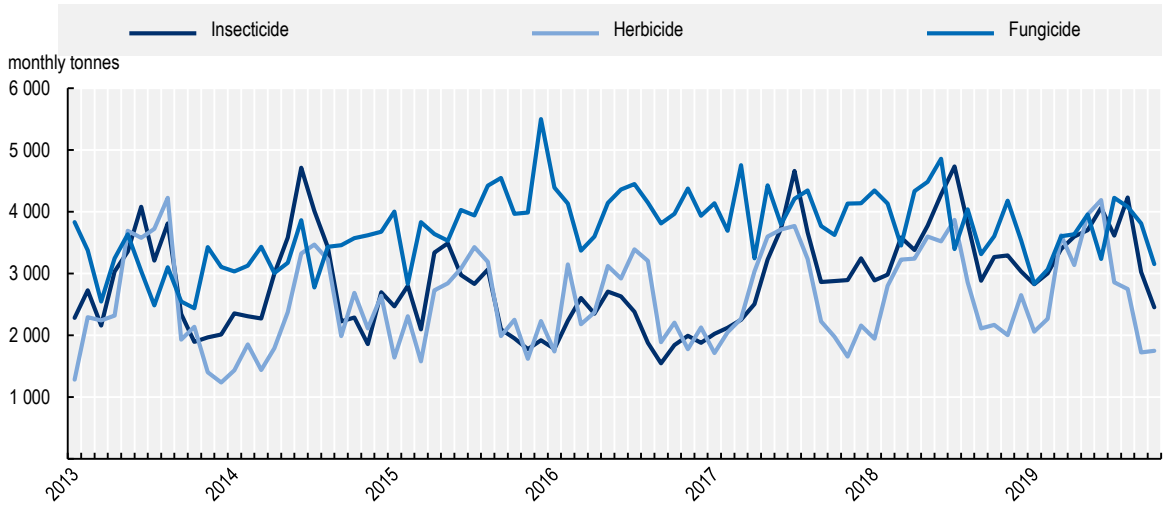
Annual sales in real 2013 MXN million pesos.

	Insecticides		Fungicides		Herbicides	
	Annual sales	y-y growth	Annual Sales	y-y growth	Annual sales	y-y growth
2013	$3 287	-	$2 790	-	$3 705	-
2014	$3 770	14.7%	$2 917	4.6%	$3 380	-8.8%
2015	$3 627	-3.8%	$3 312	13.5%	$4 833	43.0%
2016	$3 737	3.0%	$3 469	4.8%	$4 906	1.5%
2017	$4 719	26.3%	$3 449	-0.6%	$4 644	-5.3%
2018	$4 767	1.0%	$3 554	3.0%	$3 321	-28.5%
2019*	$4 014	-	$2 354	-	$3 028	-

Note: * 2019 figures up to Q3.
Source: Adapted from (INEGI, 2019[9]).

The volume of production follows a similar trend to that of sales value (see Figure 1.2). However, overall, the production of insecticides, herbicides and fungicides, has had a steady trend since 2013. As shown in Figure 1.2, seasonal production tends to vary between 1 500 and 4 000 tonnes per month.

Figure 1.2. Pesticides production in Mexico



Source: Adapted from (INEGI, 2019[9]).

The Mexican pesticide industry has a large market concentration, and pesticide intensity/use is lower than NAFTA partners

Mexico has long-established transnational agribusinesses that, through contract farming, implicitly control the whole production process of several thousand hectares (OECD/FAO, 2019[7]). In 2014, out of 119 companies registered as producing, formulating, assembling, importing or exporting pesticides, only 14 were actually producers, while the majority of the remaining ones were pesticide importers or formulators (Bejarano, 2018[10]). According to figures by the Federal Competition Commission, the four largest companies control 54.3% of the market share, the six largest have 64.2% and the eight largest, 71.8% (COFECE, 2014[11]).

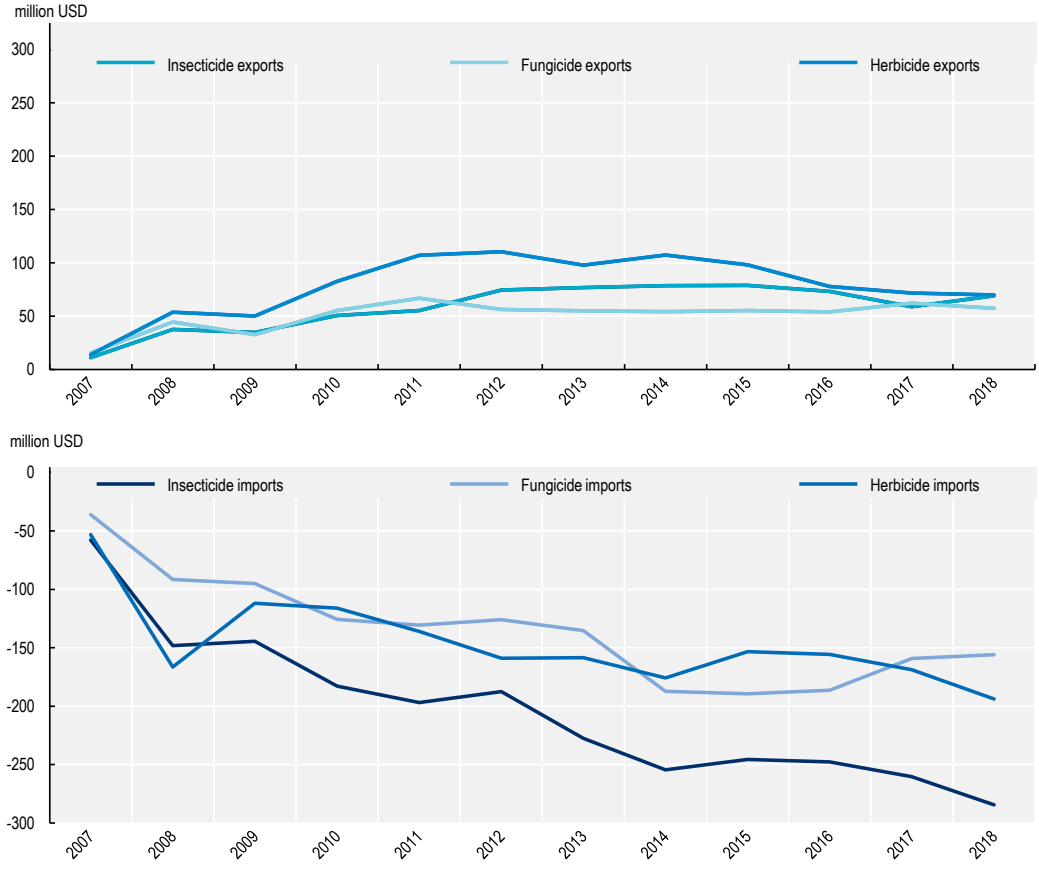
The intensity of pesticide use in Mexico in 2017 was 1.77 kg/ha. Historically, it had been increasing since the early 2000s at 0.63 kg/ha, peaking in 2013 at 2.23 kg/ha. The intensity in Mexico was lower in 2017 than Canada (2.37 kg/ha), the United States (2.54 kg/ha) and South America 5.42 kg/ha. However, Mexico has a higher pesticide intensity than the average in Europe at 1.65 kg/ha (FAO, 2017[12]).

International trade of pesticides

The Mexican pesticide industry relies heavily on international trade, Mexico's trade gap has consistently increased

International trade is a large component of the Mexican pesticide industry. At least since 2007, Mexico has been a net importer of pesticides (see Figure 1.3). The trade gap has consistently increased from USD 107 million in 2007 to USD 438 million in 2018. While imports had an average annual growth of 15.5%, exports grew at 12.4% per year. In 2018, Mexico imported 62.7 million tonnes of pesticide, for an annual value of USD 583 million (Secretaría de Economía, 2019[13]). Herbicides were the largest source of imports in terms of volume (32.4), followed by insecticides (17.6) and fungicides (12.6). In terms of monetary value, insecticides were the largest import market at USD 285 million, then herbicides at USD 194 million and fungicides at USD 156 million. Regarding exports, Mexico sold 37.4 million tonnes, for an annual value of USD196 million. Exports have a more balanced composition both in sales value and in volume.

Figure 1.3. Pesticides International Trade in Mexico



Note: The positive y-axis refers to exports, the negative y-axis refers to imports.
Source: Adapted from (Secretaría de Economía, 2019[13]).

The United States is Mexico's most important pesticide trade partner, however, Mexico has extended its trade partnerships to Europe and Asia

The largest trade partner for all types of pesticides is the United States. The total imports in 2018 from the United States added up to USD 300.3 million (see Table 1.4). The United States is also Mexico's largest export destination, with total annual sales of USD 56.8 million. Besides the United States, the largest export market for Mexico is Latin America, notably Colombia, Guatemala, Peru, Chile and Ecuador. In North America, Canada is also a big export destination for herbicides. Mexico has become an importer of pesticides from Chinese products, as well as European, including Germany, France and Spain (Secretaría de Economía, 2019[13]).

Table 1.4. Main trade partners for pesticides (2018)

All figures in USD

Insecticides			
	Exports		Imports
United States	16 864 045	United States	160 489 280
Colombia	8 451 882	Colombia	22 693 340
Chile	6 002 215	China	14 903 035
Ecuador	5 218 764	Germany	11 450 451
Peru	4 882 516	Indonesia	9 145 546
Fungicides			
	Exports		Imports
United States	22 959 601	United States	47 442 524
Italy	5 695 649	Colombia	25 248 078
Guatemala	3 446 657	France	13 041 303
Colombia	3 117 986	Spain	12 974 050
Australia	1 861 799	Brazil	10 317 764
Herbicides			
	Exports		Imports
United States	16 994 574	United States	92 345 206
Canada	8 455 561	China	31 347 070
Colombia	8 342 742	Israel	11 633 334
Guatemala	6 599 487	Germany	8 948 223
Cuba	5 812 698	India	7 448 933

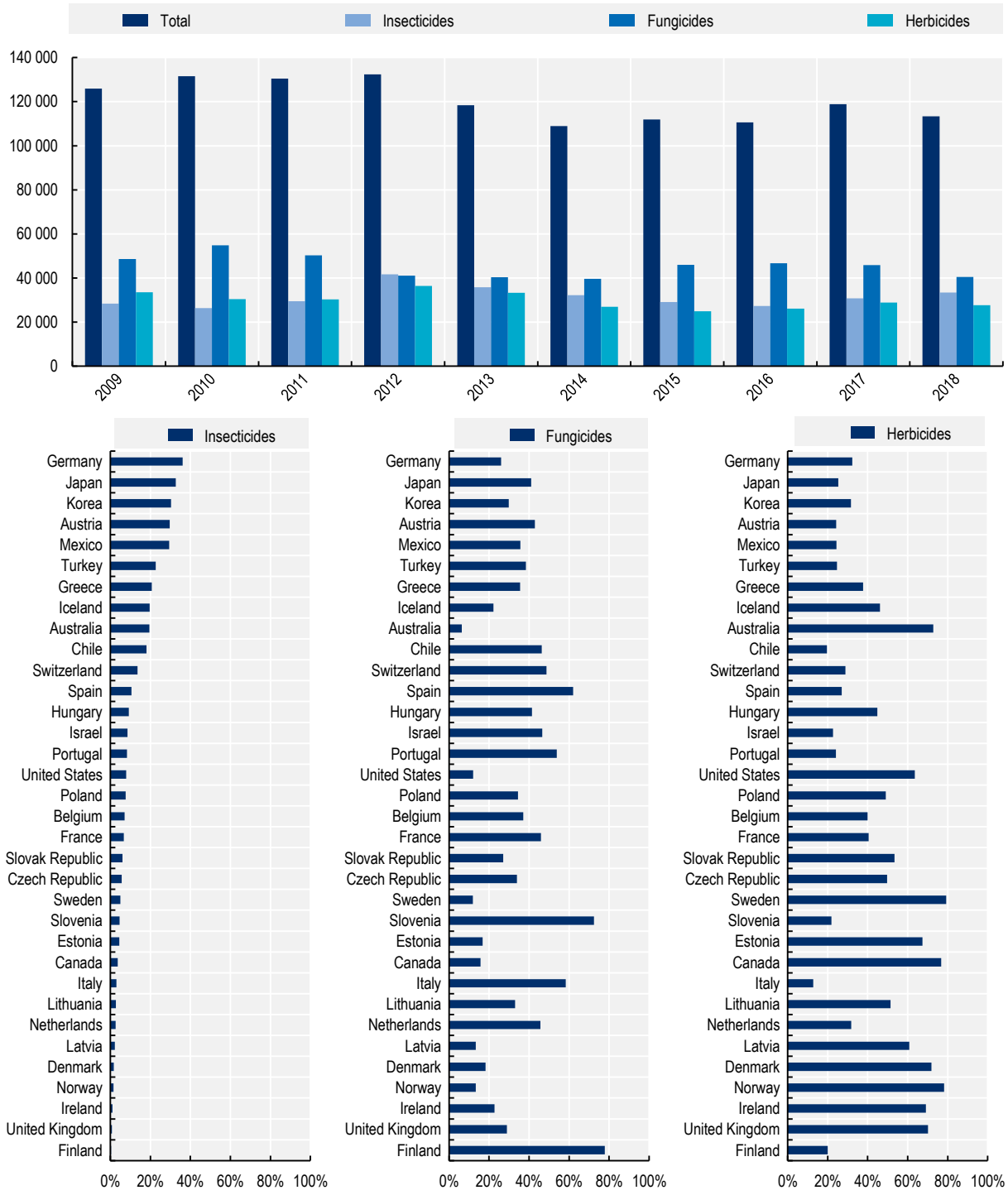
Source: Adapted from (Secretaría de Economía, 2019[13]).

Pressures on health and the environment from pesticides

Excessive pesticide use is a matter of concern in Mexico. High levels of toxic contaminants (e.g. heavy metals, pesticides) have been found in soil, water, and plants and animal species in some specific locations in Mexico, and adverse effects on human health, especially in children, have been identified (OECD, 2013[14]). Pesticides have also led to degradation of ecosystems with noted cases of bioaccumulation in aquatic species. Adverse effects on human health, especially in children, have also been identified. A reduction in use of pesticides to prevent mounting environmental costs is needed (Sud, 2020[15]).

From 2000-2014, the consumption of pesticides in Mexico rose by 59.2% (Bejarano, 2018[10]). Fungicides are the most widely used pesticides, followed by insecticides and herbicides. Figure 1.4 compares the share of types of pesticides sold within Mexico with other OECD countries. Information on the amount and type of pesticides used historically and today in Mexico is limited (INECC, 2019[16]).

Figure 1.4. Fungicides are the most widely used pesticides



Notes: Data in the right panel refers to national sales of pesticides for 2018. Some countries have not updated data in the OECD database, latest data for the following countries: Chile (2013), Israel (2016), Denmark (2017). Some of the data was not available for New Zealand, Colombia and Luxembourg. This series is in terms of active ingredient for most countries, but not for Chile and Mexico.
Source: (OECD, 2020[17]) (OECD, 2019[6]).

Data on import and export of hazardous pesticides that is available to authorities (Customs and the Secretary of Economy) via the Commercial Information System via Internet (SIAVI) platform is inconsistent. More importantly, available information shows that many of the most imported pesticides or their metabolites do not appear at all in the databases and studies, though in many cases they should, taking into account the Mexican agricultural practice. Domestic pesticide production and sales data are available from the Monthly Survey of the Manufacturing Industry conducted by INEGI but this survey has its limitations. More importantly, Mexico have very little information available on the actual uses of pesticides, how much of them are commercialised and applied (Mexican Technical Working Group on Pesticides, 2019[18]). Such information is not required by authorities in the post-registration stage, for instance during the renewal of a pesticide registration. There is no general obligation in the regulatory framework to keep the sale register of pesticides, but collection of certain data on pesticides by industry (e.g. records of aerial spraying) is required by the Mexican NOMs.

Information on pesticides sales in Mexico is presented only in terms of total volume, not in volume of active ingredient, which limits the possibility to compare the situation in Mexico with other OECD countries, which, for the most part, do possess data on active ingredients on the market.

Examples from the OECD countries of best practice in requiring and using information on pesticides by authorities, to support decision-making and developing policies and regulatory framework, for instance by using sales reporting information, are available in Chapter 3.

Moreover, a tendency towards crop specialisation according to zones/states, contributes to overuse of pesticides and encourages the use of products, which are considered to be successful in controlling certain pests, even on crops on which they are not authorised to be applied (Sud, 2020[15]). A 10% increase in insecticide intensity (sales per hectare) is associated with a 0.4% decline in the farmland bird index (Guerrero and Muñoz, 2019[19]).

Monitoring of pesticides in Mexico

Collecting monitoring data in food and environment over a prolonged period of time is essential to sound decision-making on pesticide, building public confidence about the use of pesticides and for effective compliance and monitoring (Matthews et al., 2020[20]). On the other hand, “the lack of comprehensive monitoring programme that documents how the regulatory system is working to protect consumers and the environment risks undermining the legitimacy of the system” (Matthews et al., 2020[20]).

Mexico has conducted certain monitoring activities in different parts of the country, covering some pesticides. Historically, the National Centre for Reference of Pesticides and Contaminants (CNRPyC), established in 1991, carried out an annual evaluation programme in zones where there have been malpractices regarding the use and application of pesticides. The regions and crops selected for monitoring were based on the presence of unauthorised pesticide residues. This samples monitoring commenced in mid-2000s (based on the rejections of the Mexican shipments) (Pérez-Olvera, Navarro-Garza and Miranda-Cruz, 2011[21]). Studies on contamination by pesticides were undertaken also by the National Water Commission, CONAGUA. Moreover, a residue monitoring programme, with a focus on export of food products, is in place in Mexico.

In 2019, an examination of pesticide contamination of surface water, groundwater and soil in Mexico was performed as a follow-up to the Mexican National Human Rights Commission (NHRC) Recommendation 82/2018. It was based on scientific information and feedback provided by academia and other non-governmental stakeholders. It collated information from 60 studies dealing with pesticides contamination in various environmental compartments in 125 locations in Mexico. While the study is not a comprehensive picture of pesticides contamination in the country, it clearly shows a link between the agricultural activity and the presence of pesticides in water sources and soil. For instance, in some locations, the concentration of pesticides surpassed the limits set for drinking water and the reference values for soil and water

established by Canada, the United States and WHO (Mexico does not have its own reference values for soil). While the list of pesticides detected in the studies is far from comprehensive, it could be a starting point for the authorities in the context of the increasing the scope of monitoring (Mexican Technical Working Group on Pesticides, 2019[18]).

However, up-to-date monitoring efforts in Mexico have been scattered and driven by various factors, such as scientific interest of the authors, locally determined conditions (e.g. heavy use of pesticides to combat vector diseases) or external drivers (e.g. response to the obligations under the international agreements), but have not constituted a coherent and comprehensive policy and action at national level.

In principle, there is no systematic monitoring of environmental contamination by hazardous chemicals, including pesticides, and their effects on human health in Mexico (NHRC, 2018[22]). It has been partly linked to the lack of resources to perform such monitoring. Moreover, Mexico does not also have binding national reference/limit values for the contamination of water and soil by pesticides.

There are other examples of the (miss-)use of pesticides. _In 1996, there was a mass mortality of catfish in the Mexican Bay of Chetumal due to contamination by various pesticides and other contaminants (it was the first location in Mexico where cancer in fish was detected). The event resulted in more strict control of the sale and use of restricted pesticides. More recently, the exposure of biota to many pesticides (e.g. lindane, DDT, DDE or aldrin) was detected in the areas of Coatzacoalcos and Veracruz, while in Sonora the shrimp production was affected by high concentration of chlorinated pesticides and their metabolites (SEMARNAT, 2017[23]). The presence of prohibited or never registered pesticides in monitoring results in Mexico points for the need of enhanced enforcement efforts (SEMARNAT, 2017[23]).

In relation to human beings, adverse effects of pesticides on human health were found in floriculture applicators who used chlorinated pesticides, women exposed to DDT, DDE or DDD and children living in the areas were chlordane and endosulfan were used. Correlation between exposure to DDE and an increased risk of breast cancer in females and worsening of sperm quality in men was observed (SEMARNAT, 2017[23]).

While Mexico has been monitoring human pesticide poisoning, data have not been updated since 2011-12. . Earlier data shows that there were 2518 deaths from 1995-2011 (Anglés-Hernández, 2018[24]) and almost 68 000 of poisoning from 1995-2012 (NHRC, 2018[22]). It makes it challenging to provide reliable information to decision-makers, for instance in relation to trends in poisoning, effects of initiatives supporting the safe use of pesticides or a potential number of chronic diseases related to poisoning. It is worth noting that the Mexican industry runs two programmes in relation to intoxications by pesticides – ATOX and SINTOX. Some OECD countries, like Canada or the United States (see Chapter 3) require pesticide registrants to report to them all incidents associated with their products.

A study undertaken in the state of Sinaloa found DNA mutations in pilots occupationally exposed to pesticide during aerial application in agricultural fields, a frequent application method in Mexico (Martínez-Valenzuela et al., 2018[25]).

A comprehensive pesticides monitoring programme would assure Mexico's trading partners of the robustness of its regulatory framework. It would also support a timely identification and response to the inappropriate use of pesticides, enhancing confidence among the public that agricultural chemicals remain safe. In this context, it could be noted that many of Mexico's trading partners, such as Canada, the European Union and the United States, have comprehensive residue monitoring programmes in place and release regular reports summarising the findings of these programmes .

Additionally, there are on-going efforts, for instance in Europe under the European Human Biomonitoring Initiative (HBM4EU), to provide information on the actual exposure of humans to chemicals like pesticides and their possible health effects. Such initiatives, aiming to support policy-making can also be of interest to Mexico (HBM4EU, n.d.[26]).

Legal, policy and institutional framework for managing risks to health and the environment from pesticides in Mexico

A pesticides management framework can include various types of instruments, both regulatory-based and market-based.

> *The optimal regulatory strategy does not have to be composed of single policy tools but can involve a mixture of measures and actions such as tax schemes, direct controls, farm certification and self-regulation. In this way the different measures may compensate each one's deficiencies (Skevas, Oude Lansink and Stefanou, 2013[27]).*

The existing policy, or one under development, should take into account various elements such as the human health and environmental benefits from its implementation, and the costs for pesticides users and for authorities. To be able to reflect these elements and to support the transition to more environmentally friendly uses of pesticides, decision-makers need information at their disposal. For instance, on pesticides production or indirect effects of pesticide use (Skevas, Oude Lansink and Stefanou, 2013[27]).

In order to effectively implement the pesticide policy and regulatory framework in the short and long term, a clearly established division of responsibility between the authorities involved in pesticides management at the national and local level is also needed. This should be combined with efficient enforcement provisions and coupled with adequate human, financial and technical resources.

Policy framework

A clear description of the principal objectives of the system is important for authorities, stakeholders and the public. It allows these parties to understand what the system is aiming to achieve. It is also very important to present a hierarchy of objectives to support decision-making, if two or more objectives could be mutually excluding.

Some of the OECD countries, for instance European Union member states in line with Directive 2009/128/EC on the Sustainable Use of Pesticides, adopt national policy documents which set, among other things, objectives, targets, measures and timetables in order to reduce risks and the impact of pesticides on human health and the environment.

Mexico does not have a specific overarching national policy on pesticides. The National Development Plan, which is the country's highest-level policy statement, does not specifically address pesticides. Instead, goals and objectives are included in various policy and regulatory instruments dealing with these substances (SHCP, 2019[28]).

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 specific 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 plan.

Instead, goals and objectives are included in various policy and regulatory instruments dealing with pesticides. For instance, in line with SENASICA's internal rules of procedure, its role is to propose to the Secretary of Agriculture a national policy aiming to reduce the risks in agro fishery production and to the public health. Similarly, COFEPRIS has the authority to propose to the Secretary of Health a preventive public policy on hazardous substance (covering pesticides) (NHRC, 2018[22]). Moreover, each of the laws,

regulations or Official Technical Standards linked to the pesticides management include specific goals and objectives either in its preamble or as part of the provisions within the main text.

Taxation of pesticides

> *Pesticide and fertiliser taxes can form an important component of a coherent set of policies aimed at reducing use and risks. (…)The low price elasticity of demand necessitates that the tax rate for pesticide and fertilisers be set relatively high to generate decline in their use. Pesticide tax rate in France and fertiliser tax rates in the United States have been too low to incentivise reduction in use (Sud, 2020[15]).*

A tax on pesticides can correct certain market failures, for instance their social and environmental costs, and can generate revenues that could support addressing the negative impacts of pesticides or adopting more sustainable practices. The design of the tax entails the definition of the tax base, the tax rate, the point of application and the revenue allocation. Tax rates can vary depending on the toxicity of the substance. Measures can be included in the tax design to streamline the tax revenues to the agriculture sector and support its acceptance by affected stakeholders (UNDP, 2017[29]).

> *Unlike uniform taxes (ad valorem or per unit), differentiated taxes rates that place a higher burden on substances with higher environmental (and health) risks, create incentives for a move towards lower-risk substances. Such differentiated tax systems have been employed for pesticide taxes in Sweden, Norway, Denmark, France and Mexico (Sud, 2020[15]).*

Differentiated taxes are considered superior to undifferentiated taxes because allow faster reaching the policy goals (Böcker and Finger, 2016[30]).

Mexico is one of the few OECD countries (others are Denmark, France, Italy, Norway and Sweden) that have implemented broad pesticide taxes to reduce pesticide risks (Guerrero and Muñoz, 2019[19]). The Mexican Tax Administration Service (Servicio de Administración Tributaria, SAT, in Spanish) is responsible for taxes at federal level. Pesticides are taxed in Mexico depending on their acute toxicity hazard category. Category 1 and 2 pesticides are taxed at the 9% tax rate, category 3 at 7% rate and category 4 at 6% rate. The least toxic pesticides are exempted from taxation (SAT, 2014[31]). The tax currently does not take into account chronic toxicity. All parts of the supply chain are subject to the tax. The tax revenues from the pesticide tax were USD 109 million (MXN 2 133.32 million) from February 2014 to September 2017 period (Sud, 2020[15]).

Taxation of pesticide was introduced in 2014 and it would be of benefit to evaluate the effects of the pesticides tax in Mexico after a set period of time to determine if it brought the expected results in decreasing the use of the most hazardous products. Moreover, the impact of the current system of VAT exemption for pesticides could also be analysed. Should the latter be shown to have a negative impact on realising the benefits of the pesticide tax, this could suggest that co-ordination among the regulators could be improved.

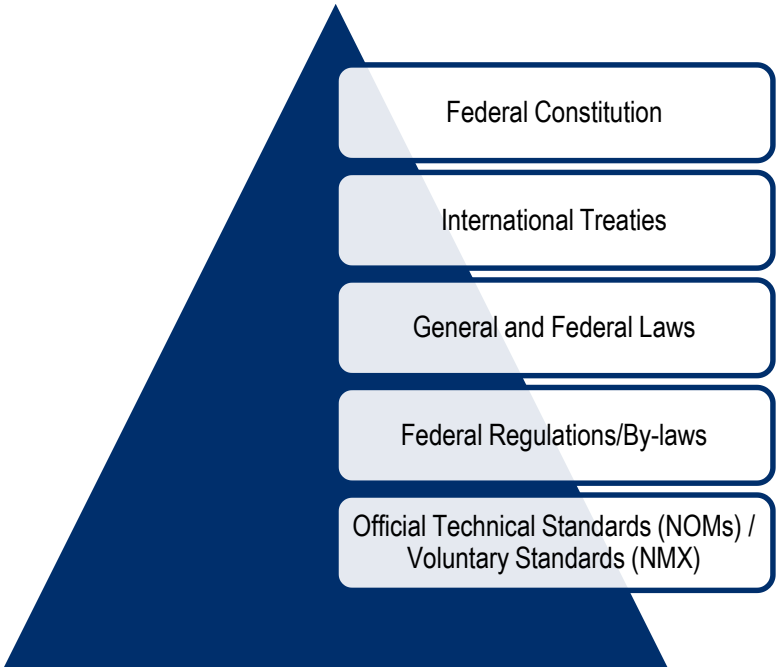
Legal and regulatory framework on pesticides management

This chapter provides an overall presentation of Mexico's policy framework including the legal and regulatory structure. However, the regulatory framework is also discussed in more detail in Chapter 2, mostly as it relates to the assessment and registration of pesticides.

Many factors influence national pesticides regulatory frameworks. They include culture, politics, economy including trade, health or food security aspects. The level of the development of the country is also relevant. In some cases, even if legislation is sufficient, compliance monitoring and enforcement can be inadequate due to the lack of resources for inspections (Handford, Elliott and Campbell, 2015[32]).

As background to the regulatory framework in Mexico, the following describes the general hierarchy of various legal instruments in Mexico (Figure 1.5).

Figure 1.5. Hierarchy of the Mexican sources of law



Source: Author's elaboration.

The Federal Constitution is the ultimate source of law in the country. Federal laws in principle distribute powers across the federal, state, and local levels and establish overarching policies. They are implemented by federal regulations. Finally, the Official Technical Standards, known as NOMs, are legally binding technical regulations. In principle, the subject of the regulatory actions must be reflected at all levels of law set out above to be operational. The laws, regulations and NOMs need to be coherent and complement each other.

Federal Constitution and a historical evolution of the regulatory framework on pesticides in Mexico

The protection of health and the environment (linked to the sound management of pesticides) is reflected in several articles of the Mexican Federal Constitution. Article 1 addresses the protection of human rights, Article 4 the protection of human health, Article 6 the right to information, Article 27 water and soil and Article 123 the protection of workers (Albert, 2019[33]).

The first Mexican regulatory framework dealing with pests, the Law on Pests, dates back to 1924. The 1940 Plant and Animal Health Law was adopted just before synthetic pesticides began to be used around the world (including in Mexico) and remained in force until 1974. In 1982, an official report analysed the deficiencies of the regulatory system for pesticides in Mexico. It supported implementing a regulatory framework addressing pesticides control, and that framework was issued in the 1980s. The regulation of occupational safety in relation to pesticides began in the 1990s (Albert, 2019[34]).

Pesticide regulation in Mexico is scattered in different laws…

The following three general or federal laws constitute are the most important for the pesticides management framework in Mexico:[2]

- the 1984 General Law of Health (GLH), regulating main elements of the life cycle of pesticides;
- the 1988 General Law of Ecological Balance and Environmental Protection with a goal to prevent soil and water contamination (GLE); and
- the 1994 Federal Plant Health Law (FPHL).

GLH focuses on human health effects of pesticides use and defines responsibilities for the Secretary of Health (SALUD). The GLE mostly regulates impacts on soil and water contamination due to pesticides and defines responsibilities of the Secretary of Environment and Natural Resources (SEMARNAT). The FPHL regulates the impact of pesticide in vegetation and defines the responsibilities of the Secretary of Agriculture and Rural Development (SADER). Table 1.5 summarises the role of these laws in the pesticide management scheme in Mexico.

Table 1.5. Main general or federal laws on pesticides in Mexico

	Key role of the legislation
General Law of Health	Establish the classification and characteristics of the different pesticide products in order to categorise them according to the risks they pose directly or indirectly on human health. Authorise the ingredients used in pesticides and plant nutrients, as well as materials used as inputs, which should not be toxic or increase the toxicity of pesticide or vegetal nutrient. Authorise the process of persistent and bio-cumulative pesticides, of any chemical composition, for those which do not harm or imply a peril to human health and when their substitution is not possible. Establish, in coordination with relevant authorities, technical regulations that specify the conditions that pesticides must comply with regards to formulation, packaging, transportation, commercialisation and use, in all of its lifecycle. SALUD will outweigh the opinion of other regulators when human health must be safeguarded. Develop technical regulations for the protection, process, use and application of pesticides, vegetal nutrients and toxic or dangerous substances. Supervise that the packaging of pesticides must include, in Spanish, the information of the risks implied in using the product
Federal Plant Health Law	Develop the specifications for field studies that establish maximum residue limits of pesticides. Evaluate the biological efficacy of pesticides and regulate their phytosanitary use. Direct SADER to cooperate with SALUD to supervise and implement the compliance of technical regulation. Develop a National Supervising Program for Pesticides' Residues, to determine that phytosanitary inputs are complying with established limits. Promote a program to reduce contamination risks for agricultural production through empty containers collection, in collaboration with Semarnat
General Law of Ecological Balance and Environmental Protection	Ensure that the use of pesticides is compatible with the ecosystem equilibrium and must consider its effects on human health. In case of soil contamination due to toxic waste, conduct necessary actions to recover or establish the initial conditions, so that any activity permitted in the urban development plan can be carried out. Define the criteria to prevent and control soil contamination, which should be considered in the authorisation to produce, import, use activities related to pesticide Forbids the authorisation of pesticide imports which use has been banned in the country of origination. Defines as federal jurisdiction the rules for the fabrication of pesticide raw materials.

Source: (Congreso de la Unión, 2019[35]), (Congreso de la Unión, 2017[36]) and (Congreso de la Unión, 2017[36]).

Apart from the three general or federal laws described above, the 2003 General Law on Prevention and Integral Management of Waste (LGPGIR) requires that pesticides and their containers are treated as hazardous waste and subject to a management plan (NHRC, 2018[22]). The 1970 Labour Law provides power to the Labour Secretary for its participation in pesticide regulation since it aims to promote safety in the workplace (Romero Torres, 2006[37]). Moreover, certain aspects of pesticides management are addressed by the legislation on sustainable rural development, roads, bridges and car transport, custom law and external commerce law (Albert, 2019[34]).

In relation to storage and transport of pesticides in Mexico, pesticides cannot be transported together with food or other products that can be contaminated by them, for instance toys or clothes. They cannot be stored next to the driver or in the vehicle cabin. Companies in Mexico are required to store pesticides in a separate, clearly marked area (identified within the plan of the site) and should take into account potential risks, like leakage. Companies are not permitted to store pesticides together with fertilizers or other products (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 1984[38]).

Definitions

According to FAO and WHO, a regulatory framework on pesticides should include a clearly defined scope and definitions (aligned with those provided in the FAO and WHO Code of Conduct on Pesticide Management or the applicable pesticides and chemical multilateral environmental agreements) (FAO & WHO, 2013[39]).

Under the FAO and WHO Code of Conduct on Pesticide Management, the term "pesticide" is defined as: "any substance, or mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any pest, or regulating plant growth" (FAO & WHO, 2013[39]).

The principal definition of a "pesticide" in the Mexican regulatory framework is included in Article 278 of the 1984 General Law of Health. It defines a pesticide as: "any substance of mix of substances aimed at controlling any plague, including the vectors transmitting human and animal diseases, unwanted species that cause harm or interfere with the agricultural and forestry production, as well as defoliant and desiccant substances" (Congreso de la Unión, 2019[35]).

It is not, however, the only definition included in the Mexican laws, as Article 5 of the Federal Law of Plant Health (LFSV) defines a pesticide as: "phytosanitary inputs aimed at preventing, repelling, fighting and destroying the biological organisms harmful to plants, their products or byproducts" (Congreso de la Unión, 2017[36]).

The PLAFEST Regulation applies the definition used in the General Law of Health and additionally defines different types of pesticides based on their composition (e.g. chemical or botanical pesticide) and use (e.g. for agriculture or forest use) (Chapter 2).

Harmonisation of the two definitions used in GHL and LFSV could be considered by Mexico to streamline the existing legal framework and provide more clarity to stakeholders.

On the other hand, it has been raised by stakeholders that the current regulatory framework for pesticides in Mexico does not easily accommodate new, lower risk products (e.g. bio-pesticides). In particular, existing definitions create challenges for both regulators (in the evaluation and registration processes) and industry (for instance in relation to the data to be provided).

Highly hazardous pesticides

According to FAO and WHO guidelines, Highly Hazardous pesticides (HHPs) are

> *pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as WHO or GHS or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous (FAO & WHO, 2016[40]).*

In 2015, the SAICM International Conference on Chemicals Management adopted a resolution that recognised HHPs as an issue of concern and encouraged countries to strengthen national regulatory capacity to address such pesticides. It proposes, among other things, to identify such pesticides by examining the lists of registered pesticides and to revise the registration systems by:

- defining protection goals and unacceptable risks in the pesticide legislation;
- strengthening registration procedures; and
- performing risk assessment based on HHP criteria (FAO & WHO, 2016[40]).

The Mexican General Law of Health 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. The General Law of Health mentions only "acceptable risk" and only in relation to the transplantation of organs. The PLAFEST Regulation refers to the risk to the environment or human health that cannot be managed but only in the context of registration of pesticides destined solely for export and not to be commercialised in Mexico. Mexico has a pesticide classification in place (via the Official Technical Standard NOM-232-SSA1-2009), where the toxicity classification is based on the WHO criteria (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 1984[38]). This NOM 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 also lead to inconsistencies in decision making.

A key subordinate regulation is the 2004 Regulation on the subject of registrations, import and export authorizations, and export certificates for pesticides, plant nutrients, and toxic or hazardous chemicals and materials (PLAFEST)(Box 1.1).The PLAFEST regulation was last reformed in 2014.

Box 1.1. The PLAFEST Regulation

Topics addressed in the PLAFEST Regulation:

- Definitions;
- Responsibilities of the Agriculture, Health and Environmental Secretaries in Mexico (and their decentralised bodies, like SENASICA and COFEPRIS);
- Pesticides studies required for registration (with exemptions) on physico-chemical, toxicological, ecotoxicological, environmental fate and physical properties;
- Pesticides registration procedure (more detailed information can be found in Chapter 2);
- Pesticides import authorisations;
- Pesticides export authorisations and certificates.

Source: (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 2014[41]).

However, there are at least 10 additional applicable regulations (by-laws) on pesticides, for instance the implementing regulations for GLE or GLH (Albert, 2019[34]). This, together with a broad scope of the existing framework (covering vegetal nutrition inputs, fertilisers, as well as other hazardous materials), can make the regulatory environment complex and difficult to understand and implement, with responsibility shared across multiple ministries and agencies.

Official Technical Standards (NOMs)

As of the 1990s, Mexico has adopted Official Technical Standards (NOMs) to address certain technical aspects of pesticide management. Currently there are more than twenty NOMs dealing with pesticides. For instance, seven NOMs are linked to the evaluation of data, nine on procedural aspects of registration, and four on labelling and packaging. However, there are no NOMs that regulate the amount of pesticides in soil, sediments, surface water, wastewater or air (Albert, 2019[34]). In line with PHL, the NOMs should

take into account applicable international standards, directives and recommendations, whose provisions may not have been totally observed in the past (NHRC, 2018[22]).Table 1.6 lists some of the key NOMs for the Mexican pesticide management framework.

Table 1.6. Main Mexican Technical Standards (NOMs) on pesticides management

NOM ID	Date of issue	Description
NOM-032-SAG/FITO-2014	11-Aug-2015	Establishes requirements and phytosanitary specifications regarding the conduct of biological efficacy studies of pesticides.
NOM-033-FITO-1995	1996-06-24	Establishes requirements and specifications regarding the notification of the start of operation, which is required from those interested in the commercialisation of agricultural pesticides It creates, among other things, obligations to sell only registered pesticides and not to sell expired, counterfeit or illegal pesticides, or re-labelled/re-packed pesticides. It also requires training for personnel that sell pesticides.
NOM-034-FITO-1995	1996-06-24	Establishes requirements and phytosanitary specifications regarding the notification of the start of operation, which is required from those interested in the production, formulation or import of agricultural pesticides It makes those who are subject to the NOM responsible for information included on the label (direction of use, authorised crops, common and scientific name of the pest, field application instructions, and pre-harvest intervals). It obliges the subjects of the NOM to provide technical advice to distributors and retailers, and to control produced or formulated pesticides (quantity, date of production and distribution).
NOM-052-FITO-1995	1997-06-10	Establishes requirements and phytosanitary specifications regarding the notification of the start of operation, which is required from those who dedicate themselves to the aerial application of agricultural pesticides. It obliges, among others, persons subject to the NOM to use only registered pesticides and not to apply expired, counterfeit pesticides, or pesticides outside of their specifications. It also requires that users make sure that pesticides are applied in line with the conditions stipulated by the registry and only in appropriate environmental conditions, as well as to capacitate its personnel. Verification that the application equipment meets technical criteria for efficient application is also needed.
NOM-057-FITO-1995	1996-07-30	Establishes requirements and specifications to issue the technical opinion of the pesticides waste analysis.
NOM-082-SAG-FITO/SSA1-2017	2017-10-04	Establishes, for the first time in Mexican history, setting MRLs in food, as well as includes technical guidelines and authorisation and revision procedures.
NOM-232-SSA1-2009	2010-04-13	Establishes requirements for containers, packaging and labelling of pesticides.
NOM-003-STPS-2016		Establishes health and safety conditions for agricultural activities, especially during the use of pesticides. Its limitation is that it does not apply to a significant part of the agricultural zones in the country

Institutional framework

In line with FAO/WHO recommendations, a competent authority (or competent authorities) should be in place to co-ordinate the implementation of the pesticides regulatory framework and be equipped with the power to regulate, charge fees and enforce (FAO & WHO, 2015[42]).

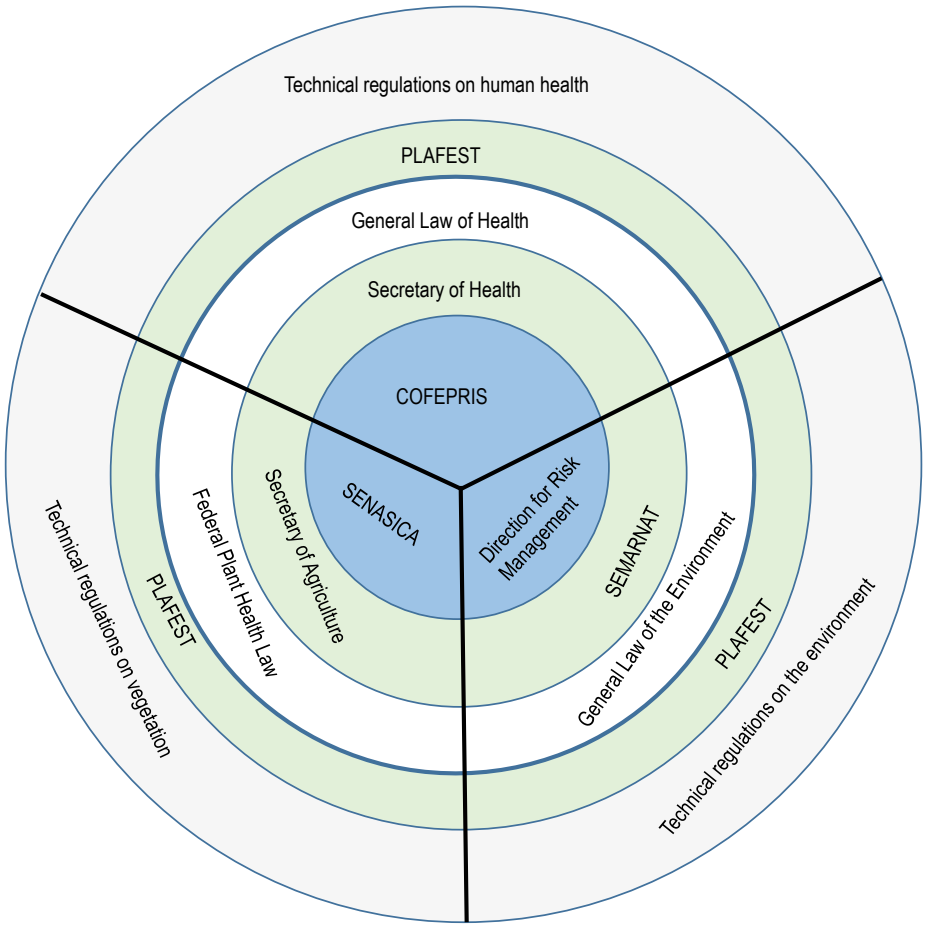
To co-ordinate the work of various Mexican authorities on pesticides, In 1987, an inter-institutional body was established, the Inter-Secretarial Commission on the Control of the Process and Use of Pesticides, Fertilizers and Toxic Substances, known as CICLOPAFEST (Albert, 2019[34]).

In practice, the same authorities, responsible for Health, the Environment and Agriculture (in 1987 also Commerce and Industrial Development and later on Communication and Labour were included) are in charge of pesticides management in Mexico now. They include the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), a deconcentrated body under the Secretary for Health and

established In 2003, the Secretary for Environment and Natural Resources (SEMARNAT) and the National Service of Sanitation, Safety and Agricultural Quality (SENASICA), a decentralised body of the Secretary for Agriculture (SADER). Pesticides registration, production, import, export and use are granted jointly by the COFEPRIS, SEMARNAT and SENASICA.

These three authorities are responsible for the pesticide registration process. Figure 1.6 shows the relationship between the main legal instruments and COFEPRIS, SENASICA and SEMARNAT. The diagram also shows how each authority is responsible to manage the NOMs related to their portfolio.

Figure 1.6. Authorities and legal instruments involved in pesticide registration in Mexico



Note: For a complete list of NOMs and legal instruments related to pesticides (see Annex A).
Source: (Congreso de la Unión, 2019[35]), (Congreso de la Unión, 2017[36]), (Congreso de la Unión, 2019[43]).

COFEPRIS is the authority for regulation, control and enforcement in relation to activities that require an authorisation or sanitary permit, linked to the elaboration, manufacture, preparation, export and import of pesticides. COFEPRIS is authorised to regulate and control human health risks generated by sites where pesticides are managed, therefore it can regulate the use, import, export, application and disposal of hazardous pesticides, including by preparation of the NOMs. COFEPRIS is the authority that can propose to the Secretary of Health a national policy on sanitary risk protection covering pesticides. COFEPRIS is in charge of issuing the certifications for registration, as well as for import and export licenses. COFEPRIS is led by the head Commissioner and has five inner commissions: Commission for Evidence and Risk Management, Commission for Sanitary Promotion, Commission for Sanitary Authorization, Commission for Sanitary Operation, Commission for Analytic Control and Coverage Expansion. Additionally,

COFEPRIS has a Federal Coordination Direction, which leads the regional offices of COFEPRIS (NHRC, 2018[22]) (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 1984[44]) (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 2014[41]). COFEPRIS was designed as a regulator with technical and operation independence within the Secretary of Health. However, during this review COFEPRIS was absorbed by the Undersecretary of Health.

SEMARNAT is in charge of designing and overseeing the implementation of regulation that protects soil and water resources, among others. It works to make sure that the fabrication and use of pesticide is not causing environmental damage. It is responsible for environmental risks and impact of pesticides (i.e. for emitting technical opinions linked to the environmental protection and authorisation of export and import of pesticides), pesticides waste management and empty containers. Within SEMARNAT, there is a body called Federal Attorney for Environmental Protection (PROFEPA). PROFEPA investigates and litigates breaches of law from industry regarding environmental law (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 1984[44]) (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 2014[41]).

The main goal of **SENASICA** is to protect the safety of agriculture, cattle and fishery resources from plagues and diseases. Moreover, it has the goal of certifying risk reduction systems and quality of food systems. It is responsible for biological efficacy, pesticides residues in the field, phytosanitary aspects of MRLs, and determining what pesticides can be used in the case of emergency. SENASICA has four General Directorates that manage the technical responsibilities: General Direction for Plant Health, General Direction for Agri-food, Fisheries and Aquaculture Safety, General Direction for Animal Health, General Direction for Plan and Animal Health Inspections. Additionally, SENASICA has a General Legal Direction and a Management and IT General Direction (NHRC, 2018[22]) (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 1984[44]) (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 2014[41]).

In line with FPHL, **SADER** is responsible for the promotion, co-ordination and control of phytosanitary activities. It is also responsible for their harmonisation with international standards and directives, for instance in the area of field studies required for establishing MRLs. SADER also runs the National Monitoring Programme for residues of pesticides in plants. Many of these responsibilities are executed through SENASICA.

The **Secretary of Economy** (SE) is a key agency in the design, development and implementation of technical regulation in Mexico. The General Direction for Technical Regulation manages the process to publish NOMs, including those proposed by COFEPRIS, SEMARNAT and SENASICA related to pesticides. SE manages the public consultation process specifically designed for NOMs and heads the working groups that include government agencies and other stakeholders.

Secretaries of Finance and Public Credit, Communication and Transport, Labour and Social Security are also involved, to some extent in pesticides management in Mexico. The Secretary of Labour regulates and works as the oversight body for labour regulations. In this sense, it has the responsibility of establishing safety conditions for workers in the pesticide industry (and in the workplace in general) and to ensure that said regulation is being implemented accordingly. The Tax Revenue Authority, a body within the Ministry of Finance, has a big stake in international trade for pesticides. This authority designs and manages tariffs for international trade and oversees the customs. The Health Secretary (SALUD) manages a registry of intoxications and deaths related to pesticides.

In general, it is the Mexican National Institute of Ecology and Climate Change (INECC) that is responsible for environmental monitoring of pesticides (SEMARNAT, 2017[23]). CONAGUA is an administrative, technical advisory commission of Mexico's Ministry of the Environment and Natural Resources (SEMARNAT). CONAGUA administers national waters, manages and controls the country's hydrological system, and promotes social development.

As described above, several Mexican authorities are responsible for the implementation of various aspects of pesticides management. This renders the effective implementation of the system difficult. As expressed by the NAFTA's Environmental Co-operation Commission, the regulatory framework for chemicals in Mexico is one of the most complicated and confusing parts of the country's environmental framework (Albert, 2019[34]). Moreover, as different regulators implement the pesticide regulatory framework in the context of their own overarching legal framework, they may have varying priorities and policy goals in relation to pesticides, which in turn, affects the processes, timelines and co-ordination mechanisms in place. Chapter 3 presents examples of streamlining the institutional framework for pesticides management in Australia, Canada and the United States and its relevance for achieving pesticide policy objectives.

Potential challenges with the implementation of the pesticide management framework in Mexico

The provisions of the Federal Constitution are sufficiently broad to allow addressing pesticides management in Mexico comprehensively. However, the provisions led to the adoption of separate legal instruments dealing with pesticides (e.g. General Law of Health or Law of Ecological Balance and Environmental Protection), therefore not necessarily supported consistency and co-ordinated approach.

Mexican laws require a specific regulatory framework to be operational (both implementing regulations and Official Technical Standards). In this respect, one may observe that many Mexican Technical Standards were adopted many years ago would require revision, If fact, some are in the process of the revision and some have just been adopted or need to be adopted. A vast number of legal instruments on pesticides in Mexico require efforts to ensure their coherency and to avoid gaps and loopholes in the regulatory framework.

A Mexican author specialising in pesticides management, analysed conditions for the regulatory framework to be effectively implemented in Mexico and concluded that in practice many conditions are not fulfilled and there is no real control of the use of pesticides in Mexico. She compared the existing framework in Mexico with the model FAO directives and also revealed certain loopholes. Many of the suggestions for improvement are echoed in the National Human Rights Commission Recommendation 82/2018 (Chapter 2). The author also proposed to prepare a study to estimate the direct and indirect costs stemming from the gaps and inefficiencies of the existing regulatory framework in Mexico (Albert, 2019[34]).

While Mexico has had co-ordination mechanisms for pesticides management for many years, the co-operation between the authorities has not always been smooth. To improve this, an inter institutional co-ordination body, Inter-Secretary Commission on Pesticides Regulation, was established in 2019 (Chapter 2).

As of 2010, Mexico has also in place an Inter-Institutional Committee for the Evaluation and Monitoring of the National Monitoring Programme for the Control of Residues and Contaminants in Animal Products and Sub Products. It is co-ordinated by SADER with the participation of SEMARNAT and industry and academia. SENASICA is responsible for the monitoring of the Programme and CENAPA (under SENASICA) is the official laboratory (Albert, 2019[34]).

It is also important to demonstrate whether the pesticide management system is achieving its objectives. This includes communicating the outcomes of monitoring and enforcement activities (Matthews et al., 2020[20]). In practice, Mexico does not have a formal process for measuring the performance of national authorities responsible for pesticides management activities including monitoring, compliance and enforcement. Chapter 3 presents the Regulatory Performance Framework, an annual self-evaluation required by all regulators in Australia, that include multiple indicators. This framework allows for external scrutiny from other government agencies and from private stakeholders.

Resourcing of pesticide management in Mexico

The main funding source of the work of the authorities responsible for the pesticide management is the federal budget proposed by SCHP and approved by Congress. The authorities are also authorised to charge fees for their services, in line with the Federal Law on Rights. In principle, they should cover the total cost of the service. The fees are adjusted on a yearly basis, based on the National Consumer Price Index (SENASICA, 2020[45]). The fees depend on the toxicity of pesticides, similarly as the tax on pesticides in Mexico. They vary between USD 1 000 and 4 000 (for the most toxic products). Fee for the renewal of the registration is 50% lower (Secretariat of the Rotterdam Convention, 2019[46]). However, revenue from these fees is collected by the central treasury from the Ministry of Finance, not by pesticide regulators. This differs from the practices of pesticide regulators from OECD countries. Having adequate and predictable resourcing is essential to deliver high-quality regulatory services, and to keep technology infrastructure updated. An updated cost-recovery model has proven successful in Canada and Australia.

The information provided by authorities in the process that took place in 2017-18 and led to the preparation of the NHRC Recommendation 82/2018 showed that additional resources are needed. For instance, SENASICA indicated that it does not have the necessary human or technical resources to verify the quality of pesticides (NHRC, 2018[22]).

In 2019, SENASICA had six employees dealing with pesticides tasks, including preparing the biological efficacy opinions, technical opinions for the registration of pesticides, as well as performing certification and training. (SENASICA, 2020[45]). SENASICA and SEMARNAT had two employees dedicated to pesticides registration only. COFEPRIS is said to have more, but the exact number is not available (Secretariat of the Rotterdam Convention, 2019[46]).

The authorities, like SENASICA, often have annual training programmes for their employees. This allows them to enhance their capacities in dealing with pesticides, subject to available financing. However, at the same time the general view is that Mexican authorities struggle with insufficient trained resources. For instance, SENASICA considers that increased capacity is needed to address new pesticide technologies (e.g. bio-pesticides or application by drones), for conducting field studies to establish MRLs and to perform risk management (SENASICA, 2020[45]). However, there is a lack of resources for training.

In general, Mexico has not assessed the implementation costs of its regulatory framework on pesticides, with the exception of the costs of the collection of empty containers. In this case, a study estimated that 30 million Mexican Pesos are needed yearly. The responsible authorities receive about 10% of this amount (SENASICA, 2020[45]). A useful example is Australia's effort described in Chapter 3, to understand its necessary funding to cover an efficient pesticide management system.

Support to agriculture and the share of most distorting forms of support decreased since the 1990s in Mexico. This trend has partly changed since the 2000s, as input-based and market price support (considered to have potential to harm the environment) have increased. Few support programmes in Mexico require compliance with good environmental practices. This could be improved by imposing environmental conditionality (OECD, 2019[1]).

Stakeholder engagement

Stakeholders demand information on pesticides. Public perception and awareness of the health and environmental impacts of pesticides are increasingly becoming important factors affecting pesticide management schemes and food supply chains.

One of the major challenges in providing relevant practical information and available solutions for pesticide management in Mexico is the large number and diversity of agricultural producers (Sud, 2020[15]).

In line with the Mexican Federal Law on Metrology and Standardisation,[3] industry and other stakeholders are involved in the preparation of the NOMs. Moreover, the Mexican General Law for Transparency and Access to Public Information establishes that all information is public, except that classified as reserved or confidential (SENASICA, 2020[45]).

The first Mexican National Forum on Pesticides, grouping governmental and non-governmental (industry, NGOs and academia) stakeholders took place in 2018. It gathered over 100 participants from national and local government, industry, academia and NGOs to discuss the possibilities to improve the Mexican regulatory framework on pesticides. The discussion focused on three areas, agricultural regulation, environmental regulation and sanitary regulation (SEMARNAT, INECC, UN Environment and PAHO[47]). In the follow-up to the Forum, a Technical Working Group has prepared a set of proposals, "Elements for the Development of an Integral Strategy for Responsible Pesticides Management in Mexico" (Mexican Technical Working Group on Pesticides, 2019[18]). As described in Chapter 3, the UK has been using, for many years, its Pesticides Forum as a tool for stakeholders' engagement and in support to its National Action Plan for Sustainable Use of Pesticides. Chapter 3 also presents the platforms used by the United States to engage with stakeholders in different pesticide subjects.

Mexico is open to recognising industry efforts, for instance, in relation to good agricultural practice, accreditation of permit and registration holders, and training and licensing requirements for the supply and use of pesticides. This is addressed in detail in Chapter 2.

International regulatory co-operation for pesticide regulation

Mexico's international activities related to pesticides management focus on three main areas:

- work with Canada and the United States;
- implementation of the FAO/WHO Codex Alimentarius and relevant Multilateral Environmental Agreements; and
- co-operation under the OECD umbrella.

Mexico co-operates on pesticides also as part of other multilateral or bilateral agreements, for instance under the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, the Pacific Alliance, the AsiaPacific Economic Cooperation or in co-operation with Colombia, Ecuador, Israel and Turkey. Having mandates and explicit criteria on how to accept international assessments in the area of pesticides management is key to attain benefits from international integration while ensuring domestic independence. Australia has adopted a well-specified criteria to accept international standards (see Chapter 3).

North American co-operation: NAFTA/T-MEC

In 1994, the North American Free Trade Agreement (NAFTA) came into force, which led to co-operative efforts to harmonise pesticide regulatory requirements between Mexico, Canada and the United States. The NAFTA Agreement included provisions on agriculture, sanitary and phytosanitary measures to protect human, animal or plant life or health. In 1996, as a way to increase regulatory co-operation among NAFTA countries, the Technical Working Group on pesticides (TWG) was created (NAFTA Technical Working Group on Pesticides, 2001[48]).

The TWG includes representatives from the most relevant Mexican authorities for pesticides: SADER (SENASICA), SEMARNAT and COFEPRIS, as well as Health Canada's Pest Management Regulatory Agency (PMRA) and the U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP).

The main goal of the TWG is to reduce trade barriers generated by regulatory differences and address issues such as differing data requirements for pesticide registration, dissimilar formats for data submission and disparate scientific assessments of pesticide data. In consequence, in 2001 the TWG identified relevant elements that should be improved in order to minimise barriers to trade:

- Data requirements;
- Relevant test protocols;
- Data submissions (dossiers) and study report formats (monographs);
- Data review and risk assessment practices;
- Regulatory decision making; and
- Administrative processes and procedures (NAFTA Technical Working Group on Pesticides, 2001[48]).

The TWG has produced guidance documents, organised capacity building workshops and every five years produced a document with the strategy and priority areas for the period. For instance, the NAFTA Maximum Residue Level (MRLs)/Tolerance Harmonisation Workgroup developed a spreadsheet to calculate pesticide MRLs to co-ordinate the pesticide regulatory framework among NAFTA countries (Handford, Elliott and Campbell, 2015[32]). This was later replaced by the use of the OECD MRL calculator.

Another product of this international co-operation was the 2006 NAFTA Import Tolerance Guidance Document that details the product chemistry, residue chemistry, and toxicology data requirements that meet NAFTA standards for the establishment of import tolerances or MRLs in Canada and the United States. This common approach to establishing import tolerances was expected to promote trade between North America and the rest of the world. Mexico has not, however, participated in this project (EPA[49]).

The NAFTA Agreement was replaced in 2018 by the T-MEC Agreement,[4] but the co-operation on pesticides continues under the TWG. Currently such co-operation takes place under Chapter 9 of the T-MEC Agreement on Sanitary and Phytosanitary Measures (SPS) and under the supervision of the Committee on Sanitary and Phytosanitary Measures (Box 1.2).

The T-MEC Agreement (as it was with the NAFTA Agreement) does include provisions and mechanisms that provide an opportunity for strengthened co-operation on pesticides management between the countries. Unfortunately, these provisions and mechanisms have not been fully explored by Mexico to date. One of the reasons for this situation could be the complexity of the regulatory and institutional framework on pesticides management in Mexico. With the adoption of the PLAFEST Regulation in 2014, and the inclusion of a provision on the joint evaluation request therein (Chapter 2), Mexico has evidently tried to boost the tripartite co-operation. Unfortunately, this provision has not yet been applied in practice.

The most recent policy and regulatory efforts in Mexico as well as changes expected in the future, described in more detail in Chapter 2, constitute a major opportunity to reinvigorate the co-operation on pesticides under the T-MEC Agreement. Moreover, the objectives of the co-operation agreed under the current 2016-20 Strategy of the TWG (e.g. on pesticides' registration review and re-evaluation or minor uses) (Box 1.2) can clearly support the on-going regulatory discussions and reforms in Mexico.

Box 1.2. Tripartite co-operation on Pesticides under the T-MEC Agreement

Main objectives of the co-operation on sanitary and phytosanitary measures (Article 9.3):

- protect human, animal, or plant life or health in the territories of the Parties while facilitating trade between them;
- strengthen communication, consultation, and co-operation between the Parties, and particularly between the Parties' competent authorities;

- ensure that sanitary or phytosanitary measures implemented by a Party do not create unnecessary barriers to trade;
- enhance transparency in and understanding of the application of each Party's sanitary and phytosanitary measures;
- encourage the development and adoption of science-based international standards, guidelines, and recommendations, and promote their implementation by the Parties;
- enhance compatibility of sanitary or phytosanitary measures as appropriate; and
- advance science-based decision-making.

The Agreement states (Article 9.16.5) that if there is mutual interest, partiers are encouraged to:

- if feasible and appropriate, undertake science-based joint risk assessments;
- if applicable and in accordance with the procedures, policies, resources, laws, and regulations of each Party, provide access to their respective completed risk assessments and the data used to develop risk assessments; or
- if appropriate, co-operate on aligning data requirements for risk assessments.

Objectives of the work of the Technical Working Groups (Article 9.18.4):

- engage, at the earliest appropriate stage, in scientific or technical exchange and co-operation regarding sanitary or phytosanitary matters;
- consider any sanitary or phytosanitary measure or set of measures identified by any Party that are likely to affect, directly or indirectly, trade, and provide technical advice with a view to facilitating the resolution of specific trade concerns relating to those measures;
- serve as a forum to facilitate discussion and consideration of specific risk assessments and possible risk management options;
- provide an opportunity for Parties to discuss developments relevant to the work of the technical working group;
- discuss other issues related to this Chapter; and
- report to the SPS Committee on progress of work, as appropriate.

Objectives of the 2016-20 Strategy of the Technical Working Group on Pesticides:

- Identify trade barriers and approaches to promote equal access and simultaneous introduction for pest management tools.
- Encourage co-operation on joint reviews of new pesticides and uses (including minor uses), and the re-evaluation/re-registration review of pesticides to increase efficiency and quality of decision-making.
- Work co-operatively on priority science and regulatory issues and practices including data requirements, science approaches and policies for data interpretation, and risk assessment and communications of regulatory decisions.

Source: (Government of Mexico, 2019[50]; NAFTA Technical Working Group on Pesticides, 2016[51]; USMCA[52]).

FAO/WHO Codex Alimentarius and multilateral environmental agreements

FAO/WHO Codex Alimentarius

FAO/WHO Codex Alimentarius, or "Food Code" is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission (FAO & WHO[53]). Mexico adopted to the Codex Alimentarius in 1969.

The Mexican industry has in place voluntary programmes implementing FAO and WHO guidelines on pesticides management that could be considered as co-regulatory mechanisms, including the international code of conduct on pesticide management (FAO & WHO, 2014[54]) and registration toolkit (FAO, n.d.[55]). Initiatives like CUIDAGRO-BUMA, *Campo Limpio* and SINTOX are described in more detail in other parts of this report.

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

The Rotterdam Convention covers pesticides and industrial chemicals banned or severely restricted for health or environmental reasons. Its objectives are to promote shared responsibility and co-operative efforts in the international trade of certain hazardous chemicals and contribute to their environmentally sound use, by facilitating information exchange (Secretariat of the Rotterdam Convention[56]).

In 2005, Mexico ratified the Rotterdam Convention. The provisions of the Convention are legally binding. The Convention makes the implementation of the Prior Informed Consent procedure mandatory and defines the steps that Parties should follow for the movement of pesticides and industrial chemicals (United Nations Environment Programme, 1998[57]).

The main authorities responsible for the implementation of the Rotterdam Convention are COFEPRIS, SEMARNAT and SENASICA. The Secretary of Foreign Affairs is also involved.

In line with the provisions of the Rotterdam Convention, in 2008, Mexico notified to the Secretariat of the Convention national final regulatory actions prohibiting 16 pesticides not belonging to the Annex III of the Convention (chemicals subject to the prior informed consent procedure). All of these pesticides were restricted in Mexico in the 1990s, before it ratified the Rotterdam Convention. Mexico does not undertake risk evaluation in the decision-making process in restricting or prohibiting pesticides (Secretariat of the Rotterdam Convention, 2019[58]).

In line with the obligation in the article 10 of the Rotterdam Convention, as of March 2021, Mexico provided the Secretariat of the Rotterdam Convention with import responses for 30 pesticides or pesticide formulation, but did not transmit such response in relation to five pesticides. Mexico allows importing one pesticide regulated under the Rotterdam Convention without any conditions and 10 pesticides or pesticide formulations under specific conditions. The last import responses were provided in 2012 (Secretariat of the Rotterdam Convention, n.d.[59]).

The Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention aims to protect human health and the environment from so-called Persistent Organic Pollutants (POPs) by, among others, prohibiting and eliminating intentionally released POPs, restricting their production and uses, as well as reducing and eliminating releases of unintentionally produced POPs (Secretariat of the Stockholm Convention[60]). In July 2020, the Convention covered over 30 chemicals or groups of chemicals, including 18 pesticides (Secretariat of the Stockholm Convention[61]).

Mexico ratified the Convention in 2003. SEMARNAT is responsible for the implementation of the Convention and the Secretary of Foreign Affairs is also involved. In 2007, SEMARNAT published the National Implementation Plan (NIP) of the Stockholm Convention (Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT), 2007[62]). As a result, the National Coordinating Committee was established with the objective of supervising the implementation of the Plan. This body includes the participation of representatives from the private sector, NGOs, academia and government and comprises eight working groups with its own action plan. The NIP was updated in 2016. It stated, among others, that there were still records for the use of two POP pesticides: pentachlorophenol and sulphuramide (PFOS, perfluorooctane sulfonate). It also noted that Mexico require further efforts to collect information from the

holders of small amounts of POPs pesticides as well as strengthening of pesticides management, in particular waste management and disposal (SEMARNAT, 2017[23]).

In addition, some of the POPs pesticides covered by the Stockholm Convention, namely chlordane and lindane (the latter is also covered by the Rotterdam Convention) had undetermined valid registrations in Mexico. This led the Mexican National Human Rights Commission to recommend the Mexican authorities to strictly comply with the multilateral agreements regarding toxic substances contained in pesticides and to prohibit or regulate their use in Mexico (NHRC, 2018[22]).

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal

The objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes, by the reduction of hazardous waste generation, promotion of their environmentally sound management and restriction of their transboundary movements (Secretariat of the Basel Convention[63]). Mexico ratified the Basel Convention in 1991. SEMARNAT is responsible for the implementation of the Convention and the Secretary of Foreign Affairs is also involved

OECD Pesticides Programme

The OECD Pesticides Programme has three main objectives:

> *To help OECD governments share the work of pesticide registration and re-registration – the licensing of new products and re-licensing of old ones. This involves finding ways for governments to work together in assessing pesticide risks to human life and the environment.*
>
> *To harmonise the data and methods used to test and assess pesticide risks. Harmonisation not only helps governments work together but also ensures the quality of the data and the rigour of the assessments.*
>
> *To help OECD governments reduce the risks associated with pesticide use. In this case, the Programme focuses on the variety of things that governments can do to supplement pesticide registration and further reduce risks that may result even when registered pesticides are used properly (OECD[64]).*

To assist countries to co-operate in the review of pesticides, the OECD has created internationally agreed formats for the two main documents used in registering agricultural chemical pesticides: the “dossiers” of pesticide test data submitted by industry, and the “monographs” containing OECD governments’ evaluation of the test data. These agreed formats improve the quality and consistency of pesticide reviews. They also make it easier for OECD countries to work together and reduce the workload for industry by making it possible to submit similar data packages to different countries.

The OECD Test Guidelines is a set of internationally agreed testing methods used by government, industry and other stakeholders in identifying and characterising potential hazards of chemicals. The OECD Test Guidelines for the pesticide residue chemistry aim to assess pesticide exposure by identifying these residues in food or animal feedstuffs for purposes of dietary risk assessment and setting MRLs. They have been developed and based on guidelines in use in OECD countries and by the FAO (OECD, 2013[65]). The OECD has also developed an MRL calculator to harmonise pesticide MRLs across the OECD countries (see Chapter 2).

The OECD works to address several issues related to pesticide risk reduction, including better user compliance, container management and labelling, better training and education programmes, and reducing pesticide spray drift. Other risk reduction issues being addressed include protecting pollinators from the risks of pesticides and fighting illegal trade of pesticides. The OECD also deals with the issue of minor uses (i.e. a small-scale pesticide use for pest control in a low acreage crop or a small pest problem in a large acreage crop). More information and examples of the OECD work are referred to in Chapter 2.

COFEPRIS and SEMARNAT are designated as the main contact points for the OECD Pesticides Programme. However, the participation of Mexico was limited in the last years. In the light of ongoing reforms in Mexico in relation to its pesticides management scheme, the country might wish to consider which of the areas of the work undertaken by the OECD might correspond best to the Mexican efforts and might therefore benefit from an increased engagement from the Mexican stakeholders.

Better regulation tools to improve pesticide management

Better regulation in Mexico

In 2018, the government issued the General Law on Better Regulation (GLBR), which aims to strengthen the regulatory framework for improving the quality of the regulation. This General Law substituted the previous Federal Law on Better Regulation. The main objective of this law is to ensure the existing regulation is fit-for-purpose and the regulation to be issued brings more benefits than costs in the overall. The main elements in the GLBR include:

- *Ex ante* and *ex post* RIA
- Public consultation
- Annual Plan of Better regulation for all government agencies (national and subnational)
- National Registry of formalities and services and subnational registries of formalities and services
- The creation of the National Observatory of Better Regulation
- The creation of the National Council of Better Regulation

CONAMER is the oversight body in charge of providing the general guidelines for the implementation of the *ex ante* and *ex post* assessment of the regulation, as well as all the other better regulation tools. The CONAMER has to co-ordinate with all subnational better regulation authorities to ensure a sound and comprehensive regulatory framework.

Regulatory impact analysis process and the public consultation

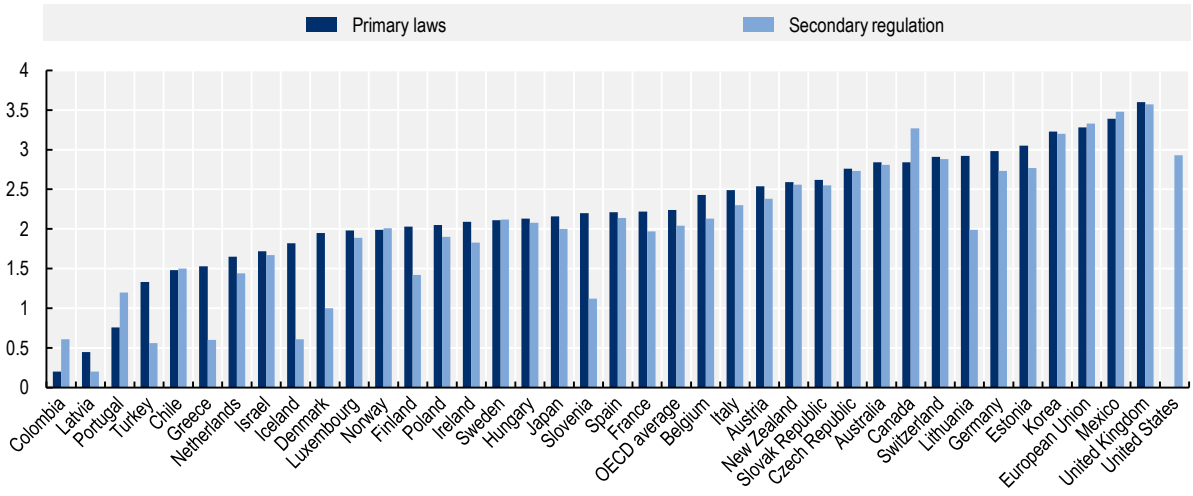
All the entities of the public administration belonging to the Executive branch have to present a RIA before issuing a regulation, seeking positive net-benefit for citizens.[5] Within the elements of the RIA, the government agency is required to have a public consultation with stakeholders.[6] At subnational level, each entity has to have an oversight body for the implementation of the RIA.

The OECD composite indicators on RIA include methodology, oversight, quality control, systematic adoption and transparency. As seen in Figure 1.7, Mexico has the second highest ranked RIA system, both for primary laws and secondary regulation, only after the United Kingdom.

At national level, CONAMER has different types of RIA, depending on the impact of the regulation to be issued. Each of the RIAs consider a specific type of impact, which could be an antitrust effect, a high-impact effect, medium-impact effect or even an emergency RIA. At national level, the CONAMER has guidelines for the *ex post* RIA since 2012. This tool applies only to NOMs that were classified as high-impact, medium-impact or those which have an impact on competitiveness during the RIA process. This process includes modification of pesticide regulation.

Since the PLAFEST was issued in 2004, it has been reformed only once, and the reform went through the RIA process. In 2011, COFEPRIS sent a RIA for approval to CONAMER (COFEMER at the time), to reform the PLAFEST to add the renewal process for pesticide registrations (CONAMER, n.d.[66]). This reform was finally published in 2014. Other changes in the pesticide regulatory framework have not generated compliance costs, and therefore CONAMER exempted regulators from conducting a RIA.

Figure 1.7. RIA composite indicators



Note: United States only has data available for secondary regulation.
Source: Indicators of Regulatory Policy and Governance Surveys 2014 and 2017, http://oe.cd/ireg.

However, there have been some important regulatory changes which have affected import of certain pesticides. They have been implemented through the modification of import tariffs, which fall into the category of Tax policy and therefore, according to the GLBR (and the former Federal Law of Administrative Procedure), are exempted from RIA. If a list of prohibitions or restrictions of the use, manufacture or import of pesticides were to be added to the PLAFEST, modifications to this list are likely to require a RIA. (Chapter 2 covers the prohibition of substances in detail).

The framework for public consultation, for all technical regulations, including pesticides, at national level in Mexico is well-designed and highly ranked among OECD countries. The LGMR describes the obligations on public consultation. The national government agencies of the executive power have to perform a public consultation with stakeholders before issuing a regulation,[7] through a web portal available to all public, in which the regulation is posted for at least 30 days. Agencies are obliged to respond to all comments submitted during the public consultation.

Ex post *assessment of regulation*

Ex post assessment of regulation allows government agencies to understand whether their regulations are indeed achieving their stated policy objectives. In Mexico, the GLBR mandates that each agency submits their regulations for an *ex post* assessment every five years (Art 77). Similar to the RIA, the *ex post* assessment has to include a 30-day public consultation.

Having this mandate for all regulations is a considerable effort, and the expectation is that only a low percentage of relevant regulations will be considered for *ex post* assessments. The GLBR also expanded the mandate; before this only NOMs were subjected to periodical revisions, now regulation in a broader sense is considered. Up to now, there haven't been any technical *ex post* assessments of pesticide regulations in Mexico. Box 1.3 below states the OECD recommendations to implement *ex post* assessment that can help Mexico's implementation efforts of this tool.

Box 1.3. OECD principles for *ex post* assessment

- Regulatory policy frameworks should explicitly incorporate *ex post* reviews as an integral and permanent part of the regulatory cycle
- A sound system for the *ex post* reviews of regulation would ensure comprehensive coverage of the regulatory stock over time, while "quality controlling" key reviews and monitoring the operations of the system as a whole.
- Reviews should include an evidence-based assessment of the actual outcomes from regulations, against their rationales and objectives; they should note any lessons and make recommendations to address any performance deficiencies.
- There need to be oversight and accountability systems within government administrations to provide ongoing assurance that significant areas of regulation will not be missed and that reviews are conducted appropriately.
- There are benefits in institutional arrangements that combine oversight of the processes for *ex ante* as well as *ex post* assessment, and that do so across the whole of government.
- The type of *ex post* review, and its timing or "triggers", are generally best determined at the time regulations are being made.
- Departments and agencies should provide advance notice of forthcoming reviews of regulation (ideally in the form of an annual "forward regulatory review plan").
- There should be explicit provision in agency budgets to cover the costs of reviewing the regulations for which they have responsibility.

Source: (OECD, 2020[67]).

The one-in-one-out rule

The one-in-one-out rule is a mechanism to control the stock of regulation. It consists of eliminating one regulation, whenever an agency is to issue a new one. This rule can work with different criteria, as one-in-one+-out, which means that agencies have to eliminate at least the equivalent number of new regulations issued.

In 2018, Mexico enforced a *compliance-cost-based* rule, for any entity of the federal administration that proposes to issue or modify regulations. That is, rather than trying to keep the regulatory inventory with a lower number of regulations, the rule is trying to reduce the compliance cost of the regulatory stock:

> *For the issuance of regulations, the Obliged Subjects must expressly indicate in their regulatory proposal, the regulations to be modified, abrogated or repealed, in order to reduce the cost of compliance by an amount equal to or greater than that of the new obligations of the Regulatory Proposal that is intended to be issued and that refers to the same subject or regulated sector. (Art 78, GLBR).*

This raises a number of practical challenges for Mexican regulators. The first, is that this rule is more complex to implement than the classical one-in-one-out that it usually focuses on burden (Trnka and Thuerer, 2019[68]). The real cost of compliance is hard to assess, since there are hidden, opportunity, and shadow costs, for instance. If regulators only take into account the explicit cost of a procedure, the fee for an application for example, they would be underestimating the real cost of the regulatory stock. It would imply a high effort to conduct a full measure of compliance costs every time a regulator is to issue a new one.

The second challenge arises from the fragmented nature of the management of the pesticide regulations. As discussed in this chapter, pesticide regulation in Mexico is managed by a large number of agencies. This means, that each agency has a small portion of the overall regulatory stock of pesticides, which reduces the room for manoeuvre if an agency is to issue a new regulation. Otherwise, agencies can co-ordinate with other regulators to simplify stock managed elsewhere, which raises co-ordination challenges. By streamlining the number of authorities involved in pesticides, this rule could bring further benefits.

Notes

[1] Constant 2010 USD.

[2] In broad terms, a general law establishes regulatory powers and provisions for the three orders of government in Mexico – federal, state and municipal levels. In contrast, a federal law only sets regulatory powers for the federal level.

[3] Which was abrogated in July 2020 and replaced with the new Law on Quality Infrastructure (http://www.diputados.gob.mx/LeyesBiblio/pdf/LICal_010720.pdf, last access on 5 May 2021)

[4] In November 2018, Canada, Mexico and the United States signed a new trade agreement, the Mexico-United States-Canada Agreement (called T-MEC in Mexico, CUSMA in Canada and USMCA in the United States). The name applied by Mexico will be used in this report. T-MEC entered into force on 1 July 2020.

[5] The other branches include the legislative and judicial powers. Additional elements could be considered to comprise the constitutional autonomous bodies, such as the Central Bank and the Telecom Regulator. Although the GLBR establish that some of its provision also apply to these additional elements, in terms of RIA they are not obliged to follow this process.

[6] There are exception to carry out both RIA and public consultation. The former when the agency demonstrates that there are no complying costs for the regulatee, and the latter when the consultation endangers the intended public policy objective of the regulation, amongst other cases. However, to be exempted from these processes, the agency must request clearance from CONAMER through a fully justified submission. CONAMER can deny the request if deemed appropriate.

[7] Except in cases in which CONAMER grants an exception, as discussed before.

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2 Central aspects of pesticide regulation: registration, evaluation and enforcement

This chapter focuses on the state of play in relation to the assessment of pesticides and the process of approval/(re)registration of new and existing active ingredients and pesticide products. In particular, it describes the registration scope, strategy, process, and data requirements, and how Mexico performs the evaluation of pesticides during this process. It also presents information on how Mexico revokes pesticide registrations of pesticides already registered and on the market. This chapter also includes a review of the current approach to how regulators monitor and enforce compliance with regulatory requirements as they relate to pesticide management.

Mexico has a mandatory registration scheme for pesticides in place

Pesticide registration is a scientific, legal, and administrative procedure undertaken before a pesticide product can be sold and used. It aims to ensure that the product is effective for its intended purpose and does not pose an unacceptable risk to human or animal health or the environment (Frezal and Garsous, 2020[1]; FAO & WHO, 2013[2]).

Companies that want to produce a new pesticide or active ingredient must submit a registration dossier to the competent government authority in the country of intended use. A pesticide product will be authorised for sale or export in a specific country only after a complete review and assessment of the submitted pesticide dossier and approval by the responsible authority (Frezal and Garsous, 2020[1]).

Internationally recognised elements of a pesticide registration scheme

Each country remains independent in deciding on its pesticide registration scheme. Nevertheless, the OECD (OECD, n.d.[3]), FAO and WHO have developed guidelines for governments concerning potential elements of such schemes to support countries' efforts and, where feasible, promote international harmonisation. They call for, among other things, that governments introduce the necessary legislation for the registration of pesticides. This should include establishment of a registration procedure, based on the principle that the sale and use of pesticides that have not been registered are prohibited. A comparison of FAO and WHO guidelines with the situation in Mexico is provided in Table 2.1. As it is observed in Chapter 1, the Mexican pesticide management framework covering the pesticide registration scheme does not currently have one unified objective or aim.

Table 2.1. Comparison of the FAO and WHO guidelines on the regulatory elements of the pesticides registration scheme and Mexico's requirements

FAO and WHO guidelines	Mexico's regulatory framework
Application procedure	Yes
Data requirements	Yes
Main criteria for decision-making on registration	Limited to formal aspects (e.g. If an applicant does not provide additional information requested, the application is considered null and void)
Communication of the justification of the decision	Yes
Validity periods for registrations	Only for pesticides registered after 2005
Provisions that a registration can be reviewed at any time (which could lead to cancellation of the registration)	Registration can be cancelled, but no systematic process of re-evaluation of pesticides registrations in place
Enshrined appeal procedure;	Yes
Provisions on confidentiality, protection of Intellectual Property Rights	Yes
Provisions on dissemination of publically available information.	Yes
Defining the "unacceptable risk"	No

Source: Author based on (FAO & WHO, 2013[2]; FAO & WHO, 2015[4]).

In many countries, the evaluation of the biological efficacy of a pesticide is part of the registration procedure. Companies submitting a product for registration must supply data on its efficacy on the crops or for the uses involved. An assessment of the efficacy of a pesticide usually includes data on its direct efficacy, the sustainability (Box 2.1) of its application and (sometimes) the economic impact of registering the product. In relation to agronomic sustainability, key questions include whether registering the pesticide is compatible with or contributes to sustainable production practices or existing integrated pest management (IPM), and whether it may jeopardise the future development of IPM in the crop (FAO, 2006[5]).

Box 2.1. Best practice – crop profiles and crop timelines

Crop profiles and crop timelines, as they are produced for instance in North America, may be a useful tool for sustainability assessments. Crop profiles are descriptions of crop production and pest management practices compiled on a regional or national basis for specific commodities, and crop timelines are descriptions of generalised crop phenology, pest occurrence and human activity for specific crops.

Source: (FAO, 2006[5]).

The environmental risks posed by pesticides have encouraged several countries to include in their registration schemes an environmental-risk assessment of pesticide products. It is aimed, for instance, to evaluate potential negative consequences to non-target organisms and environmental compartments. (Frezal and Garsous, 2020[1]).

Human health risk assessments are aiming to present the level of risk of a pesticide, under specific use conditions and are recommended to be conducted for pesticides that human health hazards are of concern (FAO, n.d.[6]). Human health risk could be divided into occupational risks and dietary risks (FAO, n.d.[7]). Human risks assessments may concern risks to workers and users at different stages of the product life cycle and risks to public health with special attention to vulnerable groups.

During the registration process, appropriate procedures should be in place to ensure that products submitted for registration comply with specifications or standards for pesticides, that the quality of the product be verified and that the labelling and packaging of approved pesticides comply with set standards (FAO & WHO, 2011[8]).

Further information can be requested for instance on the technical material and/or the formulated pesticide product. Information on authorisations in other countries, refusal of registration or cancellation of registration (including reasons) in other countries, existing pesticides assessments, established residue limits in other countries can also be requested, similarly as the safety data sheets of the products (FAO & WHO, 2013[2]).

Pesticide registration also involves the regular review of already registered pesticides to ensure that they meet the latest health and environmental risk-assessment standards. This re-evaluation process can lead to the removal of some products from the market (i.e. pesticide de-registration) (Frezal and Garsous, 2020[1]).

Furthermore, it is suggested that governments should make provisions for the effective monitoring and enforcement of pesticide regulations, including the establishment of licensing and inspection schemes for importers and retailers (FAO & WHO, 2013[2]; FAO & WHO, 2015[4]).

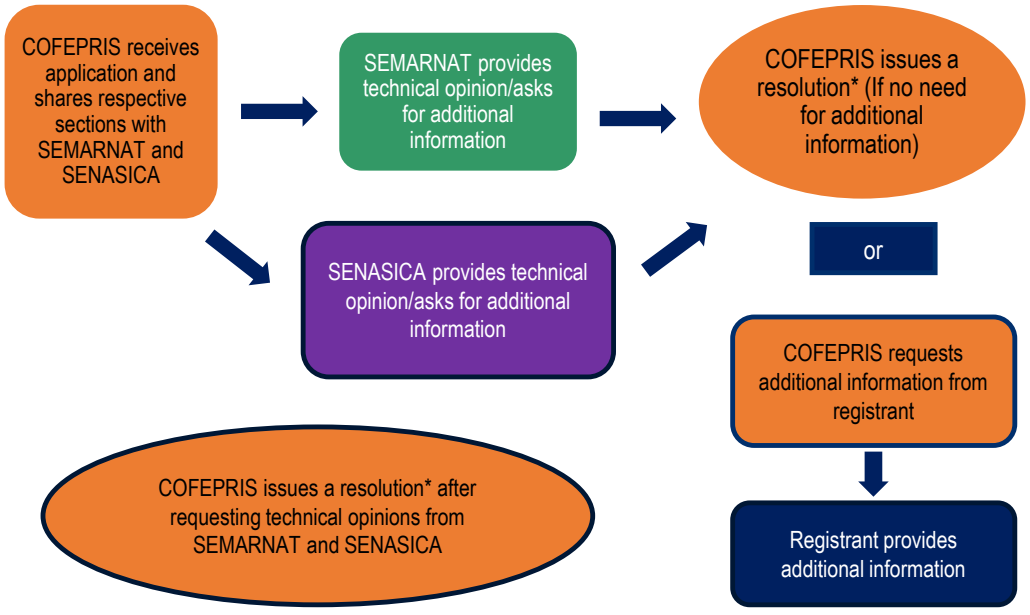
Legal grounds and scope of pesticides registration in Mexico

Article 376 of the General Law of Health (*GLH*) (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 1984[9]) states that a registration is required, among others, for pesticides, fertilisers and toxic or hazardous substances. It clarifies that a registration can only be granted by the Secretary of Health. In the case of pesticides, COFEPRIS is acting on its behalf.

The PLAFEST Regulation (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 2014[10]) concerns the registration requirements and procedures (see Figure 2.1) for more information on the institutional framework). In line with Article 7 of this legal instrument, the following chemical and biological pesticide products that are applied in the field or greenhouses on agricultural crops are subject to registration:

- chemical pesticides:
  - Technical pesticide (a pesticide in which the active ingredient is at its maximum concentration, resulting from its synthesis and that of its related compounds, and used exclusively as raw material in pesticides formulation);
  - Formulated products for agricultural use;
- biochemical pesticides for agricultural use (e.g. pheromones);
- microbial pesticides for agricultural use (consisting of a microorganism like bacterium or fungus, the active ingredient);
- botanical pesticides for agricultural use (made of substances extracted from plants or metabolites obtained from their extracts, and used for pest control purposes);
- miscellaneous pesticides for agricultural use (products having no pesticide physico-chemical and toxicological properties, but having characteristics enabling pest control).

Figure 2.1. The pesticides registration process in Mexico is managed jointly by COFEPRIS, SEMARNAT and SENASICA



* Not issuing resolution by COFEPRIS within statutory deadlines is understood as a negative response to the application request.
Source: Author based on the PLAFEST Regulation (Congreso de la Unión, 2004[11]).

Both active ingredients and formulated products have to be registered. Adjuvants and inert ingredients do not need registration, but information on the latter should be provided under data requirements.

Aerial spraying of pesticides

The Official Mexican Standard NOM-052-FITO-1995 regulates the requirements for the start of operation of aerial application of agricultural pesticides. These requirements apply to the civil or legal persons, as well to the owners of the starting/landing runways and the related aircraft.

The Official Mexican Standard NOM-003-STPS, published in 1999, includes a provision related to the safety of the aerial application of pesticides. Persons other than the Signaller ("banderero" in Spanish) should not have access to the application area. The norm also prescribes the list of PPE to be provided to the Signaller. The company is responsible for the demarcation of the treatment area and the buffer zones in a way that it is clearly visible for the pilot (SENASICA, 2019[12]) Proposed updates to NOM-003-STPS (in consultations from 2016) include an important obligation (in particular from the occupational health and safety perspective), for the civil or legal persons using the services of the workers to apply pesticides, to supervise that the Signaller follows the prescribed risk reduction measures and takes a shower and changes clothes after pesticide application.

2.1.3. Data requirements for pesticides registration in Mexico

Each country is independent in determining the scope of data required for pesticides registration, taking into account its national circumstances. However, the OECD guidance and information materials (OECD, 1994[13]) & (OECD, 2005[14]), as well as the FAO and WHO guidelines provide information on certain types of data that can be required for these purposes (FAO & WHO, 2013[2]).

In line with the 1994 OECD survey, most of the OECD governments require information on:

- identity (of the active ingredient as well as any inert ingredients in the pesticide product formulation);
- physical-chemical properties;
- function, mode of action and handling;
- manufacturing, quality control and analytical methods (to detect residues in food or water);
- residues (the quantity and characteristics of residues likely to occur in food);
- efficacy (in controlling the target pest);
- toxicity (to man);
- ecotoxicity (to wildlife and beneficial insects);
- fate and behaviour in the environment (OECD, 1994[13]).

A comparison of the FAO and WHO guidelines for data requirements with Mexico's requirements is provided in the Annex 4D.

In relation to the data registrants are required to submit, Mexico applies a two-tier approach. According to the PLAFEST Regulation, certain common information is requested for all registration requests and some specific data is required based on the type and use of a pesticide product.

The *common* information includes:

- An application form;
- For domestically produced and imported pesticides: a certified letter from the supplier, specifying:
  - commercial and common name of the product and its composition (percentage);
  - name and address of supplier;
  - name and address of the product purchaser, which must be the registrant and

  - registration number, if the product is already registered (only for domestically produced pesticides).
- For pesticides manufactured abroad by the registrant, a letter containing a sworn statement confirming veracity of this situation.

The *specific* technical data required is described in Table 2.2. For chemical pesticides there are different data requirements for the registration of active ingredients and formulated products. There are also different data requirements for biochemical pesticides, microbial pesticides, botanical pesticides and miscellaneous pesticides for agricultural use. (More detail on the data requirements can be found Annex D).

Table 2.2. Technical data requirements for the registration of pesticides in Mexico vary depending on their type

Data requirements according to Article 12 of the PLAFEST Regulation, as amended in 2014.

	Chemical pesticide – technical pesticide	Chemical pesticide – formulated product for agricultural use	Biochemical pesticides for agricultural use	Microbial pesticides for agricultural use*	Botanical pesticides for agricultural use	Miscellaneous pesticides for agricultural use
Information on identity and composition	Yes	Yes	Yes	Yes	Yes	Yes
Physico-chemical properties	Yes	Yes	Yes	Yes	Yes	Yes
Analytical methods/procedures	Yes	No	Yes	Yes	No	No
Toxicological information	Yes	No	Yes	Yes	Yes	Yes
Ecotoxicological and environmental fate information	Yes	No	No	Yes	No	No
Proposed label	Yes	Yes	Yes	Yes	Yes	Yes
Biological effectiveness opinion	Yes	Yes	Yes	Yes	Yes	Yes
Hazard category	Yes	No	No	No	Yes	No
Other information	No	MRLs for each crop requested Information and documentation required for technical pesticide unless already registered by registrant		Information on the agent's biological properties Product stability information	Storage stability study	No

* Certain specificities are applicable to information required for registration of a microbial pesticide based on genetically modified organisms.
Source: Elaboration by author based on the PLAFEST Regulation.

In relation to biochemical pesticides for agricultural use, microbial pesticides for agricultural use, botanical pesticides for agricultural use and miscellaneous pesticides, the PLAFEST Regulation specifies that registrants may provide only a limited amount of information for registration purposes:

- if a registrant has already registered a technical pesticide or a formulation based on the same active ingredient, and the product to be registered has the same supplier holding the registration previously granted;
- if the pesticide has been identified by COFEPRIS, in consultation with SADER (SENASICA) and SEMARNAT, as a reduced risk pesticide.

Biological efficacy data is regulated separately from the PLAFEST Regulation, in the Mexican Official Standard NOM-032-FITO-1995. SADER (SENASICA) requires, among others, administrative data, product identity and composition (name, IUPAC, CAS), physico-chemical data, toxicological information, or product label. In relation to the biological effectiveness studies, Mexico does not accept studies carried out outside the country (SENASICA, 2020[15]).

The PLAFEST Regulation explicitly states that 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 and the industry is expected to submit proof of GLP certification.

In line with the PLAFEST Regulation,

> *Physico-chemical, toxicological, ecotoxicological, environmental fate and physical properties studies should be developed under guidelines recognised by the international organisations. If no guidelines exist, the method used should be described, and the corresponding justification should be included. Studies should be conducted by laboratories with quality assurance systems, or by a third party authorised. It is considered as having a quality assurance system, when the laboratory applies national or international guidelines accepted by the ISO, or when following its own good practices guidelines. (…)When conducted outside Mexico, studies should be written in Spanish or in English (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 2014[10]).*

Provisions are in place to protect confidentiality and proprietary rights held on test data submitted for pesticides registration. The information submitted under the registration application is considered confidential. The PLAFEST Regulation also requires that registrant provides information on the name of the author of the toxicological or ecotoxicological studies submitted or the name of the institution or laboratory that produced data. It is not clear, however, if registrants should provide certification of the right to use the data by the author or institution/laboratory and if the application for registration is accepted in the absence of such certification.

When filling the administrative part of the registration application, the applicant is informed that data provided under the registration procedure can contain confidential information and the latter is requested to indicate if agrees to make the data public by the authorities (COFEPRIS[16]).

If a registrant has no access to certain data required under the registration, COFEPRIS could allow using the data of the already registered product, provided that registrant obtained authorisation to access these data from the registered product supplier. For the biological effectiveness, an interested party shall provide the letter issued by SADER (SENASICA) acknowledging access to the biological effectiveness information, and the technical opinion of the supplier of the formulated product.

Equivalence registration and registration solely for export

The PLAFEST Regulation envisages a possibility to register a technical pesticide or concentrated technical pesticide that is equivalent to an already registered one. It is also possible to request registration for pesticides solely intended for export, provided that the pesticide product will not be sold or used in Mexico. In this situation, a more limited technical information is required.

Emergency use of pesticides is allowed

In special circumstances, the responsible authority may have to consider allowing the use of pesticides that are unregistered, cancelled or registered for other purposes. The goal is to control an outbreak of vector-borne disease, avert a significant risk to human health or the environment (e.g. a significant risk to endangered or threatened species or beneficial organisms) or to avert significant agricultural losses (FAO & WHO, 2013[2]).

The emergency use of unregistered pesticides is not allowed in Mexico. However, to address phytosanitary, zoosanitary or sanitary emergencies, the PLAFEST Regulation allows for a use of registered pesticides for purposes different than provided for in the registration and to import it, if it is not available or not sufficiently available in the country.

In such case, the holder of the registration has to be notified, and in the case of an imported pesticide, agree to it. The authority declaring the emergency has to notify all other authorities co-operating under the PLAFEST Regulation on the temporary use of a pesticide, location of the use and its estimated duration. In the case of import, the authority has to obtain an import permit from COFEPRIS.

Minor uses of pesticides

Minor uses, including the majority of speciality crops, are the uses of pesticides where the potential use is on a scale not sufficiently large to justify registration of that use from an applicant's perspective alone. In particular, when the associated costs of generating the data required for obtaining and maintaining regulatory approval and potential liability from those uses once approved are taken into account. This results in a situation where speciality crop industries are either without or are lacking sufficient access to pest control products to adequately protect those crops. OECD has a vision of greater harmonisation of regulatory systems such that data reviews prepared to a common format in one region or country can be used to support regulatory decisions in another country. Towards this objective, OECD has published a number of guidance documents focussing on minor uses (OECD, 2020[17]).

At this time, Mexico does not have regulatory provisions addressing minor uses of pesticides. Addressing this issue would upgrade the regulatory framework in Mexico and would support the harmonisation of regulatory systems with its trade partners. It would also support national stakeholders by providing speciality crop industries with access to pest control products to protect those crops adequately. For instance, the financial support provided by the Australian Government for the minor use grants program is considered as critically important to increase farmers' access to chemical uses (Matthews et al., 2020[18]). Another example of such support, the Canadian Growing Forward initiative, is presented in Chapter 3.

New and non-traditional pesticides

The PLAFEST Regulation includes a category of "miscellaneous" pesticides. They are defined as products having no pesticide physico-chemical and toxicological properties, but having characteristics enabling pest control.

Under this category, SENASICA has evaluated so-called "resistance inducers". However, as this type of product is not clearly defined in the Mexican regulatory framework, the registration and the evaluation for assessing biological effectiveness were considered challenging. The former was based on the qualities declared by the promoter of the product, and the latter on the determination of biological effectiveness is based on parameters adapted to the mode of action (SENASICA, 2020[15]).

Technical modification of the registration

The PLAFEST Regulation contemplates the possibility of technical modification of a pesticide registration. It includes a change or extension of use including crop, pest, dose, animal species and aspects related to the function or use; adjustment of the expiry date; changes in the formulation inert ingredients. In such situation, the following technical information is requested:

- for use modification or extension per crop, pest and dose for agricultural pesticides – the biological effectiveness technical opinion issued by SADER (SENASICA) in favour of the company;
- maximum residue limit for each crop requested, for use modification or extension per crop or animal species, for agricultural pesticides;

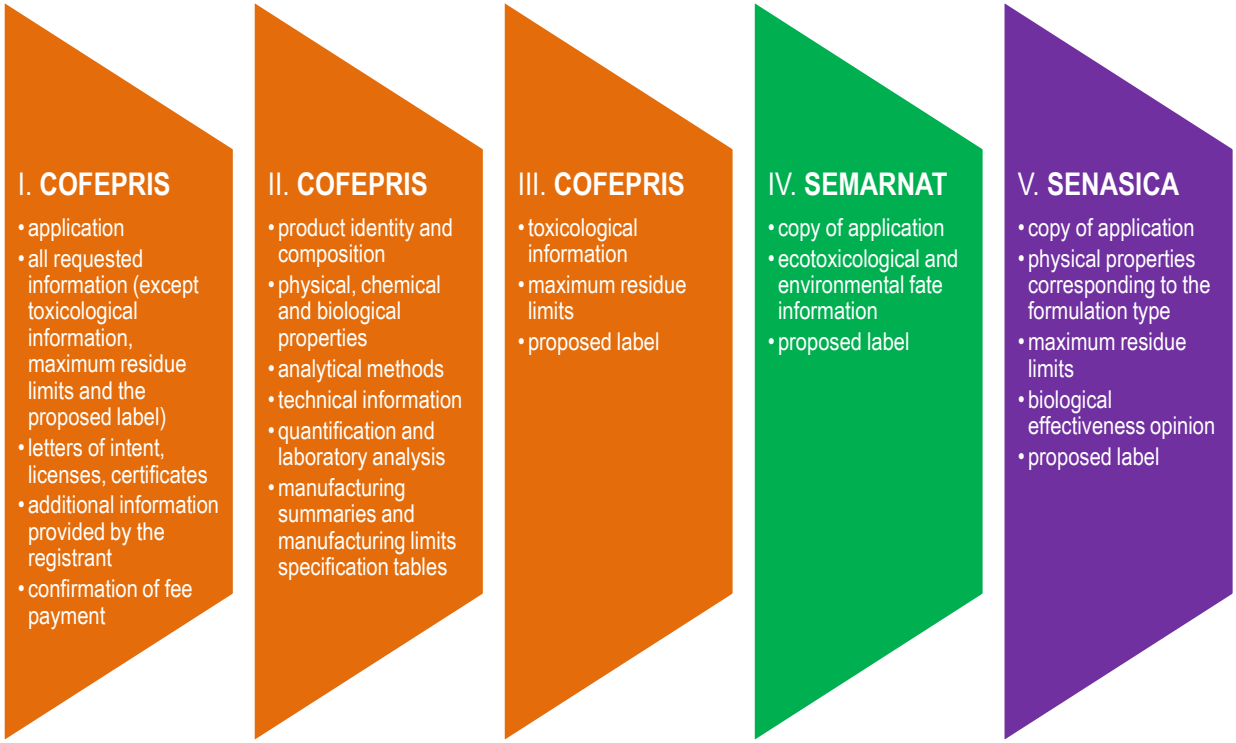
- for modifications of the expiration date, information related to the study of storage stability;
- proposed label;
- for changes in the formulation inert ingredients:
  - official letter describing the change of inert ingredients in the previously registered formulation, and the modified formulation, and specifying the reasons for such change;
  - identity and composition of the formulation previously registered and the modified formulation;
  - type of formulation; and
  - hazard category.

Current practices in relation to pesticides data sharing and exchange

In Mexico, all the documentation relevant for pesticides product registration has to be provided to COFEPRIS in a traditional, paper format (original and copy). A registrant may use an electronic form available from COFEPRIS (the PLAFEST form), but the form only concerns the administrative filing of the registration application and not the data within the data dossier. To support sharing information between COFEPRIS, SEMARNAT and SENASICA (also in the paper format), this information has to be submitted by registrants in five parts (Figure 2.2). This allows COFEPRIS to distribute parts IV and V to SEMARNAT and SENASICA respectively, while maintaining parts I, II and III for its own use.

Figure 2.2. Registration information has to be provided in five parts to support information sharing among authorities

Type of information provided by pesticides registrants to COFEPRIS and its presentation according to five parts.



Source: Author based on the PLAFEST Regulation (Congreso de la Unión, 2004[11]).

While COFEPRIS receives the full pesticide registration dossier from a registrant, SEMARNAT and SENASICA only receive the parts relevant for their specific disciplines. If the latter need other data to complete their opinion, they have to request access to the remaining part from COFEPRIS. This adds another layer of complexity and there is a risk that information from COFEPRIS arrives too late to allow SEMARNAT and SENASICA to meet their regulatory deadlines.

Moving away from a paper registration process to an on-line registration and exchange of information system (which would include the data in a dossier) for pesticides in Mexico, should provide benefits for authorities. First, it would ensure that regulatory work can continue in every condition and it would allow for a fast and secure sharing of registration information among authorities involved. It would allow access to relevant information by all relevant authorities, from everywhere, and would support the compliance and enforcement activities, particularly in the field. Stakeholders should welcome such an approach, as it will bring tangible benefits to them. It should facilitate not only regulatory work, but also the information submission process for industry and the access to updated information for the public.

This transition requires certain investments at the implementation stage, particularly in the IT--infrastructure and equipment. It might also be beneficial to retain a possibility to use “paper” communication in the mid-term, to support inclusion of all relevant stakeholders. However, the digitalisation of the pesticides registration and evaluation process seems inevitable. It has already happened in many OECD countries, for instance in Canada and the EU.

Mexico already allows for an on-line electronic information provision for one of the aspects of its pesticides management programme. A so-called PLAFEST form is used to apply for a pesticide import permit via the One-Stop-Window of the Mexican Foreign Trade Receipt System (VUCEM). An electronic signature is one of the technical requirements to use this option.

The PLAFEST form includes information on the company, the uses of pesticides, product data (e.g. commercial name, CAS number, composition of the product, its classification, toxicological data, country of production/formulation, country of export or import), information on the producer, formulator, provider and final user (Government of Mexico[19]).

The PLAFEST Regulation does not include a mechanism for exchanging confidential information with regulatory authorities in other countries. Explicitly addressing such a possibility in the Mexican regulatory framework would support the future co-operation of pesticides authorities with their counterparts in other countries, for instance for joint evaluations. The OECD Recommendation concerning the Exchange of Confidential Data on Chemicals, OECD/LEGAL/0204, recommends that adherents to this legal instrument take steps to develop the conditions which would allow for the exchange of confidential data (OECD, 1983[20]).

Mexico is encouraged to use OECD electronic tools to facilitate exchanges of pesticide data (e.g. the *Globally Harmonised Submission Transport Standard* (OECD, n.d.[21]), a standardised set of technical specifications used to assemble electronic files for any pesticide package in a predefined manner), as well as to join the OECD work on facilitating the development and adoption of other electronic tools, such as efforts to identify common global label data requirements to assess the benefits of the use of structured data in IT systems, which receive, maintain, and share label information.

Pesticides registration process in Mexico

PLAFEST regulates the process for registering pesticides (Figure 2.3). There is no pre-registration phase, so in principle the registration stage starts with the submission of the registration application to COFEPRIS. However, as a pre-requisite for applying for a registration is to obtain SENASICA’s technical opinion on biological efficacy, this pre-registration step in practice should be taken into account.

The PLAFEST regulation describes the data and information a registrant must submit to COFEPRIS as well as the timelines for the activities carried out by the relevant authorities and the applicant during the process. No additional support in terms of clarifying the requirements, such as development of guidelines, is provided to applicants.

After receiving the application, COFEPRIS provides SEMARNAT and SADER (SENASICA) with information relevant for their technical evaluation. Both authorities are able to ask COFEPRIS to request additional information or clarification from the applicant. If the authorities do not request additional information or clarification, it is understood as a positive opinion towards the registration request.

If neither COFEPRIS, SEMARNAT nor SENASICA request additional information or clarifications, COFEPRIS requests technical opinions from SEMARNAT and SENASICA. If any of these authorities abstains from providing its opinion, it is considered positive for the applicant.

If an applicant is requested to provide additional information or clarifications, the process is put on hold until the information is provided (for a maximum of 60 days, in line with the PLAFEST Regulation). The authorities can only request information once during the registration process. After receiving input from the applicant, SEMARNAT and SENASICA are requested to provide their technical opinion. If an applicant does not provide the requested information, the application is considered null and void.

COFEPRIS issues a resolution that could either be positive, which results in granting the registration, or negative, which results in rejecting the registration application.

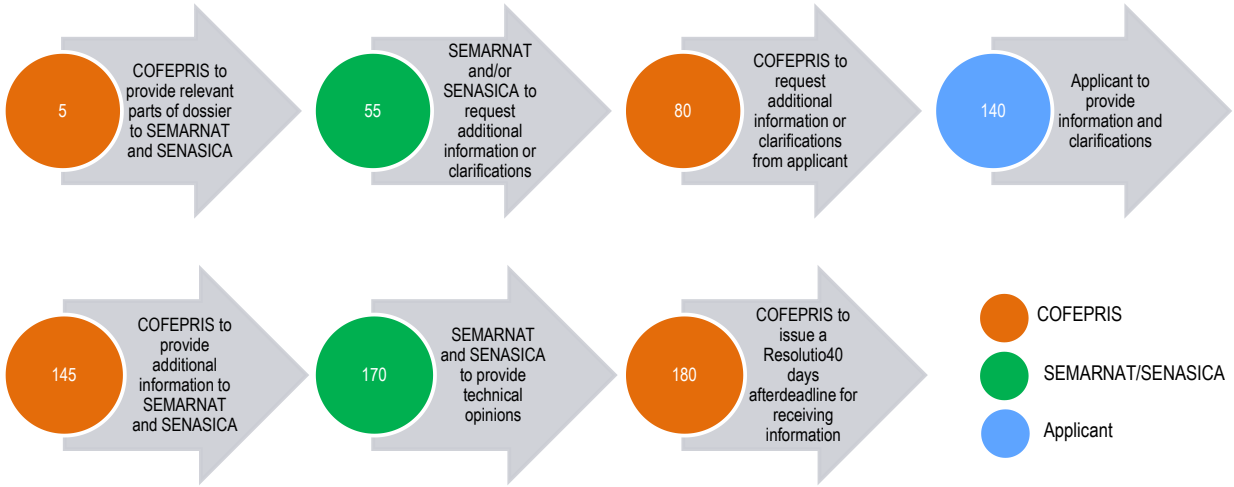
The PLAFEST Regulation also contains a provision that if COFEPRIS does not issue a resolution (i.e. a decision) within the statutory deadlines it is understood as a negative response to the application request. Some Mexican stakeholders have raised concerns that statutory deadlines linked to the pesticides registration are not always met.

The registration procedure described above does not apply to products, whose registration would be requested via the Joint Evaluation Programme conducted together with the authorities responsible for pesticides registration in Mexico's "commercial partners", as it is indicated in the PLAFEST Regulation. In such a case, a separate procedure is to be established among the Mexican authorities, authorities from commercial partner(s) and the applicant. This provision, introduced in 2014 to the PLAFEST Regulation, is aimed in particular towards the Mexican counterparts in T-MEC Agreement (i.e. Canada and the United States), has not been applied in practice yet in Mexico. On the other hand, a joint evaluation of pesticides has been put in practice by Canada and the United States (Box 2.3).

The PLAFEST Regulation establishes a timeline for a review of a pesticide registration application (Figure 2.3). Taking into account the maximum allowed time, COFEPRIS should deliver its resolution within 180 working days after receiving the registration application.

Unfortunately, detailed information on the actual average duration of the pesticide assessment period is unavailable. Nevertheless, it is possible to compare the statutory duration of the process as described in the PLAFEST Regulation with the assessment timelines in other jurisdictions in the OECD area (Box 2.2). It shows, in general, that in Mexico the timeline allocated for an evaluation of a new pesticide is much shorter than elsewhere.

Figure 2.3. Timeline of the review of a pesticide application in Mexico



Note: The numbers indicate maximum allowed working days for a given action counting from the submission of the pesticide registration application.
Source: Author based on the PLAFEST Regulation.

Box 2.2. Selected timelines for registration and evaluation of pesticides in OECD countries and the European Union

Australia

In Australia, the assessment period required for the approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and product is 18 months.

Canada

In Canada, the review timeline range for submissions to register new active ingredients and their companion end-use product(s) is between 285 and 655 days.

European Union

In the European Union, it takes between 2.5 and 3.5 years from the date of admissibility of the application to the publication of a Regulation approving a new active substance. For a pesticide product, it takes up to 1.5 years from the date of application to the granting of on authorisation.

United States

In the United States, it takes 24 months to evaluate a new registration of a conventional active ingredient for food use (18 months in the case of a reduced risk pesticide).

Note: As countries vary in the number of options for the registration of active ingredients and pesticide product, the intention was to present timelines for the most "conventional" situations, to support comparison with the standard situations described in the Mexican regulatory framework.
Source: (APVMA, 2020[22]; Health Canada, 2019[23]; European Commission[24]; European Commission[25]; US EPA[26])

While the added complexity of the EU procedures across all its member states, the European Food Safety Authority and the European Commission (e.g. with peer reviews of Rapporteur Member State Risk Assessments) explains a longer timeline in comparison with Mexico, the significant difference with Canada and the United States – the other T-MEC Agreement countries – is concerning. It suggests that certain aspects of the evaluation process could be less developed in Mexico and therefore addressing them would be essential to support the harmonisation of approach to pesticides evaluation in all three T-MEC partners and related co-operation, for instance in relation to the joint assessments of pesticides.

Policy documents (e.g. 2019 Elements for the Development of an Integral Strategy for Responsible Pesticides Management in Mexico) and feedback from the Mexican stakeholders (e.g. Proposals of the 2018 Mexican National Forum on Pesticides) suggest that the biggest room for improvement is linked to the environmental aspects of the pesticides evaluation process in Mexico

The PLAFEST Regulation also provides regulatory timelines for other activities linked to the modification and extension of a pesticide registration, as well as granting export/import permits (Table 2.3).

Table 2.3. Selected deadlines for other regulatory actions under the PLAFEST Regulation

Type of action	Timeline
Pesticide registration exclusively for export	150 working days
Technical modification of registration	150 working days
Extension of registration	32 working days
Pesticides import permit	16 working days
Pesticides import authorisation (SEMARNAT)	20 working days

Source: Author based on the PLAFEST Regulation.

COFEPRIS is obliged to publish on its website a database with granted registrations as well as with pending requests. The database should be updated at least every 30 days, supporting among other things, the transparency of the registration process. However, this obligation has not always been fulfilled.[1] Increasing efforts to publish this information within the regulatory deadline would support transparency of the registration process. Moreover, including information in the database on the starting date of the registration process, as well as of the date of registration itself, could support authorities in collecting timeframe performance statistics and analysing how they implement regulatory deadlines from the PLAFEST Regulation in general.

The database run by COFEPRIS includes the following information on registered pesticides: registration number, company name, active ingredient, commercial name, toxicology category, uses and validity. It also includes MRLs for active ingredients. Search is possible by registry number, company name or active ingredient. No information on the studies behind a given pesticides registration (e.g. study summaries) is available. Moreover, the information is not updated regularly. Information on the year each pesticide was registered would also be very useful for the users.

The Coordinated Sanitary Registry (*Registro Sanitario Coordinado*, RSCO) registration number (obligatory on the label) includes information on the type of pesticide (e.g. insecticide, herbicide), a number of active ingredient registration, type of product (e.g. liquid or suspension) and a percentage share of active ingredient (SENASICA, 2019[12]).

In February 2021, this registry database included over 7 950 entries, including some 340 cancelled registrations (COFEPRIS[27]). The number of cancellations increased significantly since 2019 (by some 90 registry cancellations), largely in response to the recent actions undertaken by authorities described previously. of this chapter. It is estimated that the validity period is indefinite for about 4 000 entires (NHRC, 2018[28])(see Box 2.5).

In 2018, 530 pesticides in Mexico were considered highly hazardous, 1 137 were classified as having high acute toxicity (according to the WHO classification), 850 were considered as probably carcinogenic to humans (according to the US EPA), 642 being endocrine disruptors (according to the GHS) and 2 464 toxic to bees. COFEPRIS calculated also that there are 90 active ingredients registered in Mexico that are prohibited or not authorised in other countries (NHRC, 2018[28]).

Many active ingredients that are registered and authorised for use in Mexico are banned or severely restricted in its main trade partners, 16 in the United States and 45 in the EU in 2017 (NHRC, 2018[28]).It can affect the Mexican population and the environment and trigger potential trade-related problems.

In the case of applications for registration of pesticide products destined exclusively for export and applications for a technical modification of existing registration, the procedure is similar as in a standard registration. However, only COFEPRIS and SEMARNAT are involved in issuing the resolution on the export registration, while only COFEPRIS and SADER (SENASICA) are involved in the technical modification of the registration.

The decision-making process on evaluating pesticides in Mexico

In order to determine whether the use of a pesticide proposed for registration poses an unacceptable risk to human health or the environment, countries consider matters such as the toxicity of pesticide, their metabolites or degradants, and potential exposure during or after application. FAO and WHO recommend risks from potential exposure pathways to be evaluated, including workers' exposure, exposure to food residues in food or the exposure of non-target organisms (FAO & WHO, 2013[2]).

As indicated earlier, a pre-requisite for pesticide registration and evaluation in Mexico is to obtain SENASICA's technical opinion on biological efficacy. In line with the Mexican Official Standard NOM-032-FITO-1995, in order for SENASICA to grant a technical opinion, a company has to provide SENASICA with the product data, including the results of the field studies conducted by an approved test laboratory.

PLAFEST Regulation establishes the regulatory framework for evaluation of pesticides and the division of responsibilities. While three authorities (COFEPRIS, SEMARNAT and SENASICA) are involved in the evaluation process, PLAFEST assigns the leading role to COFEPRIS.

SENASICA is responsible for biological efficacy and phytosanitary aspects of MRLs and SEMARNAT for environmental evaluation, COFEPRIS is responsible for the health evaluation of the pesticide registration application, and more importantly it is the only institution that is entitled to grant (and to cancel) the registration. SEMARNAT and SENASICA may not provide any explicit opinion in the registration and evaluation process. In such case, this is considered for the benefit of the applicant. However, in practice, COFEPRIS is bound in the registration process by the veto power of SEMARNAT and SENASICA as it relates to the technical opinion of the respective components of the registration application. 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 to harmonise approaches (e.g. risk management vs. hazard based) so that they can effectively work together. Additionally, as described in Chapter 1, the three main authorities involved in the process work in the context of different framework laws. They may have competing policy objectives, goals and priorities and this can impact the extent of the co-operation between them.

In line with the PLAFEST Regulation, pesticides evaluation in Mexico under the registration process is either:

- based on local evaluation (use of mainly local data and locally specific assessments); or
- equivalence (based on the determination of the equivalence or near equivalence between the submitted product and a registered product).

For the registration of an active ingredient or a microbial pesticide in Mexico, a registrant is required to submit a study of the impacts on populations of beneficial and pollinizer insects as part of the eco-toxicological information data set. In the case of a microbial pesticide, if there is scientific evidence showing that application of the pesticide does not lead to exposure or damages to non-target organisms, and does not cause environmental pollution, the applicant can be exempted from the requirement to provide a study, upon provision of the justification.

In line with the PLAFEST Regulation, studies on physico-chemical, toxicological, ecotoxicological, environmental fate and physical properties conducted in other countries are accepted.

The General Law of Ecological Balance and Environmental Protection includes a provision that pesticides prohibited in other jurisdictions cannot be legally authorised in Mexico. However, the data requirements specified in the PLAFEST Regulation do not clearly require such information. In general, it is considered that this restriction has not been effectively implemented (Bejarano, 2018[29]). Formalising the process of providing information on pesticides prohibited or restricted in other jurisdictions, for instance during the registration, modification and extension of a registration, as well as when requesting an import permit for pesticides, would support the authorities' decision-making on registration and cancellation of registrations. Chapter 3 includes information on the approach in Canada, which regulatory framework has specific provisions for a review of a registered pesticide, when an OECD country prohibits all uses of an active ingredient for health or environmental reasons.

It is unclear, to what extent Mexico uses the pesticides assessments performed in other countries and by international organisations and whether its procedures for decisions on registration reflects the granting or refusal of registrations taken under other jurisdictions. It is not explicitly reflected under the PLAFEST Regulation.

The possibility of a joint assessment of pesticides between Mexico and its trade partners is addressed in the PLAFEST Regulation as of 2014. However, it has not materialised yet and one could expect that increased harmonisation of the evaluation process in Mexico might be needed for this, as the two other T-MEC countries are already co-operating in this area (Box 2.3).

Box 2.3. Best practice – Canada and United States co-operation on the joint evaluation of pesticides

In May 2015, Health Canada's Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency's Office of Pesticide Programs (US EPA OPP) announced that they would be collaborating on a bilateral pesticide re-evaluation process for the pollinator assessment of three neonicotinoid pesticides (clothianidin, imidacloprid, and thiamethoxam). The initiative is part of the co-operation under the Regulatory Cooperation Council and the evaluation based on the jointly developed harmonised Guidance for Assessing Pesticide Risks to Bees.

These pesticides are nitroguanidine neonicotinoids, a group of insecticides that have been approved for use in the United States and Canada for a number of years. In recent years, there have been reports in scientific literature suggesting that exposure to neonicotinoids may affect pollinator health; however, these studies have generally been conducted under laboratory situations, or in the field with exposure to doses that are higher than would normally be encountered in the environment.

A summary information on joint reviews is available for instance in Canada's Pest Management Regulatory Agency annual reports.

Source: (Health Canada's Pest Management Regulatory Agency, 2016[30]).

While the PLAFEST Regulation contains detailed information on the information requested by the authorities to evaluate a pesticide registration application and the timelines of the evaluation, in principle it does not provide scientific nor technical criteria to support relevant decision-making in relation to the registration of active ingredients and pesticides products. In fact, the only explicitly mentioned common criterion is the procedural one – lack of response from the applicant to the request to provide additional information or clarifications results in no further processing of the application, if the authorities made request within statutory deadlines.

The FAO Pesticide Registration Toolkit includes information on pesticides registration criteria applied by various national registration authorities (FAO, n.d.[31]). Pesticide regulators in other countries prepare guidance documents that include scientific or technical criteria supporting relevant decision-making. Such documents can support the evidence-based decision-making as well as the interpretation of evaluation performed in other jurisdictions, including their potential adaptation to the Mexican conditions. The availability of guidance resources for potential applicants can also reduce inefficiencies during the registration process (examples of guidelines available in Australia and Canada are available in Chapter 3). Development and adoption of international guidelines would also benefit international work-sharing and potentially faster access to new pesticides.

An exception to this rule concerns a possibility to register a technical pesticide or concentrated technical pesticide in equivalence to already registered one. The PLAFEST Regulation contains a set of criteria to decide if a pesticide is chemically equivalent and its toxicological profile is equivalent to a reference profile, including:

- A maximum manufacturing level of each non-relevant impurity is not significantly higher than a maximum manufacturing level of the reference profile;
- No new relevant impurities are found;
- The maximum manufacturing level of relevant impurities is not increasing as related to the maximum manufacturing level of the reference profile;
- LD50 results for oral and dermal acute toxicity studies and LC50 for the inhalation toxicity study delivered by the interested party shall not differ by more than a factor of two times, as compared to the reference profile;
- The product to be registered that, based on toxicological studies delivered, proving to be less toxic up to a factor of ten, as compared to the profile used, may also be considered as equivalent;
- Results of dermal and eye irritability tests must prove that the product is equally or less toxic.

The PLAFEST Regulation contains no directives that would address the undertaking of a risk- benefit analysis in the decision-making on the registration of pesticides. However, it is unclear that, at the moment, a registration decision contemplates comprehensively the economic and agronomic value of introducing a pesticide (SENASICA, 2020[15]), as well as balances it with its risks to human health and the environment.

Some countries, including New Zealand and the United States have incorporated more comprehensive considerations. They address agronomic, economic, social, health and environmental benefits as well as likely consequences of the public not having access to specific pesticides. By applying a benefits test, products can be approved where the overall benefits outweigh the risks posed by their use. A risk/benefit or cost/benefit consideration is a well-established principle of good regulation in wider government regulatory decisions. It enables the balance of interests to be taken into account in rational decision-making. Despite the additional work for the regulator and increased cost for industry, a benefits test could deliver access to more chemical uses and improved safety outcomes (Matthews et al., 2020[18]).

A consultation process is enshrined in the decision-making on pesticide registration in Mexico. Moreover, a decision on registration communicated to the applicant should include a justification. Nevertheless, calls for more transparency and consistency of conclusions, have been voiced (PROCCYT, 2020[32]). It is linked to the fact that, 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 decisions. It is of particular relevance for some types of products (e.g. biopesticides) which might need to be regulated more on a case-by-case basis.

The Federal Law of Responsibilities of Public Servants includes a conflict-of-interest policy and guidelines for public officials. This is a common procedure in many OECD countries. In line with the requirements, the onus remains on public officials to proactively report and resolve real, potential and apparent conflict-of-interest situations as they arise in conjunction with their management (OECD, 2017[33]).

Maximum Residue Limits

A Maximum Residue Limit (MRL) is defined by FAO as:

> the maximum concentration of a pesticide residue (expressed as mg/kg), to be legally permitted in or in food commodities and animal feeds. MRLs are based on Good Agricultural Practice (GAP) data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable (FAO[34]).

In most of the OECD members MRLs are established at the same time or before a pesticide product is approved for use. In general, most data generated in support of MRLs are developed by the pesticide manufacturer (OECD, 2010[35]). In principle, the applicant should provide the necessary residue data generated in accordance with the Codex Alimentarius and guidelines published by the OECD on Good Laboratory Practice and by FAO guidelines on crop residues for assessment by the responsible authority (FAO & WHO, 2013[2]).

The MRLs are based on field trials and toxicological data. Reference doses and acceptable daily intake are compared with food consumption patterns, residue data and monitoring data (Handford, Elliott and Campbell, 2015[36]). The MRLs are essential in ensuring safe consumer exposure to and protecting vulnerable groups from products containing pesticide residues, MRLs can also be used as a compliance tool to investigate if the pesticide was misapplied.

MRLs are also relevant in the context of the international trade in food. For instance, foods imported to the EU countries are sampled to ensure that they do not contain pesticides above the set MRLs. In 2016, 53.1% of the Mexican samples analysed had quantified residues below or at the MRLs and only 4.5% of samples analysed had quantified residues above the MRLs (EFSA, 2018[37]).

In line with the PLAFEST Regulation, COFEPRIS and SENASICA share the responsibility for developing and implementing MRLs in Mexico. COFEPRIS is responsible for conducting risk assessments to set MRLs, while SENASICA issues a technical opinion on the phytosanitary aspects of MRLs of pesticides.

In 2014-17, SADER (SENASICA) and COFEPRIS worked on the Official Mexican Standard for MRLs. NOM-082-FITO/SSA1-2017 on Maximum Residue Limits, Technical Guidelines and Authorisation and Review Process was published in October 2017.

In line with NOM-082-FITO/SSA1-2017, an authorisation can be granted for an MRL generated during field studies conducted in Mexico or based on:

- MRLs in Codex Alimentarius (as long as they are valid and correspond to the same pesticide/crop combination or pesticide/group of crops combination);
- MRLs established by US EPA; Canadian PMRA; members of the European Union, members of the OECD, as well as Argentina and Brazil (as long as the use of pesticide is comparable, they are valid and correspond to the same pesticide/crop combination or pesticide/group of crops combination);

- MRLs generated in Mexico and based on field studies conducted in the countries indicated in the previous bullet (as long as the use of pesticide is comparable).

Prior to the adoption of NOM-082-FITO/SSA1-2017, Mexico used the MRLs from the US EPA. Its legal provisions required also consideration of Codex MRLs and Mexico would accept Codex MRLs in the absence of a national MRL (OECD, 2010[35]). The 2014 update of the PLAFEST Regulation included also a temporary provision (until NOM was published) allowing using MRLs established in the countries abovementioned, on condition that COFEPRIS conducts a relevant risk assessment.

An MRL can be revised if the status of the international source of the MRL has changed (e.g. the MRL has been modified or cancelled), based on new dietary risk analysis conducted by COFEPRIS or based on the results of the National Residues Monitoring Programme. Import only MRLs, for pesticides not used domestically, are not covered by this NOM-082-FITO/SSA1-2017.

NOM-082-FITO/SSA1-2017 describes what information related to MRLs has to be provided by the applicant during the pesticides registration process. It also recognised the use of the OECD MRL calculator in the process (Box 2.4).

Box 2.4. Best practice – OECD MRL calculator

The OECD has developed an MRL calculator (OECD[38]) to harmonise pesticide MRLs across OECD countries.

The use of this calculator has been officially recognised in Mexico in NOM-082-SAG-FITO-SSAI-2017.

The applicant is recommended to use the calculator to calculate the MRL value for MRLs generated during field studies conducted in Mexico and MRLs generated in Mexico and based on field studies conducted in the countries specified in NOM-082-SAG-FITO-SSAI-2017.

Therefore, the country has harmonised its approach with the other T-MEC countries, Canada and the United States.

NOM-082-FITO/SSA1-2017 states that the authorised MRLs shall be in the public domain and applicable to any application for registration of the same pesticide/crop combination, provided that the pattern of use of the registrant is comparable to the pattern of use of the source taken as reference. The authorised MRLs, whose reference source is CODEX Alimentarius, are exempt from demonstrating comparability of the use pattern. COFEPRIS and SADER (SENASICA) are responsible for monitoring compliance with this NOM.

In the context of 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, it could be noted that import MRLs are not covered by NOM-082-FITO/SSA1-2017.

Under the OECD Pesticides Programme, members and partners as well as other stakeholders work to develop harmonised Test Guidelines and Guidance Documents on pesticide residue chemistry to support the assessment of pesticide exposure by identifying these residues in food or animal feedstuffs for purposes of dietary risk assessment and setting MRLs. Such guidance also supports the mutual understanding of such assessments. For instance, the Expert Group on Residue Chemistry is working on developing guidance on the definition of a residue, based on a common approach to residue identification of the pesticide and its metabolites and degradation products. Mexico would be encouraged to participate in this work.

Work to complete the implementation of NOM-082-FITO/SSA1-2017 is still in progress, in particular as it relates to the relevant regulatory procedures and guidelines. For example, guidelines for accrediting laboratories that could undertake field studies in Mexico necessary to establish national MRLs are needed. There is a need for capacity building activities related to the implementation of NOM-082-SAG-FITO/SSA1-2017, including providing guidelines to the industry on the MRLs evaluation criteria and approval. In this context it is also important to note the need to ensure that information on established MRLs in Mexican public available databases is up-to-date and systematically updated.

Labelling of pesticides

The International Code of Conduct on Pesticide Management defines a pesticide label as:

> written, printed or graphic matter on, or attached to, the pesticide or the immediate container thereof and also to the outside container or wrapper of the retail package of the pesticide (FAO & WHO, 2015[39]).

Labels convey essential information from the product manufacturer to the user of pesticides about the product and the relevant safety and use recommendations. Labels may also contain information on hazards of the pesticide product. It is an important tool to protect human health and the environment. For labelling purposes, the pesticide formulation or end-use provides basis for classification, not the active ingredient (FAO & WHO, 2015[39]).

According to FAO and WHO guidelines, proposed labels should be subject to approval by the registration authority during the registration process. The sale of pesticides that are not properly labelled should be prohibited. Requirements for labels should be based on relevant international standards and recommendations on pesticide labelling (FAO & WHO, 2015[40]).

In line with the PLAFEST Regulation, the proposed label has to be included as part of the registration application. It has to be approved by the authorities. All pesticide products in Mexico have to have a label. Labelling is regulated in NOM-232-SSA1-2009 that takes into account international standards and recommendations on pesticide labelling: the FAO\WHO Guidelines on Good Labelling Practice for Pesticides and the Globally Harmonised System of Classification and Labelling of Chemicals.

The label is composed of three sections: safety information (including use and management precautions and recommendations, PPE, first aid and emergency numbers), technical information (including information on the active ingredient, formulation, target pest, validity, hazard statement and warning) and use (including use instructions, calibration of equipment, dose or re-entry time) (SENASICA, 2019[12]).

The digitalisation of the registration process in Mexico would enable better access to and dissemination of information contained on the labels of pesticides products. It allowed, for instance, the Canadian authorities to run a publicly available label transcript service, that can present information included in the pesticides labels on the market (Health Canada[41]).

Re-registration and re-evaluation of pesticides in Mexico – addressing legacy issues and supporting harmonisation with main trade partners

According to the General Law of Health, a registration can be renewed at the request of the registrant. If it is not requested, or the registrant changes or modifies the product or raw material without prior authorisation from the health authority, said authority (COFEPRIS in the case of pesticides) will cancel or revoke the corresponding registration.

The 2005 modification of the General Law of Health established a 5-year validity period for sanitary registrations (including pesticides), but only obliged holders of the indefinite registrations of pharmaceuticals and health inputs to undergo a revision of their registration. Therefore, holders of pesticides registrations granted before 2005 retained their indefinite registrations (Mexican Congress (Congreso de los Estados Unidos Mexicanos), 1984[9]).

A characteristic of the current Mexican system is that in the case of definite registrations (granted after 2005), in practice no new information is needed for the renewal of existing registration (Bejarano, 2018[29]). The procedure is simplified and short (it lasts maximum 32 working days) and, contrary to the registration process, a lack of response from COFEPRIS is considered as favourable for the applicant: "afirmativa ficta" or "silent-is-consent" rule, although this is not implemented automatically. Information required to renew registration include:

- statement from the applicant that the registered product continues to comply with conditions of the granted registration (request will not be processed if non-authorised administrative or technical modifications are indicated);
- confirmation of the payment;
- certificate of the quality control analysis;
- information on inert ingredients, density or weight;
- proposed label;
- information on MRLs for each requested crop;
- common name; and
- information on the hazard category.

According to estimations, most pesticides were registered in Mexico before 2005 and therefore has indefinite registration validity. Only few registrations have been cancelled since the 1990s (Bejarano, 2018[29]).

The period of time for which a registration is valid varies across OECD countries. An example of some validity period is provided in (Box 2.5).

Box 2.5. Validity of pesticides registration in the OECD countries

- In Australia, approval of an active constituent continues to be in force unless it is cancelled. The registration of a chemical product ends on the day entered in the Register as the date the registration ends.
- In Canada, the period of registration may be either finite or indefinite; re-evaluation and special review mechanism are in place (more details available in Chapter 3).
- In Chile, the term of validity of the registration is 10 years.
- In the European Union, active substances are approved for a maximum period of 10 years.
- In Korea, the term of the registration is 10 years.
- In New Zealand, a registration is normally valid for 5 years.
- In the United States, all pesticides registered for use on food or feed must be reviewed at least once every 15 years.

Source: (Government of Australia[42]; Government of Canada, 2020[43]; Chile's Agriculture and Livestock Service[44]; European Commission[45]; Korea Law Translation Center, 2015[46]; New Zealand Food Safety, 2019[47]; US EPA[48]).

An unlimited registration period (i.e. for those pesticides in Mexico that were on the market before 2005) means that it is very difficult to address recent developments and new information on the safety of those pesticides. Further, unlimited registration periods for existing pesticides could conceivably create a disincentive to develop new and more environmentally friendly pesticides, as those new pesticides would have to undergo a new evaluation.

A largely administrative character of information provided during the extension of registration of pesticides in Mexico does not provide authorities with updated information on the safety of the registered pesticide. Requesting more information at this stage would provide tangible benefits for the Mexican authorities. For instance, demanding updated data on the safe use of registered pesticides would support the Mexican efforts to timely address human and environmental pressures from pesticides and support removing the most hazardous ones from the list of registered pesticides in the country.

Moreover, in practice there is no systematic process of re-evaluation of pesticides in place in Mexico aside from the possibility to cancel the registration. Other countries have recently recognised the benefits of a technical review programme for pesticides. For example Japan (Box 2.6) is currently reforming its system in this direction. Examples of the pesticides review programmes in other OECD countries are provided in Chapter 3. It is also worth noting in this context that the EU applies a risk proportionate approach to its scheme for the renewal of approval of active substances by applying different renewal timeframes depending on the risk of pesticides (shorter timeframes for higher risk pesticides, longer for low risk pesticides) (European Parliament, n.d.[49]).Such approach supports prioritisation and better allocation of resource.

Box 2.6. Revision of the Pesticide Registration System in Japan

In 2018, Japan announced that it is modifying its Agricultural Chemicals Control Act (Act No. 82 of 1948) that sets out the process of the pesticide registration in Japan. The main changes include:

- A periodic re-evaluation (every 15 years) of all registered pesticides. Under the previous system, registrants renew registration of their pesticides every three years but it did not include a scientific review of new findings;
- The data requirements for re-evaluation are the same as those required for new registration;
- The GAP may be changed or the registration is revoked based on the re-evaluation;
- Specifications for technical grade active ingredients shall be established at the time of first registration and re-evaluation;
- The registrants shall report, to authorities, newly available information on the safe use of their registered pesticides once a year, e.g. information on pesticide use accidents, revocation or changes of registration in countries outside Japan, and scientific papers concerning the safe use of the pesticides.

The implementation of the reform is taking place in 2018-2021.

Source: (Sato, 2018[50]; Japan[51]).

The possibility to cancel pesticide registration is enshrined in the regulatory framework

In line with the COFEPRIS Rules of Procedure and the General Law of Health (Article 380) COFEPRIS is authorised to revoke sanitary authorisation if it becomes known that authorised products constitute a risk to human health. The possibility of revoking a pesticide due to a lack of biological efficacy, is not currently contemplated in the regulatory framework (SENASICA, 2020[15]).

A pesticide registration is considered an acquired right and cannot be revoked without the registrant consent. A potential risk presented by a pesticide is not enough to cancel registration. Scientific evidence (e.g. thorough studies) is needed to demonstrate a risk (NHRC, 2018[28]). This affects the process of cancellations of pesticides registrations in Mexico. For instance, in 2017, COFEPRIS informed the National Human Rights Commission that the use of six active ingredients, including DDT, endosulfan and lindane, was prohibited in 2015 and that it led to the cancellations of 146 sanitary registers. However, when the NHRC verified the information available in the COFEPRIS registry, only one of the six active ingredients in question had no valid (undetermined) registrations[2] (NHRC, 2018[28]).

Moreover, if a company holding a pesticide registration goes out of business, legally, authorities cannot cancel the registration unless they first inform the company – even if it no longer exists. This could be a potential explanation why some registrations are still in the registry in Mexico, even if a pesticide is banned. For instance, in February 2021, there were still three endosulfan entries in the COFERPRIS registry, all with an indefinite registration.

Above-mentioned factors have made it difficult for the Mexican authorities to restrict or prohibit pesticides in Mexico. They have hampered their efforts to ensure that the database on pesticides permitted on the market is correct and impacted their compliance with the Multilateral Environmental Agreements dealing with pesticides. Mexican authorities have recently employed alternative methods, by using custom tariff codes, to overcome this obstacle and restrict import of certain pesticides to Mexico.

Requirements for import/export certificates

In line with the FAO and WHO guidelines, import and export requirements should include an explicit prohibition of the import of unregistered, counterfeit, substandard or obsolete pesticides, and regulation of export or transit of non-registered pesticides. It should also establish a licencing system for the import of pesticides. These requirements should also reflect the provisions of the Rotterdam Convention, the Stockholm Convention on persistent organic pollutions (POPs) and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (FAO & WHO, 2015[40]).

Responsible use of pesticides

FAO Guidance on pest and pesticide management policy development recognises three steps in pesticide risk reduction:

1. Reducing reliance on pesticides;
2. Selecting pesticides with the lowest risk to human health and the environment from the available registered products that are effective against the pest or disease;
3. Ensuring correct use of the selected products for approved applications and in compliance with international standards (FAO, 2010[52]).

Considering the above-mentioned step 1, the 2006 Mexican Law on Organic Products includes in Article 1.V a goal to promote organic production systems, especially in regions where environmental and socioeconomic conditions are supporting such activity or restructuring production systems is necessary to contribute to the recovery and/or preservation of ecosystems and to achieve compliance with sustainability criteria. As it was presented in Chapter 1, organic production is on the rise in Mexico.

> *Integrated Pest Management (IPM) means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimise risks to human and animal health and/or the environment. IPM emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms (FAO & WHO, 2016[53]).*

In Mexico, IPM supporting campaigns have been undertaken in relation to, for example, avocado tree, citrus, coffee plants cotton pests or fruit flies (SENASICA, 2020[15]). IPM programmes have been adopted for tomatoes, pecan trees, broccoli or chili peppers. IPM components, such as biological control agents, have been identified for maize pests. Implementing further IPM programmes for important Mexican crops is considered beneficial in reducing the use of pesticides in Mexico, a country with – the highest quantity of pesticides per arable land in North America. A large number of growers in Mexico is considered as one of the obstacles for the greater implementation of IPM programmes (e.g. about 2 million growers of maize, working under different conditions) (Blanco et al, 2014[54]).

The OECD Pesticides Programme has an IPM Hub that provides information on IPM policies, programmes, production guidelines and IPM case studies in OECD countries and serves as a platform for information sharing and co-operation between all stakeholders (OECD, n.d.[55]).

In relation to step 2, the issue of substituting in Mexico pesticides with less hazardous ones has encountered certain problems in the past, as it has been for instance the case of the significant number of registrations of pesticides restricted or prohibited under the Multilateral Environmental Agreements ratified by Mexico or prohibited in other jurisdictions. The recent Recommendation 82 of 2018 issued by the National Human Rights Commission may be a key element to improve the substitution of pesticides in Mexico.

In relation to step 3, as it will be described in this Section, Mexico has in place guidelines, initiatives and regulatory framework to promote the safe use of pesticides. However, while the application of pesticides requires training in Mexico, there is no certification scheme in place. Such scheme would allow the Mexican authorities evaluating pesticides to better account for the occupational health and safety risks of workers, who may have different conditions, when it comes to exposure or risk profiles, than the public. Moreover, the application of pesticides and any emerging pesticide resistance is, in general, not monitored by authorities (SENASICA, 2020[15]).

The current regulatory framework in Mexico does not differentiate between the professional uses of pesticides and the use by the general public. In practice, there are no restrictions on buying pesticides, although technical advice is needed to purchase pesticides for agriculture use (to identify the pest and select the appropriate product). Such restrictions are being applied in other countries (see Box 2.7.) to minimise unreasonable adverse effects to the environment and poisoning with pesticides (OECD, 2017[56]). Regulatory options used by authorities in the OECD countries to mitigate the risks for non-professionals include authorising only some types of formulations, requiring specific packaging or only allowing uses in certain conditions. Further information can be found in the 2017 Report of the OECD Seminar on Risk Reduction and Pesticide Non-professional uses.

Box 2.7. Best practice on restricting availability of certain pesticides to the general public

In the United States, US EPA classifies pesticides as either general use (unclassified) pesticides or restricted use pesticides (RUPs). RUPs are not available for purchase or use by the general public, as they have the potential to cause unreasonable adverse effects to the environment and injury to applicators or bystanders without added restrictions.

Source: (EPA, n.d.[57]).

In Mexico, persons who apply a pesticide in a given area are required to post warning signs, but it is only recommended that such postings take place before the pesticide is applied. If it is done after the application, a date and hour of application should be provided (SENASICA, 2019[12]).

On the other hand, authorities recommend to the purchaser to verify that a pesticide is in the original packaging, in good quality, and has a guarantee seal in place, as well as to check the validity of the product and that it has a registration number when purchasing the product. Moreover, pesticides should be purchased only at sellers certified by SENASICA, which runs the public on-line register (SENASICA, 2019[12]). As described in Chapter 3, Australia has in place an online portal to improve communication between the users of pesticides and the authorities and to support reporting on non-compliance and adverse experience with pesticides.

While the Mexican regulatory framework does not prohibit advertising unregistered, illegal, or counterfeit pesticides, or misleading advertising of pesticides, as recommended by FAO and WHO (FAO & WHO, 2015[40]), the General Law of Health includes a provision that the Secretary of Health shall authorise pesticide advertising.

In general, Mexico does not require buffer zones for the application of pesticides, with the exception of aerial applications where the landing track must be located at least 500 meters away from cities, water bodies, channels or drains (SENASICA, 2020[15]).

In this context, is worth noting that the OECD has developed a website about the regulatory approaches used by governments to address the issue of pesticide spray drift. It also provides links to peer-reviewed scientific papers that are in the public domain, validated spray drift models, spray drift field study results and other information important to spray drift risk assessment and risk management. (OECD[58]). Mexico might benefit from the on-going OECD work in this regard in the context of the planned update of its Official Standard addressing aerial spraying.

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. New OECD work on responding to the use of new digital and mechanical technologies for pest management, in particular the application of pesticides by drones, may also be of interest to Mexico.

Obsolete pesticides

Stocks of obsolete, unwanted and banned pesticides continue to represent a serious public health and environmental threat (FAO, 2009[59]). FAO has a dedicated Programme on the Prevention and Disposal of Obsolete Pesticides. FAO collaborates with countries to prevent more obsolete pesticides from accumulating and assists them to dispose of their existing stockpiles (FAO[60]). According to FAO data, the stocks of obsolete pesticides in Mexico are estimated to amount to 1 151 185 tonnes (FAO[61]).

The General Law on the Prevention and Integral Management of Waste (LGPGIR) regulates obsolete pesticides in Mexico. Mexico has in place an inventory of obsolete pesticides and contaminated sites (updated in 2016), but it is descriptive and generic, and thus has limited information on the holders of small amounts of obsolete pesticides. Management plans for obsolete pesticides involving all stakeholders are needed, as well as a comprehensive plan to stop the accumulation of obsolete pesticides. The existing inventories of contaminated sites in general only provide information about the type of contaminants (e.g. pesticides) (SEMARNAT, 2017[62]).

Empty pesticide containers

In line with the FAO guidelines, empty pesticide containers should be managed to minimise risk to human health and the environment. For instance, the containers should be decontaminated and it should be possible for users to return them when empty (FAO & WHO, 2008[63]).

Empty pesticide containers are treated as hazardous waste in Mexico, in line with the General Law on Prevention and Integral Management of Waste, and information on triple rinsing of the empty containers should be included on the label. Primary Collection Centres (CAP) are places where farmers can deposit empty containers, after triple rinsing, drying and perforation. Collected containers are then sent to Temporary Collection Centres (CAT) that prepare the containers for their final disposal at the authorised recycling centres (SENASICA, 2019[13]). In 2015, there were 959 CAP and 66 CAT in Mexico. Industry associations have supported efforts by disseminating information on triple rinsing, collection of empty containers and their final disposition among the Mexican stakeholders (SAGARPA, 2015[64]).

In Mexico, approximately 50 million empty pesticide containers (in total approximately 6 700 tonnes) are disposed of each year. However, many containers are abandoned in the fields, which leads to environmental problems. The Mexican authorities, together with stakeholders involved in the production, distribution, management and disposal of the containers have implemented a national programme for the collection of empty pesticides containers "We keep a Clean Field" (*Conservemos un Campo Limpio*) (SAGARPA, 2015[64]). However, the participation in the programme is currently not mandatory and the programme does not cover certain types of pesticides, such as biopesticides.

In 2015, there were 29 formal Management and Collection of Empty Containers Plans, registered at state level (SAGARPA, 2015[64]). The establishment of container management plans has been effective in increasing the recovery of empty containers in Mexico (OECD, 2012[65]); however additional resources are needed to support better implementation. It is estimated that only 10% of the funding needed is provided to the Mexican authorities to cover the annual costs of the collection of empty containers (SENASICA, 2020[15]).

Long standing tradition of co-operation among authorities, industry and other stakeholders to promote safe use of pesticides and address emerging issues

The promotion of safe use of pesticides 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.

Since 1983, the Mexican crop protection industry has implemented an awareness campaign on the correct and safe use of pesticides. It is called Good Use and Management of Agrochemicals (CUIDAGRO-BUMA, acronym in Spanish). It is intended for final users as well as students, academia, medical personnel and the public and builds on the FAO guidelines (SAGARPA, 2015[64]).

The topics addressed in CUIDAGRO-BUMA include the risks associated with misuse of pesticides in the field, prevention of poisoning and first aid, understanding pesticide labels, transport and storage and application of pesticides and the use of PPE. CUIDAGRO-BUMA activities are co-ordinated with local and federal authorities (in particular SENASICA), UNDP and academia (SENASICA, 2020[15]).

Mexican authorities disseminate information to the public including guidance material on good practices and the safe use of pesticides, leaflets on the purchase, management and application of pesticides and the protection of pollinators.

Mexican authorities have published a catalogue of registered pesticides products in Mexico and their authorised uses for many years. The catalogue contains a list of prohibited and restricted products in Mexico. The products are listed per crop, the pesticides approved for control of plant health problems, safety intervals (days after the application before to harvest), and authorised maximum residues limits for each product (Pérez-Olvera, Navarro-Garza and Miranda-Cruz, 2011[66]). In 1991, Mexico published a list of prohibited and restricted pesticides, which included 20 and 11 entries respectively (NHRC, 2018[28]).

COFEPRIS published the latest update of this catalogue in 2016. More regular updates would support better availability of relevant information on pesticides in the market. This is particularly the case as not all of the information in the Catalogue is included in the COFEPRIS on-line database on pesticide

registrations. A potential merger of the Catalogue content with COFEPRIS database would support better dissemination of the relevant information. Also in 2016, COFEPRIS published a Catalogue of Pesticides with Reduced Risk,

In 2018, SENASICA published "General directives for the operation, certification and recognition of the Contamination Risk Reduction Systems, Good Use and Management of Pesticides and Good Agricultural Practice in the Harvesting Activities during the primary production of plants". This document sets requirements for growers to be certified, and such certification is valid for 2 years but could be suspended or cancelled in case of any infractions (NHRC, 2018[28]). Technical requirements relevant for obtaining such certificates were published by SENASICA in 2019 (SENASICA, 2019[67]).

In 2019, SENASICA published a Manual of Good Use and Management of Pesticides in the Field (see Box 2.8). The document was developed in co-operation with SEMARNAT and academia. This manual consists of two Parts. Part I describes the FAO concept of the Integrated Pesticides Management (IPM), while Part II addresses several relevant topics of Good Use and Management of Pesticides (SENASICA, 2019[12]). The document contains practical and user friendly information. When referring to international standards or recommendations at the national level only, it also indirectly points to areas of potential improvement of the Mexican regulatory framework on pesticides (e.g. lack of obligatory inventories of pesticides in companies or lack of obligatory signalling of pesticides application, except for aerial spraying).

Box 2.8. Dissemination of information on pesticides and their safe use

2019 Manual of good use and management of pesticides in the field

The manual addresses the following information linked to pesticides management:

- classifications and labelling of pesticides;
- purchasing pesticides
- transport and storage of pesticides;
- intoxications and first aid;
- how to select PPE and application equipment;
- how to behave during and after application of pesticides, including personal hygiene and cleaning of the equipment;
- empty pesticides containers and their management; and
- illegal trade of pesticides.

Source: (SENASICA, 2019[12]).

Presentations from a three-day course on Regulation and Surveillance of Agricultural Pesticides in Mexico, held in the City of Mexico in March 2019 are publicly available on the website of SENASICA. They provide general information on pesticide management in Mexico covering a number of subjects, such as:

- regulatory framework on pesticides in Mexico;
- formulation, commercialisation, storage and application of pesticides;
- Maximum Residues Limits;
- import and export of pesticides;
- environmental requirements for pesticides registration; or
- pesticides waste management (SENASICA, 2019[68]).

The use of personal protective equipment is regulated by the Mexican Official Standard dealing with work and safety conditions in the workplace: NOM-017-STPS-2008 on the use and management of Personal Protective Equipment in the workplace and the Official Mexican Standard on Safety and hygiene conditions in agricultural activities. The latter is currently in the process of revision to focus solely on pesticides. The 1999 version of this standard required the civil or legal persons using the services of the workers to apply pesticides to use only registered pesticides, not expired, in recommended dose; provide its personnel with PPE and have a list of trained personnel.

The project of the updated standard, NOM-003-STPS-2016, includes, among other things, additional obligations to verify that all containers include the original label; have Safety Data Sheets for all hazardous pesticides and use only certified personnel for aerial spraying of pesticides. It also requires to signal areas where pesticides are mixed, filled or stored and where the use of PPE is obligatory, as well as to signal containers and area of storage of pesticides.

Nevertheless, despite the awareness-raising, training and educational efforts mentioned above, there continue to exist a significant disparity in the real-life use of pesticides, which can be observed in the results of the enforcement activities. Many factors can contribute to this. The size of the country and the number of farmers that can affect reaching out to all relevant stakeholders with relevant information is one of the possible ones. Further strengthening and broadening of the joint activities of the authorities and industry, possibly merged with policy instruments (for instance taxation mentioned in Chapter 1 or completion and implementation of NOM-003-STPS-2016) could support addressing this issue in Mexico.

Regulatory compliance and enforcement of pesticides

The 2018 OECD Regulatory Enforcement and Inspections Toolkit (Box 2.9) provides guidance on practical ways that enforcement agencies can improve their practices to achieve better regulatory compliance. These principles take into account the fact that governments usually face budget limitations and suggest ways to improve enforcement under these circumstances.

Box 2.9. OECD Regulatory Enforcement and Inspections Toolkit

1. **Evidence-based enforcement**: deciding what to inspect and how should be grounded on data and evidence, and results should be evaluated regularly.
2. **Selectivity**: inspections and enforcement cannot be everywhere and address everything, and there are many other ways to achieve regulations' objectives.
3. **Risk focus and proportionality**: the frequency of inspections and the resources employed should be proportional to the level of risk and enforcement actions should be aiming at reducing the actual risk posed by infractions.
4. **Responsive regulation**: inspection enforcement actions should be modulated depending on the profile and behaviour of specific businesses.
5. **Long-term vision**: clear objectives should be set and institutional mechanisms set up with clear objectives and a long-term road-map.
6. **Co-ordination and consolidation:** less duplication and overlaps will ensure better use of public resources, minimise 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.

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 risk-focus, co-ordination and information-sharing – as well as optimal use of resources.
9. **Clear and fair process**: coherent legislation to organise inspections and enforcement needs to be adopted and published, and clearly articulate rights and obligations of officials and of businesses.
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.
12. **Reality check**: Institutions in charge of inspection and enforcement should deliver the performance that is expected from them – in terms of stakeholders satisfaction, of efficiency (benefits/costs), and of total effectiveness (safety, health, environmental protection etc.).

Source: (OECD, 2018[69]).

Throughout the pesticide life cycle, regulated parties must comply with established requirements to minimise risks to human health and the environment. In line with the OECD Guidance on Pesticide Compliance and Enforcement Best Practice, compliance and enforcement activities can be divided into three main groups: compliance promotion, compliance monitoring and responding to non-compliance (enforcement) (Table 2.4).

Table 2.4. Compliance and enforcement activities

Compliance and enforcement activity	Compliance promotion	Compliance monitoring	Responding to non-compliance
Intent	Improve regulated parties' awareness of regulatory requirements	Verify that regulatory requirements are being met	Bring a known or potential non-compliance situation into compliance
Examples	Risk communication	Inspections	Letters
	Reports	Market surveys	Meetings
	Information bulletins	Samplings	Orders
	Seminars		Recalls
	Trade shows		Administrative penalties
	Websites		Prosecutions
	Stakeholder engagement and partnerships		

Source: (OECD, 2012[65]).

In line with FAO/WHO recommendations, compliance monitoring and enforcement should:

- ensure monitoring and data collection with respect to pesticides;
- set out powers and responsibilities of authorities to impose reporting requirements on manufacturers, importers, distributors and sellers of pesticides;
- establish a mechanism for the reporting of pesticide-related incidents by all relevant authorities and parties;

- define the powers of inspectors and their qualifications;
- provide procedures and criteria for inspections and sample taking, as well as provisions for the designation of official laboratories for analysis of samples; and
- define the actions that will be considered as offences as well as determine proportional and deterrent fines (FAO & WHO, 2015[40]).

Authorities should ensure that their inspection and enforcement activities include evaluating for compliance of the label with national regulations and develop ways to identify non-compliant, illegal and counterfeit pesticides through the careful examination of the label (FAO & WHO, 2015[39]).

While an effective registration system is essential, post-registration activities such as surveillance, education and enforcement are equally important (FAO & WHO, 2011[8]). For instance, monitoring residues on food allows governments to assess consumer safety, detect residues from improper use, and protect the credibility of exporters with their customers, while training on the use of pesticides is needed to ensure that safety information reaches the individual users.

In line with the OECD and FAO/WHO guidance, good collaboration on enforcement between the pesticide authorities and other relevant agencies such as the customs department, police department and ministry of trade is crucial for the implementation of the regulatory framework. A system for co-ordination of enforcement should be formally established, as well as training for enforcement officials, on substandard and illegal products. Close collaboration between authorities and industry is key (FAO & WHO, 2011[8]).

Provisions and co-operation on compliance and enforcement in place in Mexico

Mexico has in place a regulatory framework that includes most of compliance and monitoring elements. For example, in accordance with the Mexican Federal Law of Administrative Procedures, in order to perform inspections, government inspectors have to present a signed order by the authority within the jurisdiction. Such an order has to include a precise location, reason for the inspection, the inspection scope and the legal grounds for the inspection. The inspected entities can provide feedback and evidence in relation to the inspection scope.

Following the inspection, the company will need to confirm corrective actions implemented in writing. If the authority is satisfied that the company is now in compliance, the authority issues a formal document closing the inspection procedures. If the company does not comply, the case is sent to the legal department.

Moreover, the General Law of Health and Plant Health Law oblige federal authorities to establish co-ordination mechanisms to implement these laws. This takes place in practice, for instance if SENASICA finds a violation that belongs to the competence of COFEPRIS or SEMARNAT, it informs them accordingly and these authorities undertake further actions to address the violations (e.g. for non-registered products COFEPRIS is informed, for expired products PROFEPA under SEMARNAT is informed). However, the co-operation is not formalised (e.g. in the form of a Memorandum of Understanding) and there is no common enforcement strategy, as the enforcement activities are decided by each of the authorities separately.

For example, SENASICA verifies compliance with applicable Official Mexican Standards and prioritises under its enforcement activities the good use and management of pesticides. Annual inspection plans focus on a number of companies to inspect. Selection of the companies to inspect is done based or complaints received or randomly taking into account the following criteria:

- Mexican States that do not have certified companies in the Phytosanitary Directory;
- Mexican States that have not been visited recently; and
- Mexican States with a high agriculture activity (SENASICA, 2020[15]).

In general, data on SENASICA's inspections for 2012-18 show an increase in the proportion of companies found to be non-complaint with certain aspects of pesticides management, while at the same time the overall number of inspections is decreasing since 2015 (see Table 2.5). The latter is linked to the decreased budget allocation. Only four financial fines were applied by SENASICA in this period of time (SENASICA, 2020[15]).

Table 2.5. The share of the follow-up to SENASICA's inspections is increasing

Official inspections in the establishments dealing with pesticides (manufacturers, importers, formulators, distributors and users) and their result, 2012-18

Year	Number of companies inspected	Companies with legal follow-up	Notification to Profepa	Notification to COFEPRIS
2012	96	0	0	0
2013	97	0	0	0
2014	120	21	0	0
2015	146	25	0	0
2016	128	53	17	5
2017	61	45	15	4
2018	76	n/a	n/a	n/a
Total	710	143	32	9

Source: (SENASICA, 2020[15]; SENASICA, 2018[70]).

The findings point out to key areas of non-compliance of importance for Mexico and could direct authorities in the need for follow-up actions:

- Lack of valid certificate to commercialise pesticides (distributors and retailers);
- Lack of inventory of pesticides commercialised (distributors and retailers);
- Commercialisation of not registered or expired pesticides or in bulk form (distributors and retailers);
- Lack of evidence of the capacitation of the personnel (distributors, retailers and pesticide applicators);
- No technical advice provided to the distributors and retailers (producers/importers/formulators);
- No control of imported, manufactured or formulated pesticides (producers/importers/formulators);
- Application of unauthorised pesticides (pesticide applicators) (SENASICA, 2020[15]; SENASICA, 2018[70]).

During 2014-17, COFEPRIS held 893 visits to the formulators and retailers of pesticides and fertilisers and, in consequence, suspended the activity of 123 establishments. It also confiscated over 68 000 tonnes of irregular pesticides and fertilisers in the same period of time (COFEPRIS, 2017[71]).

Increased co-ordination efforts might lead to staff and budget capacity benefits for all authorities involved, but it might require formalisation of co-operation, for instance via Memoranda of Understandings. Scheduled joined inspections could allow for a comprehensive and co-ordinated approach to the regulated entities, at the same time reducing their administrative burden. Moreover, it might be also feasible to evaluate the effectiveness of the inspection efforts, which is currently challenging for the Mexican authorities.

In line with the PLAFEST Regulation, acts or resolutions issued by authorities implementing this regulation can be appealed in line with the procedure established in Article 83 of the Federal Law of Administrative Procedure.

In summary, there is co-operation on enforcement between the main authorities for pesticides, for example in relation to the notification of infringements. However, compliance and enforcement activities in Mexico are complex and fragmented and there is room for improvement, for example through a more centralised approach – joint inspections or establishing Memoranda of Understanding among the authorities. Moreover, as elsewhere in the world, the enforcement activities are impacted by decreasing resources available. Challenges in this area also derive from data gaps in pesticide monitoring efforts as well as in relation to the uses and application of pesticides in Mexico, as described in other parts of this chapter and in Chapter 1.

Illegal trade of pesticides

International shipments of illegal pesticides[3] (e.g. counterfeit, unregistered, illicit or otherwise unauthorised active ingredients and finished products) are a significant challenge for pesticide regulators and custom offices, and is a growing concern for governments. Illegal trade can have significant impacts on human health, food chain safety, and the environment, and it undermines national registration and governments' risk reduction schemes, and public confidence in such schemes. It also distorts pesticide markets by replacing legitimate products with cheaper and possibly more hazardous products.

The share of illegal pesticides in the global market is estimated to be between 10 and 25%. The European Union Intellectual Property Office (EUIPO) estimates that both direct and indirect effects of counterfeiting in the pesticide sector cause approximately EUR 2.8 billion of lost sales to the EU economy (EUR 1.3 billion for the EU pesticides industry). Illegal pesticides are a major concern in several Latin America countries, such as Argentina, Brazil, Paraguay and Uruguay (Frezal and Garsous, 2020[1]). It is estimated that illegal pesticides constitute 13.8% of the regular EU market (OECD, 2019[72]).

The 2019 OECD Recommendation on Countering the Illegal Trade of Pesticides, OECD/LEGAL/0446 recommends that Adherents establish or strengthen national procedures aimed at countering the illegal trade of agricultural pesticides in line with the Best Practice Guidance (Box 2.10), taking into account national priorities, policies and programmes by:

- ensuring there is an appropriate regulatory framework for the management of agricultural pesticides;
- ensuring that there are systems in place to detect and take regulatory action against illegal trade of pesticides; and
- co-operating on minimising the illegal trade of pesticides (OECD, 2019[72]).

The Council Act instructs OECD to serve as a forum, using a Rapid Alert System (RAS), for the rapid exchange of reports on suspicious or rejected shipments of pesticides, when such information is deemed relevant and urgent. The RAS is a protected website accessible to regulatory authorities for a rapid exchange of information about suspicious or rejected shipments of pesticides.

Box 2.10. OECD Best Practice Guidance to Identify Illegal Trade of Pesticides

Best Practice Guidance provides a tool-box with over 100 practices throughout the life cycle of a pesticide

The document provides guidance for inspectors and regulatory authorities on best practices for identifying and tackling illegal pesticides throughout the complete lifecycle of a pesticide, that is for the following:

- Manufacture (Manufacturing and storage facilities, Inspectors);

- Formulation;
- Export (List of exporters, Record keeping and templates/forms, Registration in destination country, Export certificates);
- Transportation (Pre arrival, In transit);
- Import (Importer obligations, Inspectors);
- Sale/Retail (Distributors, Record keeping and templates/forms, Inspectors and inspections, Education);
- Use (Professional users, Inspectors);
- Disposal (Pesticide packaging, Illegal pesticides).

Source: (OECD, 2018[73]).

The General Law of Health prohibits the illegal and unregistered use of pesticide, and includes both a criminal sanction of up to 8 years in prison and a monetary fine of up to two thousand days of minimum salary equivalent. To support the fight against illegal trade, SENASICA certifies authorised pesticide dealers) and disseminates recommendations on how to identify illegal pesticide products. Stakeholders in Mexico are also encouraged to notify the General Prosecutor and COFEPRIS about illegal activities, via free and anonymous hotlines (SENASICA, 2019[12]). Mexico, to date, has not participated in OECD activities on illegal trade of pesticides nor posted (or reviewed) any information on the RAS.

On-going reforms of pesticides management in Mexico

Recent years have witnessed many positive developments in the area of pesticides management in Mexico. Policy development resulting from the Mexican National Commission for Human Rights recommendation on pesticides is of particular relevance, as it could be considered as a decisive moment in the country's path to upgrade its pesticides management framework, taking into account that certain developments were in progress already before it (e.g. the revision of certain NOMs on pesticides or the adoption of the NOM on MRLs).

In December 2018, NHRC issued a Recommendation 82/2018. In line with its title, this recommendation addresses "the violation of human rights to food, clean water, clean environment and health, due to the breach of the general obligation of due diligence to restrict the use of highly hazardous pesticides, to the detriment of the population in general"(Box 2.11) (NHRC, 2018[28]).

Box 2.11. Recommendation 82/2018 of the National Human Rights Commission

Recommendation 82/2018 was issued in response to a complaint filed by 43 persons in 2017, denouncing that the federal Mexican authorities do not comply with the international treaties to which Mexico is a Party, by failure to act administratively, normatively and via public policies to restrict the use of highly hazardous pesticides.

Following investigation, the Commission issued Recommendation 82/2018 that includes 61 recommendations addressed to the Secretary of Environment, the Secretary of Health, COFEPRIS and SENASICA. A copy of the Recommendation was also given to the Mexican Parliament.

Main recommendations:

- Urgently adopt regulatory measures for pesticides to protect water quality, the environment and human health, building for instance on the directives of the FAO Code of Conduct. Adopt the definition of highly hazardous pesticide.
- Modify the existing regulatory framework, including NOMs, to better address highly hazardous pesticides in their life cycle.
- All authorities should adopt a common strategic action plan addressing clearly responsibilities on monitoring, control and compliance with the regulatory framework and the mechanisms of co-ordination should be strengthened.
- Establish a multi-stakeholder Special Committee on the identification and investigation on the adverse effects of highly hazardous pesticides.
- Ensure strict implementation of the multilateral international agreements dealing with pesticides of which Mexico is a party.
- Undertake necessary actions to be able to cancel or revoke existing pesticides registries. Establish stricter and more restrictive rules on the uses and management for new pesticides registrations, as well for the renovation of the registration and existing registrations.
- Identify registrations that authorise the use in Mexico of active ingredients or pesticides prohibited in other jurisdictions, in order to analyse, which could affect the environment or human health in Mexico.
- Establish the National Programme of Monitoring Pesticides Residues and make the monitoring, contamination and intoxication information publically available.
- Elaborate studies (e.g. water and soil contamination by pesticides, intoxications) and prepare capacity building activities and educational campaigns on the safe use of pesticides for the Mexican population.

Source: (NHRC, 2018[28]).

Of particular importance is that many recommendations from the NHRC Recommendation 82/2018 are addressed jointly to the relevant authorities in Mexico and therefore should support synergy in their actions. All the authorities to which Recommendation 82/2018 was addressed have accepted its conclusions and undertaken efforts to address them.

In May 2019, the establishment of an inter-institutional working group, consisting of COFEPRIS, SEMARNAT and SENASICA was announced. The objectives of this group are to address issues raised by Recommendation 82/2018 and to modernise and strengthen the regulatory and surveillance framework on pesticides in Mexico. The group was established for an indefinite period and a representative of the NHRC was invited to participate in all its meetings, as well as representatives of academia and NGOs. The agreement on the establishment of the group also obliged COFEPRIS and SENASICA to continue working on the cancellations of registration of the most hazardous pesticides (SEMARNAT, 2019[74]).

Since the publication of Recommendation 82/2018, a “Diagnosis on the pesticide contamination of surface water, groundwater and soil” (INECC, 2019[75]) was published in 2019. The same year saw the publications of the “Elements for the Development of an Integral Strategy for Responsible Pesticides Management in Mexico” (Mexican Technical Working Group on Pesticides, 2019[76])(Box 2.12) and the “Manual of good use and management of pesticides” (SENASICA, 2019[12]).

Box 2.12. 2019 Elements for the Development of an Integral Strategy for Responsible Pesticides Management in Mexico

In 2019, a Technical Working Group on Pesticides prepared an analysis of possible elements of the future Mexican integrated strategy for pesticides management. The group was composed of the governmental stakeholders (Secretary of Health and Secretary of Environment), representatives of international organisations (UNEP and PAHO/WHO) and non-governmental stakeholders (INECC and Mexican Toxicological Network).

Proposals included in the document

In relation to the needed changes to the Mexican regulatory framework, the document proposes, among others, to:

- Eliminate indefinite validity of pesticides registrations from before 2005 and establish a procedure for the cancellation of the pesticides registrations;
- Strengthen procedures for renovation of pesticides registrations;
- Update to international standards ecotoxicological and environmental requirements linked to new pesticides registrations;
- Strengthen regulatory framework on pesticides in relation to their environmental impacts (e.g. in relation to their uses);
- Revise health related aspects of the current regulatory framework;
- Enhance the publication of official information on pesticides (e.g. the Official Pesticides Catalogue).

In relation to the control and surveillance of the commercialisation and use of pesticides in Mexico, the document proposes, among others, to:

- Strengthen control over and requirements of establishments dealing with pesticides;
- Control the sale of pesticides (e.g. by establishing obligatory sale registry);
- Control the use of pesticides (e.g. aerial spraying, establishing a register of the uses of pesticides);
- Establish a national programme of environmental and health monitoring of pesticides, strengthen monitoring of pesticides residues in agricultural products;
- Establish procedures to avoid importing pesticides prohibited in other countries.

Source: (Mexican Technical Working Group on Pesticides, 2019[76]).

A discussion on improvements to the Mexican pesticides management system was also held under the first Mexican National Forum on Pesticides in 2018, and it focused on three aspects: agricultural, environmental and sanitary (Box 2.13).

Box 2.13. Proposals of the 2018 Mexican National Forum on Pesticides

Agricultural aspects

- Elimination of prohibited and expired pesticides;
- Substitution of highly hazardous pesticide

It could be achieved via, for instance, enhanced compliance and enforcement efforts.

Environmental aspects

- Following the analysis of the existing framework, adopt a comprehensive law on hazardous substances that would include pesticides and would regulate their whole life-cycle. The law should include the definition of a pesticide and a highly hazardous pesticide; specify the obligations of each involved authority; address monitoring of pesticides and contaminated sites;
- Establishing a national pesticides monitoring programme and setting maximum levels of pesticides in water and soil and establishing infrastructure that would allow verifying compliance;
- Introducing a risk evaluation methodology into the registration process for pesticides;
- Establishing a national statistical database of sales and use of pesticides (obligation included in the comprehensive law).

Sanitary aspects

- Strengthening compliance and enforcement in the area of pesticide sales;
- Strengthening monitoring of the use of highly hazardous pesticides;
- Capacity-building activities for the users of pesticides.

Source: (SEMARNAT, INECC, UN Environment and PAHO[77]).

In November 2019, the tariff codes were changed by the creation of 19 new tariff codes, modification of 3 existing and suppression of 15 codes, to better identify hazardous pesticides and to prohibit their export and import (e.g. of endosulfan or alaclor) (Secretaría de Economía, 2019[78]).

Moreover, authorities also established a special committee to co-ordinate activities related to the identification and investigation of highly hazardous pesticides (CEIIEAPAP for its acronym in Spanish).

Possible elements for consideration by Mexico in its reforms

On-going Implementation of the proposals contained in the Recommendation 82/2018, in the 2019 Elements for the Development of an Integral Strategy for Responsible Pesticides Management in Mexico, as well as in the 2018 Mexican National Forum on Pesticides suggest that work is in progress, but a lot still has to be done. Many of the proposals included therein also align with the findings of this report.

One of the options for further actions, raised in the on-going discussions and in Chapter 1, is to support better harmonisation of the regulation of pesticides and their uses with T-MEC partners and other international partners, as well as streamlining the currently dispersed rules at the national level, through the adoption of a comprehensive law dealing with pesticides (Mexican Technical Working Group on Pesticides, 2019[76]). It would address Mexico's civil society's human health and environmental concerns linked to the use of pesticides. It could also help to address other relevant issues, including, inter alia, minor uses, emergency uses, lifecycle of pesticides, application through new technologies or development

of new molecules (Mexican Technical Working Group on Pesticides, 2019[76]). The suggestion for developing such a law seems to be supported by the Mexican authorities (SEMARNAT, 2019[74]). With all its benefits, this option would have one potential challenge – time needed to adopt the law, its regulations and relevant NOMs to implement the new framework and put it into practice.

Now might be the ideal time to streamline efforts to upgrade the Mexican pesticides management system. The renewal of the trilateral co-operation between Mexico, Canada and the United States under the T-MEC Agreement is an opportunity for re-invigorating the co-operation in the environmental area. It also seems that there is a momentum as many stakeholders in Mexico are in favour of upgrading the regulatory framework of pesticides management, albeit sometimes with difference reasoning behind it.

Moreover, many OECD countries have recently undergone or are undergoing revision of their pesticides programmes, for example Australia, Japan or the European Union (under its Regulatory Fitness and Performance programme, REFIT (EC, 2020[79])). This could be a source of inspiration for the Mexican efforts. For instance, the goals of the on-going review of the system in Australia could be applied to the Mexican situation. The reforms there are seeking to create a "future regulatory system that is efficient, predictable, adaptive, nationally consistent, open and accountable, and places at its centre the protection of human, animal, plant and environmental health and safety" (Matthews et al., 2020[18]).

Finally, FAO launched its online toolbox in 2016 that could support the efforts on the ground in Mexico. Mexico has already benefitted from FAO training in 2019 that covered, among others, the pesticides registration and evaluation parts of the Toolbox (FAO[80]). The training was requested by Mexico in the follow-up to the NHRC Recommendation 82/2018.

It may be argued that major reform of the pesticide management framework in Mexico will face a challenge. In many OECD countries current reforms have as one of their main priorities cutting "red tape" due to the fact that their legislation have been developed over many decades with increasing obligations for industry and increasing environmental and health consideration. However, this is not the case in Mexico, particularly with respect to environmental considerations. Therefore Mexican reforms should support both streamlining of the legislation, making it more efficient and effective, but at the same time incorporating missing elements.

Increasing the environmental risk management scope in the registration and evaluation procedure in Mexico could lead to extending the time needed for pesticide registration, but it might be counterbalanced with increased health and environmental benefits in Mexico. If the need to better reflect the environmental risk management is reflected, it would require bigger involvement from SEMARNAT in terms of both human and financial resources. It might also require reflecting this increased obligation in the regulatory framework.

Many elements of the current regulatory framework on pesticides management in Mexico have been in place for over 20 years. Adaptation of the framework to the technological and environmental changes and challenges, as well as meeting the changing needs of industry and civil society would be beneficial. Moreover, some of the changes in the past have been made in a piecemeal fashion. Ideally, a simultaneous comprehensive revision of all relevant laws, regulations and NOMs could be considered to streamline and reduce the complexity of the regulatory framework.

Eventual reforms could be based on the principles suggested under the on-going review of the Australian system:

- objectivity – the system should be evidence and risk-based in its decision-making;
- independence – decisions of the authorities should be independent;
- efficiency – using the most efficient regulation required to achieve the objective;
- consistency – one coherent national system;

- access – the system should be harmonised as much as possible with international regulatory systems, processes and timeframes;
- simplicity – one legislation that is modern, outcomes focused, free from unnecessary prescription and is simpler and easier to understand and implement;
- certainty – provide confidence about regulatory processes and timeframes;
- shared responsibility – the system should facilitate the sharing of responsibility among government, suppliers and users (Matthews et al., 2020[18]).

In line with the FAO and WHO guidelines, the main reasons for updating pesticide legislation are to:

- ensure consistency in the overall regulatory framework with effective connections between pesticide legislation and other relevant legislation with minimal contradiction or overlap;
- clarify any issues related to responsibilities, authority or mandate of the institutions involved;
- incorporate provisions to address new requirements stemming from recent developments or updated priorities;
- facilitate multidisciplinary approaches to pesticide management;
- comply with requirements of international agreements and recommendations; and
- harmonise requirements with countries within the region (FAO & WHO, 2015[40]).

As described in this report, a majority, if not all, of these reasons apply to Mexico.

Notes

[1] For instance, in February 2021, the latest available information on the applications for pesticide registration concerned January-May 2019: https://www.gob.mx/cofepris/documentos/consulta-de-ingreso-de-solicitudes-de-registro-sanitario (accessed on 2 July 2020).

[2] At the time this review was carried out.

[3] For the purposes of this report, "illegal trade of agricultural pesticides" is defined as in the 2019 OECD Recommendation on Countering the Illegal Trade of Pesticides, OECD/LEGAL/0446: Any form of trade of an agricultural pesticide that leads to a violation of domestic law, including counterfeiting, fraud and other forms of deception (OECD, 2019[72]).

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3 International best practices on pesticide regulation

This chapter reviews best pesticide regulation practices from Australia, Canada, the United Kingdom and the United States. Reasons for selecting these OECD countries include, but are not limited to, their recent efforts in reforming pesticides regulatory management, certain similarities (e.g. reliance on the import of pesticides), their close co-operation with Mexico on pesticides management (e.g. under the T-MEC Agreement) or their involvement in the preparation of this report.

Regulatory management of pesticides is a widely, internationally discussed subject. In part, given the high volume of international trade of agrochemical products and substances. International co-operation can help reducing unnecessary duplication of efforts. For instance, the OECD Pesticide Programme aims to harmonise the testing and assessment of agricultural pesticides and to promote work sharing and risk reduction. It supports OECD countries in co-operation in the review of both chemical and biological pesticides used in agriculture. The OECD Network on Illegal trade of Pesticides continues to monitor and act against illegal trade in pesticides. Sharing scientific evidence of the impact of pesticides on human health and environment can also help regulators across borders.

While pesticide regulators from OECD countries actively share experiences and regulatory best practices, it is also true that each country have its own governance model. Each country has its own take on when to accept applications for new pesticide products, and how to make sure regulation is properly enforced. However, international fora are always helpful in sharing experiences on what practices have proven successful, and what the essential areas of opportunities in the management of pesticides are.

Lessons from Australia, Canada, United Kingdom and the United States on pesticide regulatory management

- Evolution to a **single, independent regulator that manages the pesticides registration process** has brought significant improvements.
- Having **adequate and predictable resourcing is essential to deliver high-quality regulatory services**, and to **keep technology infrastructure updated**. An updated cost-recovery model has proven successful in Canada and Australia.
- **International co-operation has allowed countries to access a greater pool of knowledge and resources on pesticides management**. Having mandates and explicit criteria on how to consider and adopt international regulatory practice is key to attain benefits from international integration while ensuring domestic independence.
- **A risk-based approach has to permeate all stages of the regulatory management cycle of pesticides**. Regulators benefit also from reflecting pesticides hazards in the registration requirement criteria, and in enforcement strategies.
- **The availability of guidance resources for potential applicants reduces inefficiencies during the registration process**. Australia provides a number of documents including data guidelines, risk assessment manuals, paid consultancies for applicants and self-service queries to inform the type of application needed.
- **An explicit list of prohibited and restricted use of substances and chemical products improves market transparency** and avoids potential legal challenges, by stating what substances constitute unacceptable risks.
- To ensure an adequate regulatory compliance, regulators have **implemented different approaches, including the facilitation of reporting of illegal trade and incidents, by industry and users**.
- **Systematic stakeholder engagement allows identifying regulatory gaps and increase transparency and accountability**.

Case study 1: Canada

Context

Pesticides are key in a number of domestic industries, including agriculture, forestry, mining, and industrial and consumer products. They are also used to protect endangered species from predators, to protect native flora and fauna against invasive alien species, and to control pests carrying human pathogens, such as West Nile Virus. In 2017, 73.4% of the sales were commercial products for use in the agricultural sector and 21.4% were for use in the non-agricultural sector. Sales of pest control products in Canada increased from 92.9 million kilograms of active ingredients (kg a.i.) in 2012 to 120.1 million kg a.i. in 2016 (Pest Management Regulatory Agency, 2020[1]).

Canada is a net importer of pesticides, with limited manufacturing. According to Industry Canada data, average revenue for listed pesticide manufacturers averaged $695,000 in 2018 for roughly 50 institutions (Government of Canada, 2021[2]).

In the last decade, the total number of active ingredients registered for use in Canada has increased from just over 500 at the end of 2009 to 610 at the end of 2019. In the same 10-year period, the number of registered products increased from approximately 5700 to 7600. A number of products were removed from the market, either at the manufacturer's request or as a result of re-evaluation decisions (Pest Management Regulatory Agency, 2020[1]).

Policy and institutions governing the pesticide management system

Laws, by-laws and technical regulations

The primary federal legislation for regulating pesticides in Canada is the Pest Control Products Act and its regulations. The Pest Control Products Act states that no person shall manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under the Pest Control Products Act, except as otherwise authorised under the Act or unless specifically exempted by the Pest Control Products Regulations (Pest Management Regulatory Agency, 2017[3]).

However, there are other federal legislation relevant to the regulation of pesticides:

- Pest Control Products Fees and Charges Regulations
- Pest Control Products Incident Reporting Regulations
- Review Panel Regulations
- Pest Control Products Sales Information Reporting Regulations
- List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern
- Pesticide Residue Compensation Act
  - Pesticide Residue Compensation Regulations
  - Assessor's Rules of Procedure
- Agriculture and Agri-Food Administrative Monetary Penalties Act
  - Agriculture and Agri-Food Administrative Monetary Penalties Regulations respecting the Pest Control Products Act and Regulations
- Food and Drug Regulations

In addition, provincial/territorial and municipal governments may implement further restrictions through the enactment of legislation and by-laws, respectively, depending on local conditions. Nevertheless, provinces, territories and municipalities may not register or otherwise authorise pesticides that the PMRA has not evaluated, registered or authorised.

Institutions involved in pesticide regulation

The Pest Management Regulatory Agency (PMRA), within Health Canada, is the sole federal agency responsible for regulating pesticides throughout their lifecycle. This branch of Health Canada, created in 1995, consolidates the federal resources and responsibilities for pest management regulation.

Pesticides are regulated in Canada to ensure they pose the minimal risk possible to human health and the environment. Under authority of the Pest Control Products Act (PCPA), Health Canada has the following overarching objectives:

- Registers pesticides after a stringent, science-based evaluation that ensures any risks are acceptable;
- Re-evaluates the pesticides currently on the market on a 15-year cycle to ensure the products meet current scientific standards; and
- Promotes sustainable pest management (Health Canada, 2021[4]).

The Pest Management Regulatory Agency must register or authorise pesticides before they can be used or sold in the country. Health Canada also promotes and verifies compliance with the PCPA and takes enforcement action to address situations of non-compliance where warranted. The programs and initiatives look to improve the regulatory process and provide pest control products and strategies that are available in Canada with acceptable risk and value.

Health Canada works with provincial, territorial and federal departments in Canada to help refine and strengthen pesticide regulation across the country. These partnerships seek to ensure that the needs of the citizens are addressed at all levels of government, and that the policies that Health Canada implements meet these needs.

Beyond Canada, Health Canada also works closely with a number of international organisations including: United States Environmental Protection Agency (EPA), the North American Tripartite (NAT) Technical Working Group (formerly the North American Free Trade Agreement Technical Working Group), the Organization for Economic Co-operation and Development (OECD), and the Codex *Alimentarius*.

Regarding resources and cost recovery mechanisms in place, as mentioned above, Health Canada is the sole federal entity responsible for regulating pesticides throughout their lifecycle. A cost recovery system is in place to recover a portion of the costs (approximately 30%) incurred in the implementation of the federal pesticide program as it relates to work generated by applicants (Health Canada, 2021[5]) including pre-market assessments, amendments to registrations, or specification of maximum residue limits.

As reported in PMRA's 2019-20 Annual Report (Pest Management Regulatory Agency, 2020[1]), PMRA's resources were as follows:

Table 3.1. Funding and revenue of the PMRA 2019-2020

Million CAD

2019-2020 funding and revenue	Total
Base Funding	$26.5
Revenue – Application Fees ($5.4) and Annual (Charge $9.4)	$13.5
Non-base Funding	$12.8
Growing forward	3.3
Chemicals Management Plan	5.0
Departamental pressure funding	4.5
Total PMRA Fiscal Year 2019-2020	$52.6

Source: (Pest Management Regulatory Agency, 2020[1]), Pest Management Regulatory Agency Annual Report 2019-2020, Ottawa.

PMRA received CAD 3.3 million through the Growing Forward initiative to support the registration of minor use products. As a result, newer, more environmentally sustainable, and products that are more modern have been made available.

Through Canada's Chemicals Management Plan, PMRA received CAD 5 million to re-evaluate older pesticides, improve risk management approaches through Incident Reporting and Sales Reporting regulations, and contribute to the development of scientific and regulatory approaches with other jurisdictions on high-priority issues (Additional detail can be found on the Chemicals Management Plan webpage[1]).

Since the enactment of the Service Fees Act in 2017. In 2019–2020, PMRA completed drafting its Remission Policy for Missed Service Standards. This policy describes the scenarios under which a portion of pre-market application fees will be returned to the applicant when service standards are not met. Originally, this policy was to take effect on April 1, 2020; however, the Treasury Board of Canada Secretariat delayed its implementation for one year until April 1, 2021, due to the COVID-19 pandemic (Pest Management Regulatory Agency, 2020[1]).

There are approximately 385 full-time employees at PMRA, 73% are scientists, including biologists, toxicologists, epidemiologists, environmental scientists, and chemists.

Data collection and analysis, including IT tools in place

PMRA uses Information Technology to manage submissions as follows:

- Data Analysis:
  - Pesticide Product Information Database
  - APEX (data reporting software) used internally for analysis of submissions by staff.
- IT systems:
  - E-Index Builder for compiling an application dossier.
  - E-PRS (Electronic Pesticide Regulatory System) Secure Web Portal for submitting the dossier to PMRA and database for storing all data and documents related to a dossier.

In addition to using the information from the Electronic Pesticide Regulatory System (E-PRS), either through the Air Pollutants Exposure model (APEX)reporting or portal access, PMRA also uses the Pest Control Product Sales Reporting database to conduct analysis to support the development of policies and regulations. The Sales reporting database is not accessible publically. The Pesticide Product Information Database is publicly available, which includes information on products, active ingredients, and programs related to pesticides and other pest control products (Open Government Portal, 2020[6]).

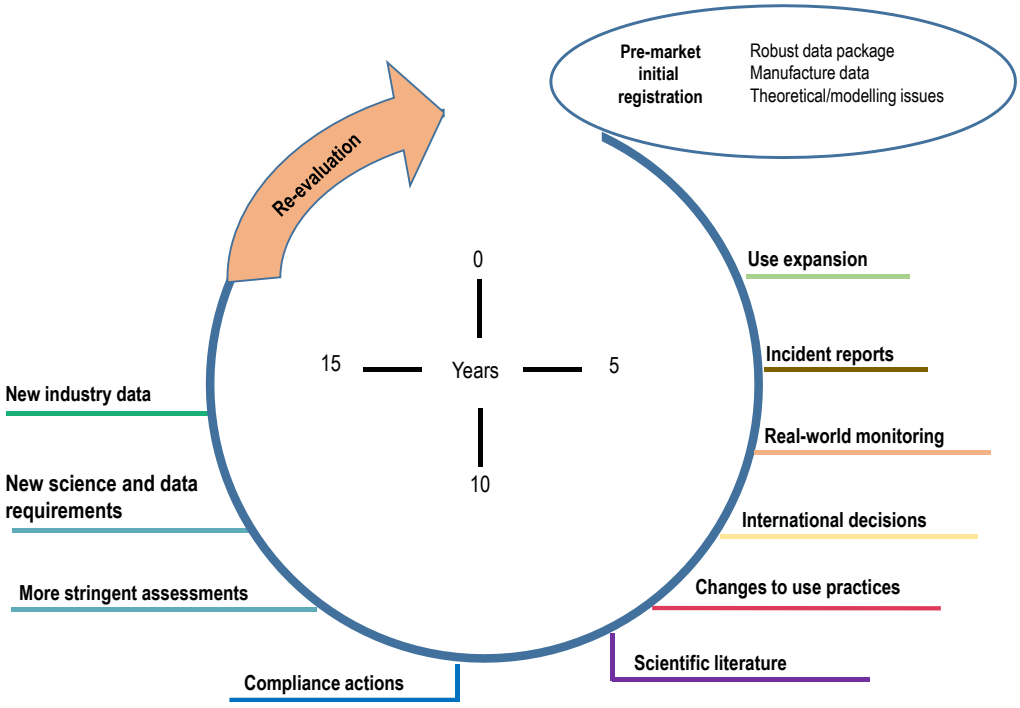
PMRA also uses various external data sources to conduct analyses, such as:

- The Global Maximum Residual Limits (MRL) database
- Pesticide import/export datasets (Statistics Canada, CBSA)
- Pesticide Product Information System (PPIS – U.S. EPA)
- Kynetec Gfk Sigma CP datasets
- Business Register database, National Account Longitudinal Microdata File (NALMF) from Statistics Canada

Pre-registration, registration and post-registration processes

Figure 3.1 shows the regulatory lifecycle of pesticides in Canada, from pre-market initial registration to the post-market re-evaluation, demonstrating that the complexity and extent of available information increases after the initial registration.

Figure 3.1. Pesticide regulatory lifecycle of Canada



Source: Replicated from (Pest Management Regulatory Agency, 2020[7]), Proposed Integrated Approach to Pesticide Evaluation, Ottawa.

Pre-market

For pre-market submissions of pesticide registration requests, PMRA follows its Management of Submissions Policy (MOSP) (Pest Management Regulatory Agency, 2017[3]). MOSP includes information on the types of submissions, associated timelines, as well as a description of the various steps in the process. Main submission types include Categories A, B, and C, from eight categories in total. Category A is for new active ingredients and major new uses (e.g. a change in use site category such as going from field crops to greenhouse crops). Category B includes changes within the existing use site category (e.g. adding a crop, change in rate, etc.), while Category C is for precedent-based applications.

Under the MOSP, PMRA typically reviews applications in chronological order (i.e., on a first-come, first-served basis) within each MOSP category subdivision. However, timelines can be adjusted under specific circumstances:

- If there is a critical need.
- When related submissions are grouped to follow the same review timeline when one submission depends upon the success of the other.
- Due to processing of a “tailgate” submission which is defined as a submission for a new or existing product for which a current submission is open, past screening and awaiting a regulatory decision. In this situation, tailgate submission cannot be reviewed until the previously submitted application has been accepted or proposed for registration).
- While a re-evaluation is underway, and submissions are received to expand, or change use patterns, or to make substantial amendments to the conditions of registration. Thus, in order to reach consistent and timely regulatory decisions, PMRA coordinates the review of these pre-market submissions and the science review component of the re-evaluation. Consequently, PMRA applies any updated science findings to any subsequent (pre-market and post-market) decisions.

- A consultation document is published for all major decisions (for example, new active ingredients and major new uses of registered pesticides) as defined in the Pest Control Products Act (Health Canada, 2002[8]). Any comments received during the consultation period are considered before a final decision is made pertaining to registration.

Post-market

Under the Pest Control Products Act, the PMRA may initiate a re-evaluation of a registered pesticide if the information required or the procedures used in evaluating the pesticide's health or environmental risks or the value have changed. In addition, the Pest Control Products Act requires PMRA to initiate re-evaluations for each registered pesticide on a 15-year cycle, based on the date of the most recent major decision affecting the registration, including its initial registration.

As part of its multi-year re-evaluation planning, PMRA explores opportunities to maximise efficiency by aligning Health Canada's re-evaluation schedule with that of other international regulatory bodies, or other parts of the Canadian federal government.

PMRA may consider other factors in the scheduling of re-evaluations earlier than the statutory requirement such as clustering similar active ingredients and re-evaluating them as a group. Whenever human health or environmental risk concerns require prompt attention, PMRA will take appropriate regulatory action regardless of the re-evaluation review status.

Any unacceptable risks identified through re-evaluations or special reviews requires the PMRA to initiate action, either by placing additional restrictions on the way the pesticide is allowed to be used or removing it from the market entirely.

Re-evaluation

The PMRA follows the Management of Pesticides Re-evaluation Policy (Pest Management Regulatory Agency, 2016[9]) which outlines the process and timelines from initiation to the publication of a final decision. Following initiation there is a scoping phase where PMRA considers previously conducted assessments to determine if they continue to meet the standards of current science/policy for health and environment in all review areas (that is, health, environment and value). Scoping reviews also include scans of other available information including, but not limited to public literature, incident reports, status of active ingredients in other jurisdictions, and conditions of product use. The scoping exercise identifies whether a re-evaluation will be of a Category 1, Category 2 or Category 3. These designations represent the amount of time and effort required to complete the re-evaluation and do not reflect or imply the level of risk associated with the pest control product or its active ingredient.

PMRA has implemented a risk-based prioritisation for re-evaluations, and considerations for risk prioritisation can be found in the current Re-evaluation and Special review Work Plan 2020-2025 (Pest Management Regulatory Agency, 2020[10]).

Another relevant document regarding the re-evaluation process is the "Policy on Cancellations and Amendments Following Re-evaluation and Special Review (Pest Management Regulatory Agency, 2018[11])", which aims to clarify expectations, obligations and communications around the implementation of the regulatory decisions.

Special Reviews

The Pest Control Products Act requires the PMRA to initiate a special review of a registered pest control product when there are reasonable grounds to believe that the health or environmental risks of the product are unacceptable. Likewise, when an OECD member country prohibits all uses of an active ingredient for health or environmental reasons. Once any of these is triggered, the evaluation will be targeted to address

the aspects of concern related to the pest control product that prompted the special review. PMRA follows the Approach to Special Reviews directive, which describes a systematic approach from preliminary analysis to assessment of the aspects of concern through to final decision (Pest Management Regulatory Agency, 2014[12])

The depth of and length of time to conduct a special review depend on the complexity of the aspects of concern associated with a given pest control product as well as the amount of information requiring assessment.

Risk-based considerations

The PCPA legislation under which pesticides are regulated in Canada requires that regulatory decisions are risk-based as opposed to hazard-based. This legislation dictates that the risks and value of a product, when used according to the conditions of registration, which includes following label directions, must be considered acceptable by the federal regulator for the product to enter and remain on the market in Canada. Assessments of health risk, environmental risk, and value are central to the PMRA's decision-making process. They provide a solid factual and contextual basis for making sound registration decisions that protect human health and the environment from unacceptable risks from pesticides. Each of the three components (health risk, environmental risk and value) must be acceptable before a pesticide can be registered. This means that products that are not effective do not have acceptable value and, therefore, would not be registered even if the health and environmental risks were acceptable. Conversely, if a product is very efficacious and useful to an important commodity, it would not be registered if health and/or environmental risks are not acceptable. The development of the required conditions of use that are feasible, is also a key part in assessing risk and value (Pest Management Regulatory Agency, 2021[13]).

The PMRA Framework for Risk Assessment and Risk Management is designed to protect human health and the environment. The PMRA uses a comprehensive body of scientific methods and evidence to determine the nature as well as the magnitude of potential risks posed by pest control products (pesticides). This approach allows for the protection of human health and the environment through the application of appropriate and effective risk management strategies. The PMRA's scientific risk-based approach to the regulation of pesticides is consistent with international standards and is similar to Health Canada's regulatory approach for other types of chemicals. This framework provides predictability and transparency to the process used to protect the health of citizens and their environment and helps ensure risk management decision-making considers all relevant criteria in a comprehensive fashion (Pest Management Regulatory Agency, 2021[13]). It also provides sufficient flexibility to incorporate alternative approaches such as Risk21 methodology and tools developed by the Health and Environmental Sciences Institute (HESI), when applicable

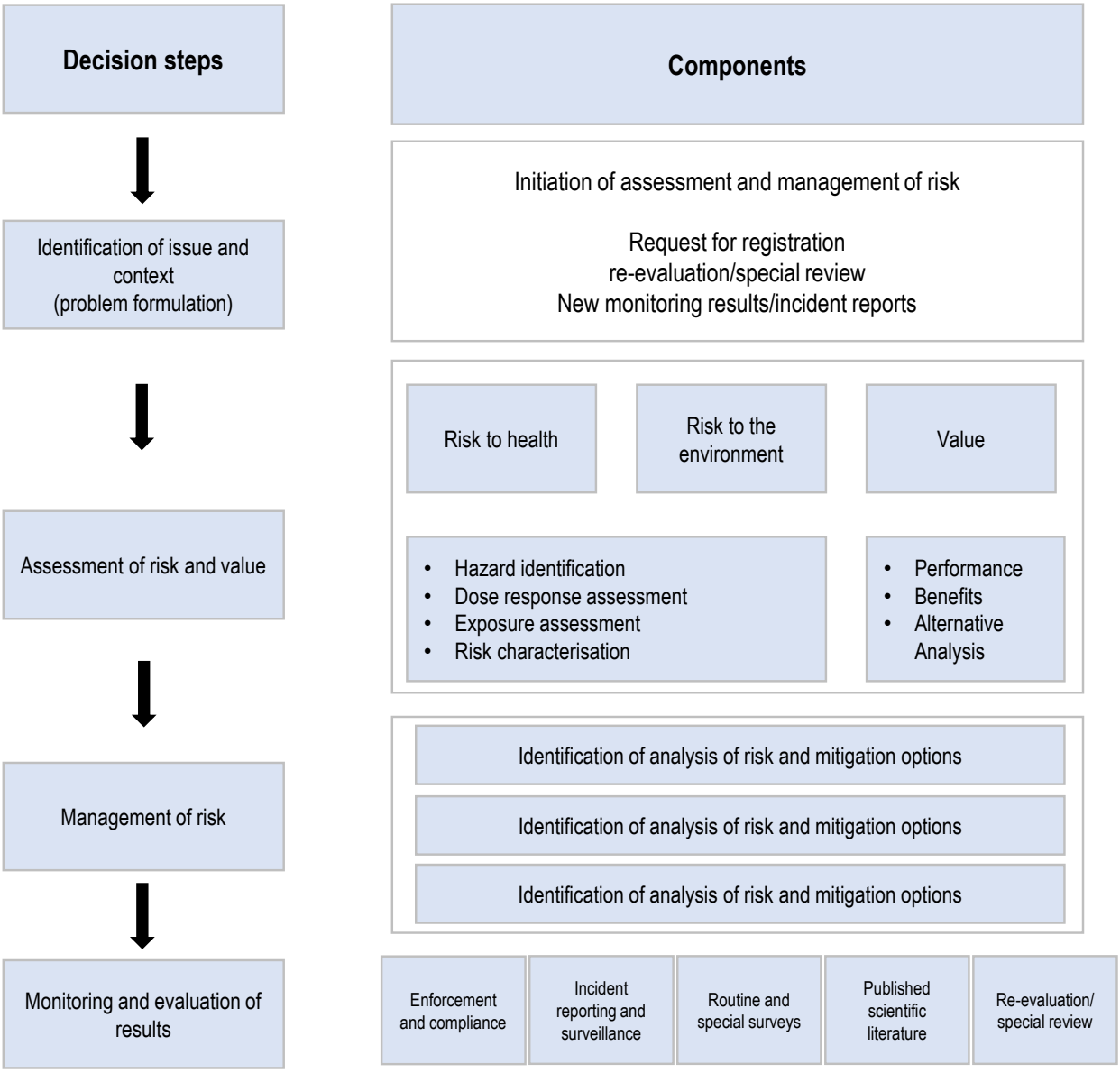
Although the framework is presented as a series of sequential steps leading from a starting point, such as an application to register a new pesticide, to a defined end point such as the decision to register, the underlying process is highly iterative and interactive. This is particularly evident in the development of risk management options. If there is a concern that the use of a product as proposed by the applicant may be associated with an unacceptable level of risk, the PMRA will consider restrictions on use or other conditions to reduce the risk to acceptable levels. The process usually results in a number of possible management options. Each of these options must be described in sufficient detail to allow quantitative re-examination of the potential risks. Typically, this requires several iterations of the assessment of risk and recalculation of risk under the different options considered (Pest Management Regulatory Agency, 2021[13]).

The majority of the registration decisions within the PMRA concern chemical pesticides. Accordingly, this framework is based largely on the processes and approaches used to arrive at decisions about a new chemical pesticide, a major new use, post-market pesticides under re-evaluation, or special review. . It may also be used when considering incident reports examined during these processes. This framework also applies to registration decisions for biopesticides (microbial and pheromone pesticides), non-synthetic

pesticides (plant extracts, or other naturally derived substances), and devices, with modifications specific to each situation.

This framework is divided into a number of identifiable decision steps and components, as noted below in Figure 3.2.

Figure 3.2. Stages of risk assessment and risk management of pest control products in Canada



Source: (Pest Management Regulatory Agency, 2021[13]), A decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency, Health Canada, Ottawa.

Better regulation tools

Monitoring and Enforcement

Health Canada promotes and monitors compliance through the Pest Control Products Act (PCPA) and the Pest Control Products Regulations (PCPR). Health Canada also responds to incidents, complaints, and situations of non-compliance. Health Canada's recently created Regulatory Operations and Enforcement Branch (ROEB) has compliance officers across Canada whose responsibilities include achieving compliance with the PCPA and PCPR.Compliance officers prioritise and deliver compliance and enforcement activities, as well as develop compliance guidance documents, strategies, and procedures.

The ISO-accredited laboratory in Ottawa provides analytical services for detecting and reporting on pesticide misuse. Pesticides are also analysed to determine whether they meet the specifications upon which registration was granted.

To carry out pesticides compliance and enforcement, PMRA Health Canada delivers promotion, monitoring, and enforcement activities in accordance with the National Pesticides Compliance Program (NPCP), administered jointly by Health Canada's PMRA and Health Canada's ROEB Compliance promotion actively prevents non-compliance by informing the public, industry, and associations about the regulatory requirements. Stakeholders and the public are invited to participate in consultations to provide feedback on regulatory decisions and issues.

Health Canada inspectors carry out compliance monitoring, who conduct regular, planned inspections for oversight of activities regulated under the PCPA. The regulated parties and regulated activities targeted by inspections may differ from year to year. Examples include inspections to determine compliance with label directions, and inspections targeting distribution of unregistered products.

Regarding enforcement, violations of the PCPA or PCPR are responded to with appropriate compliance and enforcement measures to encourage compliance. These measures include: education; enforcement letters; voluntary removal; denial of product entry into Canada; amendment, suspenction or cancellation of registration; compliance order; Administrative Monetary Penalty (Warning or Penalty); or prosecution. As part of Health Canada's regulatory transparency and openness framework, information on inspections and enforcement activities is made publicly available. In addition, persons wishing to report a pesticide incident or suspected contravention of the PCPA have the option of contacting the Pest Management Information Service.[2]

As an example, during the 2017-2018 fiscal year, Health Canada's National Pesticide Compliance Program (NPCP) delivered 253 compliance outreach activities to promote compliance with the PCPA; conducted 933 inspections; analysed 428 samples (e.g. soil, plant tissues, animal tissues, liquids, surface wipes) in PMRA's laboratory to verify compliance; and reported on rates of compliance by subsector and the most common violation types (i.e., sale (34%), possession (25%), and importation (21%)). (Health Canada, 2021[14]).

Regulatory Impact Assessment

The Cabinet Directive on Regulation (Treasury Board of Canada Secretariat, 2020[15]) applies to all regulations that are or will be registered as such under section 6 of the Statutory Instruments Act, and is guided by four principles:

- Regulations protect and advance the public interest and support good government;
- The regulatory process is modern, open, and transparent;
- Regulatory decision-making is evidence-based; and
- Regulations support a fair and competitive economy.

The regulatory life cycle approach requires departments and agencies to examine and analyse regulations through all stages of their life cycle, including (Treasury Board of Canada Secretariat, 2020[15]):

- Development of regulations: this includes a requirement that departments and agencies conduct a Regulatory Impact Analysis (RIA) on all regulatory proposals, to support stakeholder engagement and evidence-based decision-making.
- Regulatory management: departments and agencies are responsible for the ongoing management of regulations and their associated programs and activities. Regulatory program activities may include: compliance and enforcement; inspections and licensing; compliance promotion activities and outreach; data gathering; measuring performance; and providing clear and transparent information and service to citizens on regulations and regulatory and legal responsibilities.
- Review and results: this includes a requirement that departments and agencies undertake a regular review of their existing regulatory stock, which should include technical guidance and other associated policies to ensure that the regulations continue to be appropriate and effective, and achieve their intended policy objectives.

Regarding RIA, departments and agencies must conduct a triage of a regulatory proposal to determine its expected impact level and the appropriate mix of analytical requirements of the elements (Treasury Board of Canada Secretariat, 2020[15]). Table 3.2 shows the various types of impacts that the department and agencies have to consider on each of the stakeholder groups:

Table 3.2. Impacts considered for each type of stakeholder in Canada

Stakeholders	Examples of impacts considered
Citizens	Impacts on well-being (health, safety and security; ability to make informed choices) Impacts on consumers (cost of living, prices, quality and variety of goods available) Income Employment opportunities
Businesses	Costs of complying with regulatory requirements (including administrative burden) Changes in profit and revenue Business opportunities, growth and innovation Business sustainability
Government	Costs to implement and administer regulatory programs (compliance and enforcement, outreach, data management, responding to events) Costs and benefits for other levels of government (provincial, territorial, Indigenous, municipal) Impacts on government revenue

Source: (Treasury Board of Canada Secretariat, 2020[15]), Cabinet Directive on Regulation, Ottawa.

During all stages of the regulatory life cycle, regulators must seek opportunities to engage stakeholders, including Indigenous peoples; pursue regulatory co-operation and regulatory alignment, where appropriate; and co-ordinate with all levels of government to mininize cumulative and unintended impacts of regulations.

Stakeholder Engagement (including public consultation)

In delivering its mandate in registering pesticides, the PMRA is required to fulfil its consultation obligations as stipulated in the PCPA. The PMRA has to perform a public consultation process with stakeholders including federal and provincial government departments and agencies whose interests and concerns are affected by the federal regulatory system before making a decision. 1. To grant or deny an application; 2. about the registration of a pest control product on completion of a re-evaluation or special review; or 3. about any other matter if the Ministry of Health considers it in the public interest to do so.

Under the consultation obligations, the PMRA has to consult the public as to policies, guidelines and codes of practice relating to the regulation of pest control products. In addition, any person may request a special review of the registration of a pest control product, as well as may file a notice of objection to a registration, re-evaluation or special review decision within 60 days after the decision statement is made public.

PMRA uses various methods of consultation including publications, webinars, and in-person meetings. PMRA also provides information to and consults with a variety of stakeholders through various means, including: 1. Seeking advice from external participants involved in the Agency's work through the Minister of Health's Pest Management Advisory Council (PMAC) whose members include representatives from pesticide manufacturers, user groups, health and environment non-government organizations, and academia/research institutes; 2. working with other federal government departments and provincial and territorial governments to harmonise pesticides and pest management regulatory and education activities across Canada through to the Federal/Provincial/Territorial Committee on Pest Management and Pesticides[3] (Government of Canada, 2015[16]); 3. Hosting regular stakeholder webinars to provide a diverse group of stakeholders with updates on pesticide regulation, as well as opportunities to ask questions.

Regarding all major pesticide registration decisions as defined in the Pest Control Products Act (Health Canada, 2002[8]), such as new registrations or major new uses of a pesticide, re-evaluations or special reviews, a consultation document is published. The consultation document outlines major findings of the evaluations and the proposed decisions, and are made available to the public. The PMRA also solicits comments on regulatory policies, regulatory directives, and guidance documents. Any comments received during the consultation period are considered before a final decision is made.

Transparency and dissemination of information on pesticides

The PCPA requires that a "Register"[4] of the Pest Control Products be established. The Register must contain information regarding the applications, registrations, re-evaluations and special reviews.

For each application, the Register must have (among other requirements):

- the active ingredient of the product, proposed new uses for it or any uses proposed to be withdrawn; how the application was deposed of or whether it was withdrawn;
- the conditions of registration, registration number and registration validity period for each registered product.
- information that is provided by applicants and registrants in respect of each registered pest control product both in support of an application for registration or for the amendment of a registration OR for the purposes of a re-evaluation or special review
- information provided by applicants and registrants that is used to specify maximum residue limits;
- any reports of the evaluation of the health and environmental risks and the value of registered pest control products (Health Canada, 2002[8])

The PCPA also requires that an electronic public registry be established, (refer to the Pesticide Product Information Database[5]), which includes all information in the Register that is not confidential business information (CBI) and not confidential test data (CTD).

The PMRA publishes and/or posts on the Government of Canada website, the PMRA Annual Report (which details PMRA's accomplishments and activities over the last fiscal year); the Pest Control Product Sales Report (where registrants report the quantity of pesticides sold in best Canada for a calendar year); and Guidance and Policy documents.

Other regulation regarding transparency:

- The Pest Control Products Sales Information Reporting Regulations require registrants of pesticides to report the quantity of every product they make available for sales each year.

- The Pest Control Products Incident Reporting Regulations require pesticide registrants and applicants to report to the PMRA all incidents associated with their products.
- The PCPA provides the public with the opportunity to inspect the scientific test data supporting pesticide registration decisions.

International regulatory co-operation on pesticides

Canada is recognised internationally for its regulatory model, which has allowed Canada to form partnerships with other regulators, and to play a significant role in developing collaborative approaches to joint pesticide reviews, promoting international regulatory alignment, and addressing barriers to agricultural innovation and trade (Pest Management Regulatory Agency, 2020[1]).

PMRA is involved with several main four international co-operation initiatives including the Stockholm Convention the Rotterdam Convention, the WHO/FAO Codex Committee, and several OECD committees.

Regarding the Stockholm Convention, the PMRA is the federal authority responsible for meeting the obligations and for ongoing participation as it pertains to pesticides. PMRA collaborates with other federal partners by providing scientific experts to work with the Persistent Organic Pollutants Review Committee (POPRC) and the Conference of the Parties (COP) of the Stockholm Convention. At POPRC, PMRA participates in the review for identifying substances as persistent organic pollutants (POP) and making recommendations on the global management. At the COP, PMRA provides experts to negotiate international decisions on the restrictions and the elimination of each POP at the global level.

Regarding the Rotterdam Convention, in collaboration with other federal partners, the PMRA provides scientific experts to work with the Chemical Review Committee (CRC) and the COP of the Rotterdam Convention, and in the development of Canadian positions and submissions. For CRC, PMRA reviews submissions to the Rotterdam Conventionagainst established Convention criteria. At the COP, PMRA provides experts to negotiate international decisions for each substance at the global level.

In the WHO/FAO Codex Committee on Pesticide Residues, the PMRA's participation seeks to:

- Enhance Canada's influence on Codex deliberations and outcomes.
- Promote the development of science-based standards that result in fair practices in food trade (establishment of MRLs).
- Promote more effective committee's work planning.
- Promote the timely development of standards.

PMRA is also involved with several OECD initiatives, including various OECD task forces and expert group projects. PMRA participates in meetings of both the OECD Working Party on Pesticides (WPP) as well as the OECD Working Party on Biocides (WPB). Both working parties function as vehicles for global co-operation and facilitate information exchange and alignment of approaches with respect to pesticides assessment.

PMRA also contributes input (via the Canadian Delegation) to the OECD Meeting of the Chemicals and Biotechnology Committee as required. PMRA also provides experts to participate in the OECD WPP Expert Groups on Residue Chemistry, Pollinator Safety, Bio-pesticides, and Electronic Exchange of Pesticide Data. Some examples of OECD WPP initiatives include: development of a common approach to regulating novel pest control products, such as RNAi-pesticides; implementation of technical guidelines (for example, those that provide guidance on alternative approaches to animal testing); identification of residues, metabolites and degradation products; identification of relevant data requirements for regulating bacteriophages; ongoing dialogue related to integrated pest management/pollinator protection; aligning risk assessment of new digital and mechanical technologies for applying pesticides such as innovative drone technology.

PMRA also plays a lead role on the OECD WPP e-label project to identify commonalities in pesticide labels that would support development of e-label solutions. PMRA also actively contributes to the WGB's Expert Group on Claims Development for Treated Articles.

In support of the OECD WPP's objectives, PMRA has led discussions with global manufacturers of pesticides regarding new chemistries to broaden collaboration and promote global joint reviews and alignment between international regulatory partners. PMRA has also initiated discussion with OECD partners on post-market review challenges and the potential benefit of having a greater collaboration in this area.

Highlights: best regulatory practices

The PMRA continuously conducts periodical examination of its programs by leveraging internal and external audits and comprehensive reviews to find inefficiencies and eliminate duplication. PMRA launched a multi-year programme renewal project in order to build a stronger and sustainable pesticide regulatory programme that strengthens health and environmental protection and leads to improved quality of scientific decisions. This addresses the increased workload, increasing complexity of the scientific assessments and availability of key data when undertaking assessments. These efforts are guided by consultations for a new risk-based continuous oversight programme delivery model. The PMRA has planned for 2021-22 to (Pest Management Regulatory Agency, 2020[17]):

- Develop a risk-based framework for continuous oversight of registered pest control products over the course of the product's lifecycle by identifying and addressing risk sooner with ongoing risk determination information.
- Develop new and leverage existing processes to improve the timing for the identification, collection and analysis of data, and engagement on the subsequent assessments in order to better define areas of risk thereby resulting in smaller and more focused reviews.
- Advance and implement new risk management tools to prioritise pest control products for scientific review and risk mitigation.

Recent and on-going reforms

Certain broad trends in pesticide regulation in Canada that led to recent reforms include: the increased number of registered products and workload; ; the increasingly complexity of pesticide evaluations due to rapid technological advances, evolving science, etc.; multilateral collaboration and international obligations; high level of stakeholder engagement and media attention; heightened importance on food and water security; increased stakeholder expectations to balance cost of innovation and product availability).

There were also a number of challenges specific to the pesticide re-evaluation programme (Pest Management Regulatory Agency, 2020[17]). As a result, in 2018 the PMRA, through a fulsome review including consultation with stakeholders, identified some areas of opportunity in the re-evaluation process (Pest Management Regulatory Agency, 2018[18]), as follows:

- Health and environmental risks are not being addressed in a timely manner.
- Risk issues are pushed to re-evaluation resulting in substantial assessment updates required.
- Key information is not available to support re-evaluation assessments.
- Inefficient information gathering often leads to duplicative effort from redoing assessments.
- Limited engagement and transparency early in the process.
- No risk-based prioritisation of workload (Pest Management Regulatory Agency, 2020[17]).

In support of the 2018 Review of the Pesticide Re-Evaluation Program, the PMRA has:

- Conducted international comparison of post-market pesticide programmes.
- Engaged with other government departments and international partners, as well as with PMRA staff.
- Engaged broadly across Canada with stakeholder groups.
- Conducted detailed costing analysis of the current pesticide program (Pest Management Regulatory Agency, 2020[17]).

As a result of the re-evaluation programme review, PMRA's Integrated Pesticide Program will have the following elements moving forward:

- Continuous evaluation approach that proactively addresses emerging health and environmental risks and considers pesticide value throughout the pesticide lifecycle.
- An integrated approach that increases the protection of health and environment while being more efficient and timely, i.e. a) Risks are identified and addressed sooner; b) Increased oversight and risk characterization of all pesticides and c) Re-evaluations are less complex.

Case study 2: Australia

Context

The pesticide industry is relevant in Australia both in of economic and employment terms. Agricultural pesticides sales in Australia had a market value of AUS 2.7 billion (~USD 2.13 billion)[6] during the 2018-2019 financial year (APVMA, 2020[19]). According to a report by Deloitte, the agricultural chemicals contributed to over 9 200 full time equivalent jobs (Deloitte, 2019[20]).

International trade plays a big role in the Australian pesticide Industry. The same report indicates that imports represent 59% of the market for agricultural chemicals, share that has increased from 33% a decade ago.

Australia has a comprehensive pesticides regulatory framework. Its regulatory management also includes systematic efforts of international co-operation with major trade partners and international organisations. In recent years, Australia has conducted regulatory reviews of its management system for pesticides, and has reformed its legislative and regulatory practices in accordance. This case study aims to summarise some of its best practices and draw lessons from its reform efforts.

Policies and institutions governing the pesticide management system

Legislative and regulatory instruments

Australia has a regulatory framework in place that covers both agricultural and veterinary chemicals (commonly referred as agvet chemicals). This framework referred to as the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) came into full operation in 1995 and is a partnership between the Commonwealth (central) Government and the states and territories. Prior to 1995, state and territory governments were each individually responsible for the registration and control of use of all agvet chemicals. The NRS established a single national framework for the assessment and registration of agvet chemicals, with the states and territories retaining responsibilities for controlling their use once they are sold or supplied to the end-user (APVMA, n.d.[21]).

The NRS is an umbrella for legislative and regulatory instruments that govern the pesticide industry. The Australian Pesticides and Veterinary Medicines Authority (APVMA) administers the NRS in collaboration with other Commonwealth agencies, as well as state and local governments, law enforcement and the judiciary. Institutions involved in pesticide regulation.

The key pieces of legislation are the Agricultural and Veterinary Chemicals (Administration) Act 1992 that establishes a national authority for the registration of agvet chemicals and sets out the functions and powers of that authority. It contains provisions controlling the import and export of chemicals and for enforcement and inspectors. The other key piece of legislation is the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) that sets out the operational provisions for the registration of agvet chemicals, for regulating the supply of those chemicals and for compliance with, and enforcement of, the Agvet Code.

Institutions involved in pesticide regulation

Pesticide regulation, up to the point of retail sale, is implemented by an independent regulatory agency located within the Department of Agriculture, Water and Environment. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the *independent statutory authority responsible for the assessment, registration and regulation of agricultural and veterinary chemicals in Australia* (APVMA, n.d.[22]). The APVMA was created under the Agricultural and Veterinary Chemicals (Administration) Act 1992. This Act defines APVMA's functions, including the following:

- to **assess the suitability for sale in Australia of active constituents** for proposed or existing chemical products, chemical products and labels for containers for chemical products;
- to **provide information** to the Governments and authorities of the Commonwealth, the States and the participating Territories **about approved active constituents for proposed or existing chemical products, registered chemical products, reserved chemical products and approved labels for containers for chemical products** and to co-operate with those Governments and authorities on matters relating to the management and control of chemical products;
- **to keep records and statistics of approvals and registrations granted, and permits and licences issued**, by it under the Agvet Codes;
- to **evaluate the effects of the use of chemical products** in the States and participating Territories
- to co-operate with Governments and authorities of the Commonwealth, the States and the participating Territories for the purpose of facilitating a consistent approach to the assessment and control of chemicals;
- in co-operation with Governments and authorities of the Commonwealth, the States and the participating Territories, **to develop codes of practice, standards and guidelines for, and to recommend precautions to be taken in connection with, the manufacture, export, import, sale, handling, possession, storage, disposal and use of chemical products** in the States and participating Territories
- to **collect, interpret, disseminate and publish information** relating to chemical products and their use;
- to **encourage and facilitate the application and use of results of evaluation and testing of chemical products**;
- to **exchange information relating to chemical products and their use with overseas and international bodies** having functions similar to the APVMA's functions;

From this extensive list of activities, it is clear that APVMA does not only focus on technical evaluations required during the registration process. APVMA also covers a wide range of activities related to the governance cycle of pesticides. This includes international co-operation, regulatory enforcement, and stakeholder engagement. Having a one-stop-shop regulator for assessment, approval and registration and control of supply of pesticides has proven effective in Australia, since its inception more than two decades ago.

APVMA manages a wide list of regulatory and legislative instruments, from the NRS, that affect the manufacture, trade and evaluation of chemicals.[7] This includes key legislative instruments for pesticides including standards for Maximum Residue Limits (MRLs), efficacy criteria that products have to meet to be considered effective, and the application requirements for the registration of a pesticide product.

Financing

Most of APVMA's funding comes from a cost-recovery scheme that includes both fees[8] and levies.[9] A recovery levy is a tax and is imposed via a separate taxation act. The difference is that the revenue from the levy is earmarked to fund activities provided to the group that pays the levy (APVMA, 2020[21]). This way, the fees charged to the regulated industry are entrusted directly to APVMA, rather than being handed to the country's treasury. Having an independent regulator funded directly by its activities, rather than from the centralised annual budget, is a practice commonly adopted by OECD countries. This has key advantages, including budget predictability, and the fact that the size of the regulator directly responds to the demand an industry has of regulatory services.

In accordance with Australian Government cost recovery policy, cost-recovered agencies must conduct a review of fees and charges at lest every five years to ensure that fees and charges remain in line with government policy as well as the cost of the activities they relate to. The APVMA implemented its most recent cost-recovery arrangements on 1 July 2020. This reform was implemented from a recommendation of an independent review. This review found that APVMA's activities were not being covered by the current fee structure, and that the finance gap would only increase in the future if no further action takes place. The review also found that APVMA's IT system was not sufficient to support the management required (PWC, 2017[24]).

Data Collection and Use of ICTs

APVMA has made digitalisation a core strategy to improve its regulatory performance. In 2018, APVMA published a four-year digitalisation strategy that identifies the main problems of its ICT infrastructure and the objectives for improvement. APVMA's infrastructure had a series of drawbacks that were hampering its service delivery.[10] As it was, APVMA's digital infrastructure was not able to meet digital end-to-end self-service processes for staff and clients. The lack of sufficient storage infrastructure was also a barrier to digitalise more than 200,000 analogue records. These records on average have 300 double-sided pages, including both text and images. Regarding data, APVMA was also worried about losing information stored in obsolete platforms and keeping up to date with cyber security measures to minimise potential attacks (APVMA, 2018[22]).

The Australian Government provided AUS 10.1 million to the APVMA in its 2018-19 budget to fund three years' worth of its digital strategy, through its Enabling Technology Program. This programme aims to improve the efficiency of the registration process. This programme has three overarching goals: digitalising pesticide records, enhancing data analytics and business intelligence capabilities and enabling a single view for clients for on-line registration processes.

Pre-registration, registration and post-registration processes

Resources for pre-Registration

The pesticide registration process is regulated under the *Agricultural and Veterinary Chemicals Code Act* 1994 supported by regulations and other legislative instruments. Applications are required for a number of services, including registration of new products with both existent and new actives, for variations of products, and certificates for import and exports.

APVMA has a series of resources to help applicants from the start of the process. Before registration applicants have access to a tool that helps them understand whether an agricultural product needs registration. This electronic questionnaire guides the potential applicant to several questions that after responding gives you an answer on whether your intended product needs a certification. Applicants can also call for a pre-application assistance (PAA).[11] APVMA charges a *fee-for-service* basis, which conducts either by a written response, a face-to-face meeting or a teleconference. PAA can come in three different tiers.

- **Tier one** assistance has the objective of guiding applicants during the early stages of an application. In this tier, APVMA provides advice on 1) planning an application; 2) types of regulatory assessment needed for an application; 3) relevancy of efficiency criteria; 4) assessment modules, fees and timeframes; 5) clarification on guidance documents published by APVMA.
- **Tier two** assistance focuses on technical advice, and usually last two months, including a meeting if necessary. As part of the assistance of tier two, applicants may receive advice on the following: 1) types of supporting data or information appropriate to the application; 2) relevance or suitability of overseas data and/or assessment reports; 3) the types of trials needed to generate appropriate data; 4) a scientific matter relevant to an application; 5) the development of an agreed project plan for a time shift application; and 6) specific aspects of the design of a study or trial.
- **Tier three** assistance provides advice on: 1) appraisal for trial protocols before commencement on studies; 2) assistance on a proposed new methodology or variations of existing data guidelines for generating data; and 3) finalisation of project plans for Global Joint Reviews.

Australia has a relevant amount of demand of the assistance service. In 2020, APVMA received a total of 247 requests of assistance of all three tiers combined. As seen in Table 3.3, the most sought after assistance is Tier 2, which focuses on technical advice. APVMA received 161 requests of this service in 2020. Having an *optional* pre-application consultation helps to improve efficiency of the registration process itself, by reducing the probability of having misunderstandings on the assessments or lack of information submitted in the application.

Table 3.3. Requests for pre-application APVMA's assistance in 2020

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Tier 1	16	15	17	17
Tier 2	31	39	62	29
Tier 3	4	3	8	6

Source: APVMA's Quarterly Performance Reports in 2020, extracted from: https://apvma.gov.au/node/79656, https://apvma.gov.au/node/75211, https://apvma.gov.au/node/71481, & https://apvma.gov.au/node/66806.

As part of the data guidelines to build a dossier, APVMA also provides risk assessment manuals on chemistry and manufacture, environment human health, residues and trade, and spray drift risk.[12]

Registration process

The registration process is completely managed by APVMA, and varies, in terms of requirements, fees and timeframes, depending on the type of application. This follows a risk-based approach, and considerations such as whether an active ingredient has been previously approved. For a list of criteria that define the timeframe and fees for applications for registration for new products see Table 3.5. Assessment periods are defined by legislation and vary depending on the complexity of the type of application.

In 2020, APVMA received 2,118 applications, across different categories including new product applications, application for variations to existing registrations and application for permits. Within product applications, item 7 is the most common, which considers: *chemical product containing an approved active constituent, and approval of the product label, if the product is closely similar to a registered chemical product and efficacy and safety data are not required to demonstrate the similarity of the product to the registered chemical product and chemistry and manufacture data are not required.*

Table 3.4 shows the number of applications in each quarter of 2020. Of all these applications, APVMA finalised the application process on time for 97% of pesticide applications in 2020 (APVMA, n.d.[23]).

Table 3.4. Pesticide applications received in Australia, 2020

	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Total 2020
Products[1]	278	345	447	341	1 411
Permits	336	146	91	123	696
Other	0	0	0	0	0
Time-shift	1	4	6	0	11
Ingredient determination	0	0	0	0	0

[1] Product applications include: new product/ active (new active), new product (existing active), and variations.
Source: APVMA's Quarterly Performance Reports in 2020, extracted from: https://apvma.gov.au/node/79656, https://apvma.gov.au/node/75211, https://apvma.gov.au/node/71481, & https://apvma.gov.au/node/66806.

The criteria for each type of application can be found in the Agricultural and Veterinary Code Regulations 1995. The APVMA provides tailored guidance on specific requirements for each type of application on its website. For applications that do not require a full assessment, a modular assess may may apply (see Items 2 and 10 described in the table below). For a modular assessment relevant module(s) required for an individual application assessment are applied on a case-by-case basis with corresponding data requirements, fee and timeframes. This provides for an effective allocation of effort and resources in the line with the risks to be assessed.[13]

Table 3.5. Types of pesticide registration applications for new products

	Criteria	Timeframe	Fee
Item 1	Approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and product.	18 months	AUD 116 501
Item 2	Approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring less than full assessment of the active constituent and product.	Modular assessment	Modular fee
Item 3	Registration of a chemical product containing an approved active constituent, and approval of the product label, if there is no registered chemical product containing the active constituent and a full assessment of the product is required.	18 months	AUD 83 511
Item 4	Registration of a chemical product containing an approved active constituent, and approval of the product label, if there is a registered chemical product containing the active constituent and a full assessment of the product is required and there are no relevant maximum residue limits and poison schedule classification is required.	18 months	AUD 44 644
Item 5	a) Registration of a chemical product containing an approved active constituent and approval of the product label; or b) Registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or	8 months	AUD 7 566

	Criteria	Timeframe	Fee
	c) Registration of a chemical product and approval of the product label		
Item 6	a) Registration of a chemical product containing an approved active constituent and approval of the product label; or b) Registration of a chemical product and approval of the active constituent in the chemical product and approval of the product label; or c) Registration of a chemical product and approval of the product label	8 months	AUD 6 406
Item 7	Registration of a chemical product containing an approved active constituent, and approval of the product label, if the product is closely similar to a registered chemical product and efficacy and safety data are not required to demonstrate the similarity of the product to the registered chemical product and chemistry and manufacture data are not required.	3 months	AUD 2 632
Item 8	Registration of a chemical product containing an approved active constituent, and approval of the product label, if the chemical product is the same as a registered chemical product and the product is to be registered with a different name.	3 months	AUD 2 632
Item 9	Registration of a listed chemical product and approval of a product label where the product and label comply with an established standard that has been approved in accordance with section 8U of the code.	2 months	AUD 2 632
Item 10	For all situations other than those described in items 1–9: a) Registration of a chemical product containing an approved active constituent and approval of the product label; or b) Registration of a chemical product and approval of the active constituent in the chemical product; or c) Registration of a chemical product and approval of the product label (but only if a separate application for the approval of the active constituent in the chemical product has been lodged).	Modular assessment	Modular fee

Note: The fees included in the table are those to be implemented in 1 July 2020.
Source: Agricultural and Veterinary Chemicals Code Regulations 1995.

Better regulation tools

Ex ante *evaluation of regulation*

In Australia, all new or modified regulations are subject to conduct a Regulatory Impact Assessment (RIA). The limited waivers have to be approved by the Prime Minister. This *ex ante* assessment of regulation has to be prepared by the office responsible for the management of the specific regulation. That is, the Australian Government Department of Agriculture, Water and the Environment (DAWE) , responsible for the governance and oversight of the NRS, has to conduct ex ante evaluation to all the changes to its regulatory inventory or of new proposed regulation. In fact, Australia's *ex ante* system is one of the OECD's highest ranked in a composite indicator that includes the quality of the methodology, systematic adoption of RIA, transparency, and oversight and quality control (OECD, 2018[24]).

As part of the *ex ante* assessment process, DAWE has to answer a series of questions, including the costs and benefits of regulations, and to weigh different alternatives to solve a previously identified policy problem. All of the process is defined by a guide prepared by the Department of Prime Minister and Cabinet (Commonwealth of Australia, 2020[25]). These questions are further explained in the guide, and summarised in Box 3.1.

Box 3.1. Regulatory Impact Analysis elements in Australia

What is the problem you are trying to solve?

Why is government action needed?

What policy options are you considering?

What is the likely net benefit of each option?

Who did you consult and how did you incorporate their feedback?

What is the best option from those you have considered?

How will you implement and evaluate your chosen option?

Source: Commonwealth of Australia (2020), The Australian Government Guide to Regulatory Impact Analysis, (Commonwealth of Australia, 2020[25]).

Regulatory enforcement

APVMA has an active role to ensure that the industry complies with the Agvet code. APVMA conducts traditional enforcement activities, such as inspections. However, to improve communication access on non-compliance, APVMA has an on-line portal to report a suspected non-compliance and adverse experience with chemicals. The adverse experience tools allow both registrants and users file a form with information on unexpected negative consequences of produce use. The party filing the report may inform details of the product, incident, crop/plant, animal, human, and chemical use. This information may be directly sent to the manufacturer of the pesticide and to APVMA. The adverse experience reports are assessed by the APVMA and annual summaries of adverse experience reports are published registration and approval holders are required, by law, to advise the APVMA and provide to the APVMA any new information that they become aware of that shows that the agvet chemical may not meet the safety, efficacy or trade criteria.

The platform to report suspected non-compliance covers three possible scenarios: advertising and supply of unregistered agricultural and veterinary chemicals, inappropriate manufacture of agvet chemical products, and importation of agvet chemical products. APVMA ensures confidentiality in treating the reports, and considers a risk-based approach on the potential harm for people, animals, the environment and international trade, when prioritising the follow-up of incidents.

Public consultation

The APVMA seeks input from interested stakeholders throughout the agvet chemical registration and review processes as well as during the development of APVMA operational and regulatory processes. The Agvet Code requires that the APVMA seeks input before it registers an agvet chemical containing a brand new active constituent. The existing chemical review process also involves extensive stakeholder consultation.

International regulatory co-operation on pesticides

Australia has a strong programme on international co-operation for pesticide regulatory assessments including work share arrangements. APVMA works both with peers from other countries and with international organisations. APVMA allows data generated in according to international guidelines including OECD, FAO, the United States, Canada, European Food Safety Authority, EU Biocidal Products Regulation, European and Mediterranean Plant Protection Organisation.

Australia also accepts assessments form the World Health Organization, FAO, United States, Canada, New Zealand, the National Industrial Chemicals Notification and Assessment Scheme and the Office of the Gene Technology Regulators. However, Australia has specific criteria defined to accept international assessment. Please see Box 3.2 for a complete list of these criteria.

Box 3.2. APVMA's criteria for accepting international assessments

- The assessment has to be written in English;
- It has to contain a full reference list of all the studies cited in the report;
- Be an un-redacted report with an adequate level of reporting detail so that a regulatory scientist can peer review the assessment and fully understand the basis for any interpretations, conclusions, recommendations or decisions.
- Be submitted in an electronic format that is searchable, and ideally, editable. It does not however need to be specifically formatted for the APVMA.
- Be the most recent comprehensive assessment where there are multiple assessments arriving at similar conclusions. If the reports have differing conclusions then all must be submitted to the APVMA.
- Include all underlying data and studies relevant to the application, including published and unpublished studies.
- Include all original studies cited or evaluated in the international assessment including those not owned by the applicant.

Source: APVMA, Guidance for applicants – submissions of international data, standards and assessments (Last updated on 16 April 2020). Extracted from: https://apvma.gov.au/node/14186 on 17 February 2021.

Highlights: best pesticide management practices

Empty container and obsolete pesticide management schemes

Similar to Mexico, Australia has an industry-led recollection programme to reduce negative impacts of empty pesticide containers. Agsafe is the Australian, industry-led non-profit organisation that runs several programs including *drumMUSTER*, a collection and recycling of empty pesticide containers, Chem Clear, a collection of unwanted chemicals as well as accreditation and training programs.

drumMUSTER started in 1999 with the goal of installing a paradigm shift on the importance of minding environmental impacts on land management. Its main goal is to recycle and transform empty containers into a range of products. Since its inception, as part of *drumMUSTER*, Australia has collected more than 36 million containers, which avoided the equivalent of 41 thousand tons of material diverted from landfill. The programme has 837 collection sites, and has trained 1 748 inspectors over the last three years.[14] These inspectors have to conduct a re-training every three years.

Regulatory performance framework

In 2015, as part of an effort to improve regulatory delivery, Australia installed an assessment tool called Regulatory Performance Framework (RPF). The RPF has the main goal of reducing unnecessary burden that hampers competitiveness (Commonwealth of Australia, 2014[26]). All regulators have to conduct a self-assessment every year, using the RPF methodology, which has to be *comprehensive, timely, externally validated, and publicly available.* As part of the RPF implementation, the Department of the Prime Minister and Cabinet (PM&C) issue guidance on how to conduct the assessment. For this, PM&C provides examples inputs, outputs supporting the assessment, shares a selection of case studies of better regulatory practice, and advice on implementation timeframes, among others.

The content of RPF is based in six broad Key-Performance Indicators:

- Unnecessary impediments to the efficient operation of regulated entities are removed.
- Communication with regulated entities is clear, targeted and efficient.
- Actions undertaken by regulators are proportionate to the regulatory risk being managed.
- Compliance and monitoring approaches are streamlined and co-ordinated.
- Regulators are open and transparent in their dealings with regulated entities.
- Regulators actively contribute to the continuous improvement of regulator frameworks.

Each regulator has the task of breaking down each indicator into sub-indicators that reflect their portfolio of work. For example, to assess the first indicator listed above, APVMA includes a sub-indicator that measures the status of *International data guidelines, standards and assessment adopted to reduce effort to register agvet chemicals.* Then, each sub-indicator is measured with a list of evidence and concrete results.

Table 3.6. APVMA Performance Framework Regulator indicators

Performance indicator	Evidence
1. Unnecessary impediments to the efficient operation of regulated entities are removed.	Demonstrated understanding of the operating environment for the regulated entities. International data guidelines, standards and assessments adopted to reduce effort to register agvet chemicals. Efficient and effective APVMA business processes.
2. Communication with regulated entities is clear, targeted and efficient.	Level of satisfaction with information and guidance materials. Level of satisfaction with the quality and timeliness of advice on decisions. Extent and satisfaction with APVMA consultative processes
3. Actions undertaken by regulators are proportionate to the regulatory risk being managed.	Risk management frameworks and policies are in place and regularly reassessed. Lower regulatory effort is applied to activities of lower regulatory risk. Compliance and enforcement strategies are consistent with agreed risk management policies.
4. Compliance and monitoring approaches are streamlined and co-ordinated.	Monitoring and enforcement strategies allow for a range of regulatory responses. Compliance activities are responsive to business needs of regulated entities, where relevant. Information requested from regulated entities is necessary and acted upon.
5. Regulators are open and transparent in their dealings with regulated entities.	Performance information is published. Feedback mechanisms are in place and used to improve service to regulated entities.
6. Regulators actively contribute to the continuous improvement of regulator frameworks.	Level of stakeholder engagement in implementing regulatory frameworks. Feedback is provided to inform the development or amendment of regulatory frameworks.

Source: (Commonwealth of Australia, 2014[26]).

Comprehensive and transparent listing of prohibited and restricted of substances

The *Agricultural and Veterinary Chemicals (Administration) Regulations 1995* provides a list of active constituents and chemicals that are prohibited to import, export, manufacture or use, or have restrictions with specific conditions. This helps to increase market transparency, and to communicate what products have unacceptable risks. The annex divides the list in single active constituent and chemicals products defined in two or more active constituents.

Table 3.7 provides an example of a technical sheet of a single active constituent in the annex of this regulatory code. Every item in the annex provides the information stated in the table below, including common name, IUPAC name, CAS number, the precision if the item is a prescribed active constituent or

a chemical product, relevant international agreement and the condition or restriction. In this case, Australia has the prohibition of manufacturing and using Aldrin, and export/imports are prohibited with exceptions that warrant a written permit. This substance is part of the Stockholm Convention.

Table 3.7. Example of a technical sheet

Category	Information
Common name	Aldrin (HHDN)
IUPAC name	(1R,4S,4aS,5S,8R,8aR)-1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8- dimethano-naphthalene
CAS number	309-00-2
Prescribed active constituent/chemical product	Prescribed active constituent for the purposes of subsection 69CA(2) of the Act
Relevant international agreement or arrangement	Stockholm Convention
Conditions or restrictions	Import prohibited except with written permission under a stipulated clause* Manufacture prohibited in all cases Use prohibited in all cases Export prohibited except with written permission under a stipulated clause

Source: Agricultural and Veterinary Chemicals (Administration) Regulations 1995.

Recent and on-going reforms

Streamlining the regulatory framework for pesticides

As part of an effort to reduce bureaucracy, the Australian Parliament is currently considering proposed amendments to legislation through the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Board and Other Improvements) Bill 2019.* The Bill has passed the House of Representatives and is under revision by the Senate (Department of Agriculture, n.d.[138]). The proposed bill includes some aspects that will make the regulatory framework simpler and more flexible. For instance, the bill will amend the requirement legislation, so that APVMA can deal with new information provided in the application with more flexibility, and chemicals with low regulatory concern will have simpler regulatory processes. Other measures include increased computerised decision-making by APVMA, simplification of corporate requirements to APVMA and simplification of reporting requirements for annual returns.

However, while proposing system simplification, there are also additional measures on regulatory enforcement. The bill includes the establishment of a civil penalty for providing false or misleading information to APVMA, and providing suspension or cancellation when false or misleading information is presented in an application for a variation or label approval of agvet products.

On-going review of the pesticides management framework

Australia is conducted a comprehensive, independent review of its pesticide regulatory framework. The Australian government commissioned a panel of four independent experts to conduct this review, which has included stakeholder consultations. The panel published an Issues paper, through the Department of Agriculture, Water and Environment, which includes the main findings and recommendations for reform. DAWE has subjected the report to an on-going public consultation before the panel presents the final reform proposals. To enhance the discussion, the Issues paper poses a range of discussion questions about their findings. The subjects covered in this review cover broad issues such as the optimal objectives of a future regulatory system for pesticides as well as more specific issues such as waste disposal and management.

The review highlights positive features of Australia's regulatory arrangements that should be preserved. Some of these highlights might be beneficial for an eventual reform in Mexico. The report considers that having an independent regulator, with no political interference in its scientific decision-making has been essential for the success of achieving pesticide policy objectives. Moreover, stakeholders who participated in this review consider that having a centralised regulator has brought significant improvement. Previously, Australia had a separate state-based registration system. Mexico has a registration process that relies only on federal agencies, local and state governments are no involved in the process. However, the registration process includes three different agencies during the product registration process, in contrast with Australia, where APVMA conducts all the required assessments. Another essential practice that the panel encourages APVMA to keep is its risk-based approach to the assessment of product registration (Matthews et al., 2020[27]).

There are however, diverse concerns on the design of the system governance, as well as specific practices. Box 3.3 presents the main challenges summarised in the Issues Paper. To advance the regulatory system, the review presents the following main proposals:

- Increasing national consistency of control of use
- Removing consumer and non-primary production products from the system
- Introducing a benefits test
- Changing the way chemical product efficacy is managed
- Introducing a registration by reference approach
- Introducing an accredited assessor scheme.

This paper also proposes a new vision for the future system, and suggests key principles to govern the design of the future regulatory system together with a simplified hierarchy of system objectives (Matthews et al., 2020[27]).

Box 3.3. Main concerns presented in the on-going review of Australia's pesticide regulatory framework

1. Australian farmers do not currently have access to the same chemicals, in the same timeframes, as their overseas competitors. Many new products are registered overseas well before they are registered in Australia.
2. The scope of agricultural and veterinary chemicals in the Australian system is extremely broad. This leaves room for duplication/cross-over with other regulatory schemes particularly with consumer and industrial goods. This has the potential to divert government resources from regulating agricultural and veterinary chemicals used by primary producers, veterinarians and non-urban land managers as well as chemicals posing a high health risk.
3. The regulatory system being obscure and difficult to understand. Many stakeholders see it as complex, costly and slow. Governance and consultation arrangements for the system as a whole are unclear and have been argued by stakeholders to be ineffective. Commonwealth–state relationships has been identified as one of the many challenges.
4. The Australian regulatory system dedicates a disproportionate share of resources to pre-market assessment of agvet chemicals, rather than post-market compliance (regardless of the risk).
5. There is significant cross-subsidisation among chemical registration holders in respect of fees and levies paid.

Note: The concerns listed in this box are only those highlighted as the main priorities. An extensive list of all concerns may be found in the report. The list has been slightly edited for contextual clarity.
Source: (Matthews et al., 2020[27]).

Best practice highlights from the United States and the United Kingdom

Highlights from the United Kingdom

UK's Pesticide Forum

The Pesticides Forum was set up in 1996 in the United Kingdom with the objective to bring together a range of organisations with an interest in pesticides and the impacts of their use. The Forum represents stakeholders with differing views about pesticides and how the impacts of their use should be addressed.

Since 2013, the Forum has played an important role in supporting the UK's National Action Plan for the Sustainable Use of Pesticides. It provides a space for stakeholder interaction, discussing important issues. The Forum's main task is to maintain stakeholder oversight of the UK pesticides National Action Plan and provide advice, which allows monitoring progress of the Plan and developing it further. The Pesticides Forum Report combines stakeholder engagement, stakeholder activities and measuring progress. This also gives information that can be used to measure progress on initiatives (Pesticides Forum, 2019[28]).

The Forum is conformed from representatives of organisations covering the farming (conventional and organic production), farming equipment and pesticide industries; environmental and conservation groups; education and training; consumer interests and trades unions who provide a wide range of experience and views on this important sector. In addition, representatives from all the Government Departments responsible for –or those who have an interest in –pesticides in the UK also participate in the meetings.

The forum issues an annual report, which helps to monitor the delivery of the plan using a number of indicators. Indicators typically come in one of three forms:

- Indicators measuring impacts directly (e.g. residues detected in water bodies or foodstuffs);
- Indicators measuring impacts indirectly (e.g. the numbers of key farmland birds); or
- Indicators measuring the behaviour of pesticide users (e.g. users' participation in continuing professional development).

UK's Expert Committee on Pesticides

The UK Expert Committee on Pesticides (ECP) provides independent scientific advice to Ministers and Governments on the authorisation of pesticides in the UK and on other matters related to the control of pests (Government of United Kingdom, 2021[29]). ECP business involves consideration of a small proportion of the Health and Safety Executives work, generally the more difficult and novel cases. Each year it supplements this activity by undertaking an exercise to quality assure the HSE casework through a structured audit of finalised cases.

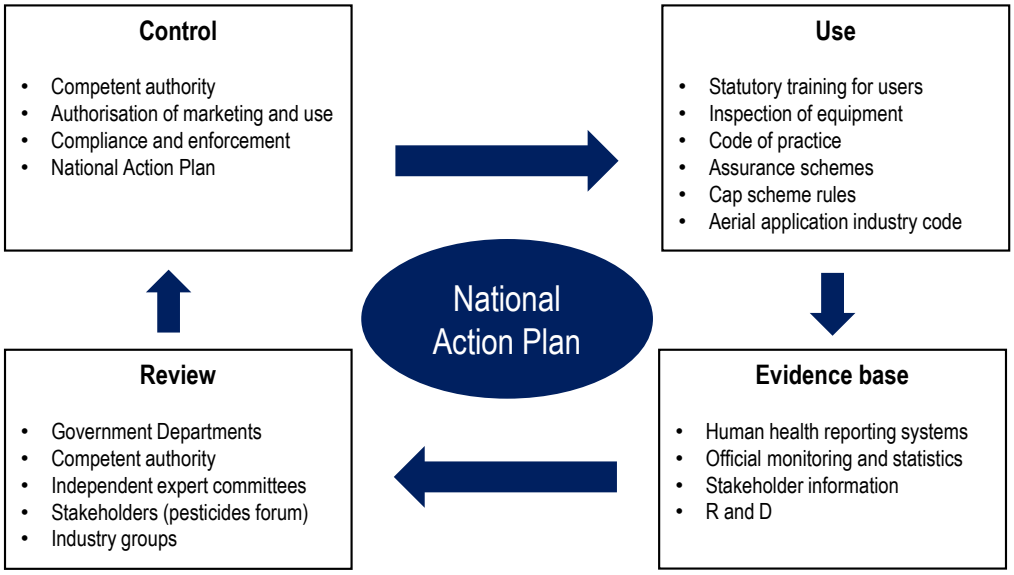
The ECP consists of 15 experts within the field with a mix of expertise. Some of the members are academics working in specialist areas of study relevant to assessing the risks and benefits of pest control. Others are members appointed to consider issues from a public perspective. In addition, it includes members with practical experience of pesticide use and regulation in the farming and amenity sectors. The members are appointed following open public recruitment. The HSE provides the Committee's Secretariat. Members of the ECP are not salaried staff but do receive a fee for attendance at meetings (Health and Safety Executive, 2020[30]).

Meetings are generally closed to the public due to the commercially sensitive information. However, the Committee aims to hold an open meeting each year. The Committee publishes an annual report, which summarises the work done throughout the year.

United Kingdom's National Action Plan

The National Action Plan (NAP) seeks to ensure that pesticides are used sustainably, by encouraging the development and introduction of integrated pest management and of alternative approaches. The NAP covers training amongst pesticide users, sales of pesticides, information and awareness raising, inspection of application equipment, aerial applications, handling and storage of pesticides and treatment of their packaging and remnants, Integrated Pest Management (IPM), and indicators. Figure 3.3 shows how the cycle of use controls, evidence, reviews and compliance fit together to underpin the National Action Plan.

Figure 3.3. UK National Plan Cycle



Source: replicated from (Department for Environment FOod and Rural Affairs, 2013[31]), UK National Action Plan for the sustainable use of pesticides, Defra, London.

Progress is in the priority areas are assessed every five years and in the light of any relevant information resulting from the calculation of harmonised risk indicators. Indicators for these and other areas are examined annually in the Pesticides Forum report to provide the quantitative measure of progress. This is also considered alongside achievement of targets set in other related areas such as in implementation of water protection legislation and uptake of measures in agri-environment schemes, which also contribute to minimisation of the use of pesticides. Recently, the UK held a consultation exercise and is now considering responses as part of the process developing a new National Action Plan.

Highlights from the United States

Stakeholder engagement approach from the EPA

EPA often makes policies and procedures available to the public through Pesticide Registration Notices (PRN), website links, or other electronic means. Other transparency mechanisms include (but are not limited to) the following:

- EPA invites the public to provide comments on registration applications received for new pesticide active ingredients, new uses, and tolerance petitions.
- EPA publishes a notice of these applications in the Federal Register (FR), which directs the public to submit comments to an electronic docket via the website Regulations.gov. Most comments are received electronically, but the FR also provides information on how written comments can be submitted by mail.

EPA also invites the public to submit comments on proposed registration decisions for new active ingredients, significant new uses (e.g. first food use, first residential use, other significant new uses), and proposed decisions for registration review of existing pesticide active ingredients. Various communication methods are used, ranging from email listserv and website updates to Federal Register notices.

Finally, test guidelines and other significant guidance may be shared with the public in draft form before being finalized. EPA engages expert peer reviewers, such as the FIFRA Scientific Advisory Panel, to provide technical advice on emerging methods and topics of scientific controversy. The Pesticide Program Dialogue Committee discusses a variety of pesticide regulatory and implementation issues. These committees include diverse representation from multiple sectors of the stakeholder community and are governed by the Federal Advisory Committee Act (FACA).

The United States has the following peer-review and stakeholder groups:

- **FIFRA Scientific Advisory Panel (SAP)**: this panel is composed of biologists, statisticians, toxicologists and other experts who provide independent scientific advice to the EPA on a wide-range of health and safety issues related to pesticides (EPA, n.d.[32]).
- **Pesticide Program Dialogue Committee (PPDC):** is a forum for a diverse group of stakeholders to provide feedback to EPA on various pesticide regulatory, policy, and program implementation issues (EPA, n.d.[33]).
- **Association of American Pesticide Control Officials (AAPCO):** an organization composed by federal and local officials from pesticide regulators of the United States and Canada. The main objective is to provide input to the EPA and states for a successful implementation of pesticide regulation. AAPCO oversees the State FIFRA Issues Research and Evaluation Group (SFIREG) (AAPCO, n.d.[34]).
- **The IR-4 Project**: is a multi-government agencies project that aids growers by facilitating registrations of pesticides and biopesticides on specialty food crops (fruits, vegetables, nuts, herbs, spices) and environmental horticulture crops (trees, shrubs, flowers) (IR-4 Project, n.d.[35]).

Risk management

EPA uses a risk-based approach that considers potential effects of exposure to a pesticide in the context of exposure that is expected to occur as a result of the proposed use. The risk assessment approach is well-established and has been heavily reviewed. EPA uses a tiered assessment approach with refinements available when needed due to complexity of the scenario or other risk management considerations. Internal technical committees routinely review assessment products to ensure consistency and provide advice on new methods and protocols. The EPA has available materials for ecological, human health, and pesticide cumulative risk (EPA, n.d.[36]).

To ensure an objective risk management, the EPA divides internally the risk management and risk assessment functions. This way objective analyses can be used to inform decision making. While distinct functions, open communication between risk assessors and risk managers is encouraged. EPA risk managers consider both potential risks and benefits of each proposed registration, consistent with the standards in FIFRA. If potential risks are identified, risk managers may employ several strategies, sometimes concurrently:

- Work with risk assessors to refine the assessment (may request additional data from registrant)
- Seek additional information on benefits (for balancing under the FIFRA risk-benefits standard)
- Suggest that the registrant (the company applicant for registration) alter the proposed use to reduce or eliminate risks
- Require advisory and/or mandatory label language (such as changes to directions for use) to address the risks
- If concerns cannot be resolved, the registrant may withdraw the application or EPA may reject it.

Notes

[1] https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan.html.

[2] https://www.canada.ca/en/health-canada/corporate/contact-us/pest-management-information-service.html.

[3] The Federal, Provincial, Territorial (FPT) Committee on Pest Management and Pesticides was established to help strengthen FPT relationships in the area of pest management and pesticides. The Committee also provides advice and direction to FPT governments on programs, policies and issues.

[4] Subsection 42 of the Pest Control Products Act.

[5] https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry.html.

[6] The exchange rate was calculated on February 12, 2021. This rate should not be taken as an official OECD statistic, as it sole purpose is to provide an approximation.

[7] For a complete list of legislative Acts that regulate Australian agrochemicals, please visit: https://apvma.gov.au/node/4131.

[8] Fees when a good, service or regulation is provided directly to a specific individual or organization.

[9] Charges imposed when a good service or regulation is provided to a group of individuals or organizations.

[10] This case study reflects the challenges presented by APVMA when its digitalisation strategy was published, noting that some of the issues may have been solved during the Enabling Technology Program that was launched in 2019.

[11] https://apvma.gov.au/node/106.

[12] APVMA's assessment manuals can be found in the following link: https://apvma.gov.au/node/45561.

[13] The following microsite has detailed information on Item 10: https://apvma.gov.au/node/68166.

[14] All facts and figures were drawn from drumMUSTER website on 18 February 2021. https://www.drummuster.org.au/our-story/results/.

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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 framework[1] 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 decisions', 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 approach[3] 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 COFPERIS 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 oblige 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 pesticides 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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Annex A. Laws, regulations and technical standards on pesticides management in Mexico

Table A A.1. Laws, regulations and technical standards on pesticides management in Mexico

Name in Spanish	Name in English	Date of issuance/ date of last reform	Link to full text
Ley General de Salud	General Health Law	24/01/2020	http://www.diputados.gob.mx/LeyesBiblio/pdf/142_240120.pdf
Ley Federal de Sanidad Vegetal	Federal Plant Health Law	26/12/2017	http://www.diputados.gob.mx/LeyesBiblio/pdf/117_261217.pdf
Ley de Bioseguridad de Organismos Genéticamente Modificados	Law of Biosecurity of Genetically Modified Organisms	18/05/2005	http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf
Ley de Productos Orgánicos	Law of Organic Products	7/02/2006	http://www.diputados.gob.mx/LeyesBiblio/pdf/LPO.pdf
Ley General del Equilibrio Ecológico y la Protección al Ambiente	General Law of Ecological Equilibrium and Environmental Protection	05/06/2018	http://www.diputados.gob.mx/LeyesBiblio/pdf/148_050618.pdf
Ley General para la Prevención y Gestión Integral de Residuos	General Law of Waste Prevention and Integral Management	19/01/2018	http://www.diputados.gob.mx/LeyesBiblio/pdf/263_190118.pdf
Ley Federal del Trabajo	Federal Law on Labour	02/07/2019	http://www.diputados.gob.mx/LeyesBiblio/pdf/125_020719.pdf
Reglamento en materia de registros, autorizaciones de importación y exportación y certificados de exportación de plaguicidas, nutrientes vegetales y sustancias y materiales tóxicos o peligrosos	Regulation on Registration, Import and Export Authorizations and Export Certificates of Pesticides, Plant Nutrients and Toxic or Hazardous Substances and Materials.	13/02/2014	http://www.dof.gob.mx/nota_detalle.php?codigo=5332473&fecha=13/02/2014 http://www.diputados.gob.mx/LeyesBiblio/regla/n109.pdf
Reglamento de la Ley General de Salud en Materia de Publicidad.	Regulation of the General Law of Health on Advertising.	19/01/2012	http://www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmp.html http://dof.gob.mx/nota_detalle.php?codigo=5230367&fecha=19/01/2012
Reglamento de Control Sanitario de Productos y Servicios.	Regulation of Sanitary Control of Products and Services.	14/02/2014	http://www.salud.gob.mx/unidades/cdi/nom/compi/rcsps.html http://www.dof.gob.mx/nota_detalle.php?codigo=5332690&fecha=14/02/2014
Reglamento de la Ley General de Salud en materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios.	Regulation of the General Health Law regarding Health Control of Activities, Establishments, Products and Services.	18/01/1988	http://www.salud.gob.mx/unidades/cdi/nom/compi/rlgsmcsaeps.html
Reglamento de la Ley Federal para el control de precursores químicos, productos químicos esenciales y máquinas para elaborar cápsulas, tabletas y/o comprimidos.	Regulation of the Federal Law for the control of chemical precursors, essential chemicals and machines for making capsules, tablets and / or tablets.	15/09/1999	http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LFCPrecQuim.pdf
Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados.	Regulation of the Law of Biosafety of Genetically Modified Organisms.	06/03/2009	http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LBOGM.pdf
Reglamento de la Ley de Productos Orgánicos.	Regulation of the Organic Products Law.	08/04/2010	http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LPO.pdf

Name in Spanish	Name in English	Date of issuance/ date of last reform	Link to full text
Reglamento de la Ley General del Equilibrio Ecológico y la Protección al Ambiente en materia de evaluación del impacto ambiental.	Regulation of the General Law of Ecological Balance and Environmental Protection in the field of environmental impact assessment.	31/10/2014	http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGEEPA_MEIA_311014.pdf
Reglamento de la Ley General del Equilibrio Ecológico y la Protección al Ambiente en materia de Autorregulación y Auditorías Ambientales.	Regulation of the General Law of Ecological Balance and Environmental Protection in matters of Self-Regulation and Environmental Audits.	31/10/2014	http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGEEPA_MAAA_311014.pdf
Reglamento de la Ley General para la Prevención y Gestión Integral de los Residuos.	Regulation of the General Law for the prevention and integral management of waste.	31/10/2014	http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGPGIR_311014.pdf
Reglamento de la Ley General del Equilibrio Ecológico y la Protección al Ambiente en materia de registro de emisiones y transferencia de contaminantes.	Regulation of the General Law of Ecological Equilibrium and Environmental Protection regarding the registration of emissions and transfer of pollutants.	31/10/2014	http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGEEPA_MRETC_311014.pdf
Reglamento Federal de Seguridad y Salud en el Trabajo.	Federal Regulation of Occupational Safety and Health.	13/11/2014	http://www.diputados.gob.mx/LeyesBiblio/regla/n152.pdf
Acuerdo que establece la clasificación y codificación de mercancías cuya importación y exportación está sujeta a regulación por parte de las dependencias que integran la Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilizantes y Sustancias Tóxicas	Agreement that establishes the classification and codification of goods whose import and export is subject to regulation by the dependencies that make up the Inter-Secretariat Commission for the Control of the Process and use of Pesticides, Fertilizers and Toxic Substances.	12/04/2013	http://dof.gob.mx/nota_detalle.php?codigo=5295791&fecha=12/04/2013
Reglamento de la Ley General para la Prevención y Gestión Integral de los Residuos	Regulation of the General Law for the prevention and integral management of waste	31/10/2014	http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGPGIR_311014.pdf
NOM-232-SSA1-2009 Plaguicidas: Que establece los requisitos del envase, embalaje y etiquetado de productos grado técnico y para uso agrícola, forestal, pecuario, jardinería, urbano, industrial y doméstico	NOM-232-SSA1-2009, Pesticides: which establishes the requirements for the packaging, packaging and labelling of technical grade products and for agricultural, forestry, livestock, gardening, urban, industrial and domestic use.	18/12/2018	https://dof.gob.mx/nota_detalle.php?codigo=5546741&fecha=18/12/2018
NOM-182-SSA1-2010, Etiquetado de nutrientes vegetales	NOM-182-SSA1-2010, Labelling of plant nutrients	21/04/2011	http://www.dof.gob.mx/normasOficiales/4371/salud1a1/salud1a1.htm
NOM-082-SAG-FITO/SSA1-2017. Límites máximos de residuos. Lineamientos técnicos y procedimiento de autorización y revisión.	NOM-082-SAG-FITO / SSA1-2017. Maximum residue limits Technical guidelines and authorization and review procedure.	04/10/2017	http://extwprlegs1.fao.org/docs/pdf/mex170706.pdf
NOM-032-FITO-1995, Por la que se establecen los requisitos y especificaciones fitosanitarios para la realización de estudios de efectividad biológica de plaguicidas agrícolas y su Dictamen Técnico	NOM-032-FITO-1995, Establishing phytosanitary requirements and specifications for conducting biological effectiveness studies of agricultural pesticides and their technical opinion.	11/08/2015	http://www.dof.gob.mx/nota_detalle.php?codigo=5403310&fecha=11/08/2015
NOM-033-FITO-1995: Especificaciones fitosanitarias para el aviso de inicio de funcionamiento que deberán cumplir las personas físicas o morales interesadas en comercializar plaguicidas agrícolas	NOM-033-FITO-1995 Requirements and specifications for the start of operation of persons interested in marketing pesticides.	27/09/1995	http://www.dof.gob.mx/nota_detalle.php?codigo=4882133&fecha=27/09/1995
NOM-034-FITO-1995, Por la que se establecen los requisitos y especificaciones fitosanitarias para el aviso de inicio de funcionamiento que deberán cumplir las	NOM-034- FITO-1995 Requirements and specifications for the beginning of operation of persons interested in manufacturing, formulation, assembly and importation of pesticides.	06/24/1996	https://www.gob.mx/cms/uploads/attachment/file/203926/NOM-034-FITO-1995_240696.pdf

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personas físicas o morales interesadas en la fabricación, formulación, formulación por maquila, formulación y/o maquila e importación de plaguicidas agrícolas			
NOM-052-FITO-1995, Por la que se establecen los requisitos y especificaciones fitosanitarias para presentar el aviso de inicio de funcionamiento por las personas físicas o morales que se dediquen a la aplicación aérea de plaguicidas agrícolas	NOM-052-FITO-1995 Official Mexican Standard, Establishing the Phytosanitary Requirements and Specifications to Present the Notice of the Beginning of Operation by the Physical or Moral Persons Dedicated to the Aerial Application of Agricultural Pesticides.	10/06/1997	https://www.gob.mx/cms/uploads/attachment/file/203946/NOM-052-FITO-1995_100697.pdf
NOM-077-FITO-2000, Por la que se establecen los requisitos y especificaciones para la realización de estudios de efectividad biológica de los insumos de nutrición vegetal	NOM-077-FITO-2000: Establishing the Requirements and Specifications for the Conduct of Biological Effectiveness Studies of Plant Nutrition Inputs.	19/12/2011	https://www.gob.mx/cms/uploads/attachment/file/204179/Mod_NOM-077-FITO-2000_191211.pdf
NOM-003-STPS-1999, Actividades agrícolas-Uso de insumos fitosanitarios o plaguicidas e insumos de nutrición vegetal o fertilizantes-Condiciones de seguridad e higiene	NOM-003-STPS-1999, Agricultural activities-Use of phytosanitary inputs or pesticides and inputs of plant nutrition or fertilizers-Safety and hygiene conditions.	28/12/1999	http://asinom.stps.gob.mx:8145/upload/noms/Nom-003.pdf
NORMA Oficial Mexicana NOM-017-STPS-2008, Equipo de protección personal-Selección, uso y manejo en los centros de trabajo	NOM-017-STPS-2008, Personal protective equipment-Selection, use and management in the workplace.	09/12/2018	https://www.gob.mx/cms/uploads/attachment/file/240382/Nom-017.pdf
NOM-047-SSA1-2011, Salud ambiental-Indices biológicos de exposición para el personal ocupacionalmente expuesto a sustancias químicas	NOM-047-SSA1-2011, Environmental Health-Biological exposure indices for personnel occupationally exposed to chemical substances.	06/06/2012	http://www.salud.gob.mx/cdi/nom/compi/NOM-047-SSA1-2011_060612.pdf
NOM-001-STPS-2008, Edificios, locales, instalaciones y áreas en los centros de trabajo-Condiciones de seguridad	NOM-001 - STPS-2008, Buildings, premises, facilities and areas in the Workplace Safety Conditions.	24/11/2008	http://www.dof.gob.mx/normasOficiales/3540/stps/stps.htm
NOM-004-STPS-1999, Sistemas de protección y dispositivos de seguridad en la maquinaria y equipo que se utilice en los centros de trabajo	NOM - 004 - STPS - 1999, Protection systems and safety devices for machinery and equipment used in work centres.	31/05/1999	http://www.iner.salud.gob.mx/descargas/normatecainterna/MJnormasmexicanas/NOM-004-STPS-1999x31-05-1999.pdf
NOM-005-STPS-1998, Relativa a las condiciones de seguridad e higiene en los centros de trabajo para el manejo, transporte y almacenamiento de sustancias químicas peligrosas	NOM-005 - STPS - 1998, concerning health and safety conditions in workplaces for the handling, transport and storage of hazardous chemicals.	02/02/1999	https://www.stps.gob.mx/bp/secciones/dgsst/normatividad/normas/Nom-005.pdf
NOM-006-STPS-2000, Manejo y almacenamiento de materiales-Condiciones de seguridad y salud en el trabajo	NOM - 006 - STPS - 2000, Material handling and storage-Safety conditions and procedures.	11/09/2014	http://www.stps.gob.mx/bp/secciones/dgsst/normatividad/normas/Nom-006.pdf
NOM-010-STPS-1999, Condiciones de seguridad e higiene en los centros de trabajo donde se manejen, transporten, procesen o almacenen sustancias químicas capaces de generar contaminación en el medio ambiente laboral	NOM - 010 - STPS - 1999, Safety and hygiene conditions in workplaces where chemicals are handled, transported, processed or stored capable of generating pollution in the work environment.	07/12/1999	http://asinom.stps.gob.mx:8145/upload/nom/10.pdf
NOM-018-STPS-2000, Sistema para la identificación y comunicación de peligros	NOM - 018 - STPS - 2000, System for the identification and communication of hazards and risks by hazardous	27/10/2000	http://asinom.stps.gob.mx:8145/upload/noms/Nom-018.pdf

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y riesgos por sustancias químicas peligrosas en los centros de trabajo	chemicals in the workplace.		
NOM-019-STPS-2011, Constitución, integración, organización y funcionamiento de las comisiones de seguridad e higiene	NOM-019-STPS-2011, Constitution, integration, organization and operation of health and safety commissions.	13/04/2011	http://dof.gob.mx/nota_detalle.php?codigo=5185903&fecha=13/04/2011
NOM-011-SCT2/2003, Condiciones para el transporte de las substancias y materiales peligrosos en cantidades limitadas	NOM - 011 - SCT2/2003, Conditions for the Transport of Hazardous Substances, Materials or Residues in limited quantities	08/12/2003	http://www.sct.gob.mx/fileadmin/DireccionesGrales/DGAF/DGA_Normas/Materiales_peligrosos/NOM-011-SCT2-2003-08122003.pdf
NOM-043-SCT/2003, Docimento de embarque de substancias, materiales y residuos peligrosos	NOM-043-SCT-2-2003, Document of shipment of substances, materials and hazardous waste	04/06/2003	http://www.sct.gob.mx/fileadmin/_migrated/content_uploads/42_NOM-043-SCT-2-2003.pdf
NOM-003-SCT/2008, Características de las etiquetas de envases y embalajes, destinadas al transporte de substancias, materiales y residuos peligrosos	NOM - 003 - SCT/2008, Packaging and packaging labelling for the transport of hazardous substances, materials and wastes (SMRP)	15/08/2008	http://www.dof.gob.mx/nota_detalle.php?codigo=5056785&fecha=15/08/2008
NOM-004-SCT/2008, Sistemas de identificación de unidades destinadas al transporte de substancias, materiales y residuos peligrosos	NOM - 004-SCT/2008 Identification System for SMRP Transport Units	18/08/2008	http://dof.gob.mx/nota_detalle.php?codigo=5056880&fecha=18/08/2008
NOM-005-SCT/2008, Información de emergencia para el transporte de substancias, materiales y residuos peligrosos	NOM-005-SCT/2008 Emergency information for the transport of SMRP	14/08/2008	http://www.dof.gob.mx/nota_detalle.php?codigo=5056547&fecha=14/08/2008
NOM-002/1-SCT/2009, Listado de las substancias y materiales peligrosos más usualmente transportados, instrucciones y uso de envases y embalajes, recipientes intermedios para graneles (RIG S), grandes envases y embalajes, cisternas portátiles, contenedores de gas de elementos múltiples y contenedores para graneles para el transporte de materiales y residuos peligrosos	NOM-002/1-SCT/2009 List of the most commonly transported hazardous substances and materials, instructions and use of containers and packaging, intermediate bulk containers, large containers etc.	04/03/2010	http://www.sct.gob.mx/fileadmin/_migrated/content_uploads/55_NOM-002-1-SCT-2009.pdf
NOM-009-SCT2/2009, Especificaciones especiales y de compatibilidad para el almacenamiento y transporte de las substancias, materiales y residuos peligrosos de la clase 1 explosivos	NOM-009-SCT2/ Special specifications and compatibility for storage and transport of explosive class 1 SMRPs;	24/11/2009	http://www.dof.gob.mx/normasOficiales/3964/sct/sct.htm
NOM-010-SCT2/2009, Disposiciones de compatibilidad y segregación para el almacenamiento y transporte de substancias, materiales y residuos peligrosos	NOM-010-SCT2/2009 Compatibility and Segregation Provisions, for the storage and transport of SMRP	01/09/2009	http://www.sct.gob.mx/JURE/doc/nom-010-sct2-2009.pdf
NOM-007-SCT2/2010 Marcado de envases y embalajes destinados al transporte de substancias y residuos peligrosos	NOM-007-SCT2/2010, Marking of containers for the transport of SRP.	06/09/2010	http://www.dof.gob.mx/normasOficiales/4146/sct/sct.htm
NOM-045-SSA1-1993, plaguicidas. Productos para uso agrícola, forestal, pecuario, de jardinería, urbano e industrial. Etiquetado	NOM-045-SSA1-1993, Pesticides. Products for agricultural, forestry, livestock, gardening, urban and industrial use. Labelled.	16/10/1995	http://www.salud.gob.mx/unidades/cdi/nom/045ssa13.html
NOM-048-SSA1-1993, Que establece el método normalizado para la evaluación de riesgos a la salud como consecuencia de agentes ambientales	NOM-048-SSA1-1993, which establishes the standardized method for the evaluation of health risks as a consequence of environmental agents.	09/01/1996	http://www.dof.gob.mx/nota_detalle.php?codigo=4865124&fecha=09/01/1996

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NOM-021-STPS-1994. Relativa a los requerimientos y Caracteristicas de los informes de los riesgos de trabajo que ocurran, para Integrar las estadisticas	NOM-021-STPS-1994, Relating to the requirements and characteristics of reports of occupational hazards that occur, to integrate statistics.	24/05/1994	http://asinom.stps.gob.mx:8145/upload/noms/Nom-021.pdf
NOM-056-SSA1-1993, requisitos sanitarios del equipo de proteccion personal	NOM-056-SSA1-1993 Sanitary requirements of personal protective equipment.	10/01/1996	http://www.salud.gob.mx/unidades/cdi/nom/056ssa13.html
NOM-161-SEMARNAT-2011, Que establece los criterios para clasificar a los Residuos de Manejo Especial y determinar cuáles están sujetos a Plan de Manejo; el listado de los mismos, el procedimiento para la inclusión o exclusión a dicho listado; así como los elementos y procedimientos para la formulación de los planes de manejo	NOM-161-SEMARNAT-2011, which establishes the criteria for classifying Special Management Waste and determining which are subject to the Management Plan; their list, the procedure for the inclusion or exclusion of said list; as well as the elements and procedures for the formulation of management plans.	01/02/2013	https://www.profepa.gob.mx/innovaportal/file/6633/1/nom-161-semarnat-2011.pdf
NOM-052-SEMARNAT-2005, Que establece las características, el procedimiento de identificación, clasificación y los listados de los residuos peligrosos	NOM-052-SEMARNAT-2005, which establishes the characteristics, identification procedure, classification and listings of hazardous waste	23/06/2006	http://www.dof.gob.mx/normasOficiales/1055/SEMARNA/SEMARNA.htm

Source: (Economia, n.d.[1]), (Congreso de la Unión, n.d.[2]).

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Economia, S. (n.d.), *Catálogo de Normas Oficiales [Official Norms Catalogue]*, http://www.economia-noms.gob.mx (accessed on 21 January 2020). [1]

FAO & WHO (2013), *International Code of Conduct on the Distribution and Use of Pesticides Guidelines on data requirements for the registration of pesticides*, Food and Agriculture Organization of the United Nations and World Health Organization, Rome and Geneva, http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/DataReq2013.pdf. [3]

Mexican Congress (Congreso de los Estados Unidos Mexicanos) (2014), *Decree reforming the PLAFEST Regulation*, http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/reglamentos (accessed on 17 July 2020). [4]

Annex B. Questionnaire submitted to Mexican stakeholders

The OECD prepared a questionnaire to collect information on the state of the pesticide regulatory framework. This questionnaire was sent to Mexican stakeholders including government agencies, and industry associations. The questionnaire was divided in six sections:

1. **Pressures on health and the environment from pesticides:** the aim of this section is to learn about the economic activities related to pesticides in Mexico as well as to assess the pressures in Mexico on health and the environment from the production, import and use of pesticides.
2. **Legal, policy and institutional framework for managing risks to health and the environment from pesticides**: the aim of this section is to learn about the government policies, legislation and institutions that are directly related to the regulation of pesticides in Mexico. It aims to identify the existence of a set of clearly identified objectives, targets, aligned with the authorities' functions and powers.
3. **Resourcing for pesticide management programme**: the aim of this section is to assess the extent to which the authorities funding and staffing are aligned with the authorities' objectives and targets.
4. **International Obligations and Co-operation**: the aim of this section is to assess how international co-operation supports addressing pesticides in Mexico.
5. **Registration of pesticides**: The aim of this section is to assess what are the registration scope, strategy and processes, what are data requirements and how the evaluation of pesticides is performed.
6. **Systematic risk management of pesticides**: the aim of this section is to assess how the systematic risk management of pesticides is implemented in Mexico and how compliance is monitored and enforced.

Annex C. Fact-finding mission

Table A C.1. Participants of the fact-finding mission

Stakeholder	Subjects discussed	Category	Date
SENASICA	• Challenges in implementation of the current regulatory framework, Biological efficacy, • MRLs and adoption methodologies, • SENASICA's role on the registry process, monitoring of compliance and enforcement, pesticide establishments, aerial applications, co-ordination among agencies, empty containers, labelling. • Implementation of provisions within the Federal Law of Plant Health such as promotion and training programs, use data and efficacy re-evaluation, establishing national program for residue monitoring/control of use, identifying pesticides for emergency pest control, future technologies aspects and biopesticides.	Government	21 September 2020 [3 hours] and 9 October 2020
COFEPRIS	• Registration and re-registration of pesticides, risk mitigation measures for pesticides, resourcing of pesticides management. • Gaps/duplication in current regulatory framework and challenges in their implementation. • Monitoring compliance and enforcement of PLAFEST Regulation including illegal trade. • Future technologies aspects and biopesticides. • Classification of substances and Catalogue of Pesticides, Setting and enforcing MRLs. • Regulation of establishments that produce pesticides. International trade permits, international cooperation, obligations and working groups.	Government	25 September 2020 [2 hours]
Agriculture Associations – Members of CNA	• Use of pesticides in Mexico, e.g. farmers assistance programmes, understanding labels, minor uses of pesticides.	Industry Association	29 September 2020 [1:30 hours]
Mexican Association of Biopesticide Producers	• Extent to which agro chemical registration data requirements are used to register bio-pesticides and whether this poses any difficulties. Unique requirements for microbials, pheromones and semiochemicals, and macrobials/invertebrates Stakeholder engagement, shortcomings on the registry process, comments on the pesticide regulation governance. • Monitoring of compliance and enforcement.	Industry Associations	29 September 2020 [1:30 hours]
FAO	• Outcomes of capacity-building workshops on pesticides in Mexico, regulatory oversight, interagency cooperation, staff resourcing. • Gaps/duplication in current regulatory framework and challenges in their implementation. Implementation of FAO Code of Conduct, FAO toolkit, guidelines and other resources in Mexico.	International Organisation	1 October 2020 [1:30 hours]

Stakeholder	Subjects discussed	Category	Date
CONAMER	• Impact assessments, inspections reform, formalities registry, public consultations for new regulation, administrative simplification.	Government	5 October 2020 [1:30 hours]
General Direction for Trade Facilitation, Secretary of Economy	• Elaboration of NOMs, National Advisory Committees on standardization, conformity assessment mechanisms. • Role of agencies which implement the NOMs (e.g. COFEPRIS) in the development of the NOMs by the General Direction	Government	5 October 2020 [0:45 min]
General Direction for Technical Regulations, Secretary of Economy	• Pesticide trade, import/export data. How does this organisation co-ordinate with the COFEPRIS • Elaborate on the roles and responsibilities of each.	Government	5 October 2020 [0:45 min]
National Commision for Water (CONAGUA)	• Monitoring of pesticides in the environment (water) in Mexico	Government	5 October 2020 [1:30 hours]
Pesticide Producers Associations – Members of CNA	• Stakeholder engagement, shortcomings on the registry process, comments on the pesticide regulation governance. • Monitoring of compliance and enforcement, impact of review/cancellation of (pre-2005) products; establishment of import MRLs; database of MRLs.	Industry Association	9 October 2020 [1:30 hours]

Annex D. Comparison of the FAO and WHO guidelines for information requirements with Mexico's requirements

Table A D.1. FAO and Who Guidelines comparison with Mexican requirements

FAO and WHO guidelines	Mexico's requirements
Applicant's company name, company address, contact name, telephone number and e-mail address	X
Trade name, brand name or trademark of the product	X
Common name (International Organization for Standardization [ISO]), International Union of Pure and Applied Chemistry (IUPAC) name, and Chemical Abstracts Service (CAS) name and number of the active ingredient	X
Names of all co-formulants in the product and whether they influence the toxicity of the product	Information on composition is required
Type of formulation (e.g. soluble concentrate, wettable powder, emulsifiable concentrate)	X
Function of the product (e.g. herbicide, insecticide, fungicide) and target pest species	X (for biochemical pesticides, microbial pesticides, botanical pesticides and miscellaneous pesticides)
Site of the application (e.g. maize, greenhouse tomatoes, houses for termite control, mosquito larvicidal applications to water)	X (for biochemical pesticides, microbial pesticides, botanical pesticides and miscellaneous pesticides)
Application rate per unit treated and concentration of active ingredient in the material as applied (for example, if the product is diluted before the application)	
Application and mixing instructions	X (a physical compatibility study in tank mixture with recommended pesticides is required)
Number, frequency and timing of applications (e.g. per year, per month, per crop cycle) and duration of protection expected	X (as part of biological efficacy data)
Proposed instructions on how to use the product, including in a manner that protects human health and the environment (e.g. buffer zones; personal protective equipment)	X (as art of the proposed label)
A statement about any risk arising from the recommended methods and precautions and handling procedures, in order to minimize those risks (e.g. precautionary statements of the GHS)	X (as part of the proposed label)
A statement about any risk for the development of resistance in the pest, resistance prevention methods and 'mode of action' codes	
Procedures for cleaning application equipment, if relevant to the proposed use	
Withholding periods, pre-harvest intervals, re-entry periods (e.g. after space spray for mosquito control), waiting periods (to avoid damage to or residues in succeeding crops) and other precautions to protect people, livestock and the environment	Re-entry time for treated places to be provided for biochemical pesticides, microbial pesticides, botanical pesticides and miscellaneous pesticides
Disposal procedures, detailed actions in the event of an accident during transport, storage or use and decontamination procedures for use in the event of accidental spillage or fire	X (as part of safety data sheet requested for biological efficacy data)
Information on antidotes, if any, and medical treatment in the case of accidental exposure; names of co-formulants that may influence the toxicity of the product	X (as part of the proposed label)
Proposed hazard classification, labelling and safety phrases and symbols	X
Proposed complete, commercial label, packaging sizes, and materials and specimens of proposed packaging	Proposed label is required

FAO and WHO guidelines	Mexico's requirements
Information on whether the application is to import or manufacture (including repacking, formulating and manufacturing from raw materials) the pesticide product. If the application is for manufacturing, the applicant should give the location of the manufacturing plant	X

Source: Author, based on (FAO & WHO, 2013[1]; Mexican Congress (Congreso de los Estados Unidos Mexicanos), 2014[2]; COFEPRIS[3]).

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Annex E. Data requirements for the registration of pesticides in Mexico

Table A E.1. Data requirements according to Article 12 of the PLAFEST Regulation, as amended in 2014

Chemical pesticide – technical pesticide	Chemical pesticide – formulated product for agricultural use	Biochemical pesticides for agricultural use	Microbial pesticides for agricultural use*	Botanical pesticides for agricultural use	Miscellaneous pesticides for agricultural use
Information on identity and composition, including a chemical name (IUPAC/CAS); common name; formula; chromatogram; minimum and maximum content of active ingredient; isomers; impurities and CAS number	Information on identity and composition, including minimum and maximum content of active ingredient; chemical and common name; inert ingredients and density/weight	Information on identity and composition, including a chemical name (IUPAC/CAS-; common name, minimum and maximum content of active ingredient; inert ingredients; type of formulation and use aspects: information on areas where the product is to be applied and target control pests, giving their common name; genus and species; and re-entry time for treated places	Information on identity and composition, including common name; taxonomical position of the microbial control agent; description of the obtention process; minimum and maximum content of the microbial control agent in the product; units of the microbial control agent per product weight or volume unit; any other adequate expression of the biological activity of the agent, according to the organism type; inert ingredients: chemical name, common name, IUPAC or CAS nomenclature and percent content, and their corresponding functions; type of formulation, and use aspects: information on areas where the product is to be applied and control target pests, specifying their common name, genus and species, and re-entry time required for the population to return into treated places	Information on identity and composition, including common name and scientific name of the plant from which the botanical extract is obtained; common name of the botanical extract of the product to be registered or its more adequate denomination; minimum guaranteed content of the botanical extract as a percentage or quantify the metabolite concentration; inert ingredients: CAS number, IUPAC or CAS nomenclature and percent content, and their corresponding functions; type of formulation, and use aspects: information on areas where the product is to be applied and control target pests, specifying their common name, genus and species, and re-entry time required for the population to return into treated places	Information on identity and composition, including common name(s); chemical or scientific name(s); minimum and maximum content of active ingredients; inert ingredients: chemical name, common name, IUPAC or CAS nomenclature and percent content, and their corresponding functions; type of formulation, and use aspect: information on areas where the product is to be applied and control target pests, specifying their common name, genus and species, and re-entry time required for the population to return into treated places

Chemical pesticide – technical pesticide	Chemical pesticide – formulated product for agricultural use	Biochemical pesticides for agricultural use	Microbial pesticides for agricultural use*	Botanical pesticides for agricultural use	Miscellaneous pesticides for agricultural use
Physico-chemical properties, including weight; physical state; colour; odour; pH; melting and boiling point; decomposition point; pressure; water and organic solvent solubility; partition coefficient; density; flammability; explosiveness, reactivity and oxidising properties	Physical properties corresponding to the type of product (e.g. powder, granules, emulsion), including humidity content; humectability; foam persistence; suspensibility; wet granulometric analysis; dry granulometric analysis and average particle size in microns; emulsion stability and redispersion properties. When label recommends mixture with other products, a physical compatibility study in tank mixture with recommended pesticides shall be delivered. Storage stability study that defines the expiration date in weeks should also be provided	Physico-chemical properties of the active ingredient: physical state (colour and odour); vapour pressure; chromatogram or absorption spectrum; and describe temperature conditions to keep the product in storage and time ensuring stability at conditions specified. Information above is declarative and no support studies or information is required Physical properties corresponding to the formulation type: foam persistence; emulsion stability and redispersion properties	Physico-chemical properties of a formulated product: physical state; colour and pH Physical properties corresponding to the type of product (e.g. powder, granules, emulsion), including humidity content; humectability; foam persistence; suspensibility; wet granulometric analysis; dry granulometric analysis and average particle size in microns; emulsion stability and redispersion properties. When label recommends mixture with other products, a physical compatibility study in tank mixture with other agricultural pesticides shall be delivered. Storage stability study that defines the expiration date in weeks should also be provided	Properties: density for liquids or specific weight for solids of formulated product; physical state and colour Physical properties corresponding to the formulation type, including humidity content; humectability; foam persistence; suspensibility;; dry granulometric analysis and average particle size in microns; emulsion stability and redispersion properties. When label recommends mixture with other products, a physical compatibility study in tank mixture with recommended pesticides shall be delivered. Information on the obtention procedure of essential components should be provided.	Physical, chemical and physico-chemical properties: physical state; colour; density for formulated liquids, and for fatty acids and dry yeast, specific weight Physical properties corresponding to the formulation type, including humidity content; humectability; foam persistence; suspensibility; wet granulometric analysis; dry granulometric analysis and average particle size in microns; emulsion stability and redispersion properties. When label recommends mixture with other products, a physical compatibility study in tank mixture with other agricultural pesticides shall be delivered. Storage stability study that defines the expiration date at high temperatures should also be provided
Analytical methods to measure the active ingredient and its residues in food, soil and water, and, if the technical product is manufactured, formulated or packaged domestically; the sampling methodology and the analytical technique to measure the product in the working environment		Analytical methods to assess active ingredients	Procedures and/or methods used to identify and determine the purity of the microbial control agent (either biological, genetic, biochemical, analytic, physical, chemical, serological or other, as needed)		

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Toxicological information, including acute toxicity studies for mammals; repeated oral toxicity studies; chronic toxicity studies; carcinogenicity studies; toxicity for reproduction studies; neurotoxicity and mutagenicity studies. Information should also address toxic effect of metabolites, isomers or degradation products, as well as a hazard category of the technical product. Information on allowed daily intake should also be provided		Toxicological information: studies for a mammal species. For registration applications of products based on straight-line lepidopteran pheromones, documentary information can be delivered, on condition that it is public and published by international organisms with participation of the Mexican State. For non-lepidopteran pheromones, and other biochemical pesticides, the following toxicology studies must be delivered: oral (LD50), dermal (LD50), and hazard category	Toxicological information: acute oral toxicity (LD50); primary eye and skin irritation; acute dermal toxicity (LD50) and hypersensitivity or allergy. If available, pathogenicity studies for humans or other mammals proving that the product contains no pathogens or genetic variants	Information on acute toxicity for one mammal species: oral (LD50) and dermal (LD50)	Toxicological information: acute toxicity studies for mammal species – skin and eye irritation, unless knowing the material is corrosive, and hypersensitivity or allergy
Ecotoxicological and environmental fate information, including degradation information and data on concentration in environmental compartments; identification of metabolites found in compartments; effects on terrestrial and aquatic flora and fauna; information on the impact on beneficial insects and pollinators; product lixiviation, mobility, accumulation persistence in water and soil, photo decomposition studies; hydrolysis decomposition and chemical adsorption			Ecotoxicological information: studies of the pesticide effects on terrestrial flora and fauna; studies of the pesticide effects on aquatic flora and fauna and study of impacts on populations of beneficial and pollinizer insects. If there is scientific evidence showing that the application of the microbial pesticide causes no exposure or damages on non-target organisms, and does not causes environmental pollution, the interested party shall deliver the corresponding justification		
Proposed label	Proposed label	Proposed label	Proposed label	Proposed label	Proposed label
	Copy of the biological effectiveness opinion	Copy of the biological effectiveness opinion	Copy of the biological effectiveness opinion	Copy of the biological	Copy of the biological

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	issued by SADER to the company aiming to register the product. When the technical opinion is issued in the name of other company, a confirmation of the rights to use it or the access to the biological effectiveness information is needed	issued by SADER to the company aiming to register the product. When the technical opinion is issued in the name of other company, a confirmation of the rights to use it or the access to the biological effectiveness information is needed	issued by SADER to the company aiming to register the product. When the technical opinion is issued in the name of other company, a confirmation of the rights to use it or the access to the biological effectiveness information is needed	effectiveness opinion issued by SADER to the company aiming to register the product. When the technical opinion is issued in the name of other company, a confirmation of the rights to use it or the access to the biological effectiveness information is needed	effectiveness opinion issued by SADER to the company aiming to register the product. When the technical opinion is issued in the name of other company, a confirmation of the rights to use it or the access to the biological effectiveness information is needed
Hazard category presented when registering technical product	Hazard category	Hazard category	Hazard category	Hazard category	
	MRLs for each crop requested In addition, information and documentation required for technical pesticide must be provided, except if the interested party or the supplier have a registration for the technical pesticide or for a formulation based on the same active ingredient, and the product to be registered has the same manufacturer of the active ingredient authorised in the registration previously granted. In this case, the number of the sanitary registration referred must be specified		Information on the agent's biological properties: background information such as: history, distribution, presence, uses; common name, genus and species attacked by the microbial control agent and specificity level for the target organism(s); optimum environmental factors for the microorganism viability and virulence; interaction of the biological agent with pathogenic organisms on a crop or vertebrate species; natural presence of the organism and its relation with other species, and distribution mechanisms of the active agent in different meteorological conditions	Storage stability study determining the product expiration date, with the following to options to comply with this requirement: accelerated high-temperature stability test, analysing the physical properties corresponding to the formulation type before and after the test, or bioassay assessing the main product effect or function, toxicity for one pest, repellence or any other, before and after the test to determine its useful life or, determination of the extract percent content before and after the test	
			Product stability information: either temperature conditions preserving the viability of the		

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			infective inoculant in storage, and the time ensuring its viability under conditions specified or storage stability study determining the product useful life in weeks		

* Certain specificities are applicable to information required for registration of a microbial pesticide based on genetically modified organisms
Source: Elaboration by author based on the PLAFEST Regulation.

Regulatory Governance in the Pesticide Sector in Mexico

A clear, efficient, and modern regulatory framework for pesticides is essential for addressing their impacts on human health and the environment, supporting a life-cycle approach to their management, and ensuring crop protection and a sustainable agricultural industry. This report identifies the gaps, barriers, implementation flaws and inefficiencies that affect the regulatory framework of pesticides in Mexico. It takes stock of the regulatory framework and recent reforms, and identifies both the areas that pose the greatest challenge for the effective regulation of pesticides and those where regulation – or lack of it – in pesticides most affects policy objectives and economic activity. These challenges and practices are assessed in view of OECD principles and country experiences, and recommendations are provided to support better regulation efforts. The report finds that Mexico would benefit from adopting a comprehensive, mutually-agreed policy strategy for pesticides, recognising that pesticide management is a shared responsibility across national and local governments, the pesticide industry, pesticide users, as well as the general public.

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