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

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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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