

US EPA ARCHIVE DOCUMENT



Overview of Mexico's Pesticides Regulation Review

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**Federal Commission for the Protection
from Sanitary Risks (COFEPRIS)**

Ministry of Health



General Health Act (Article 376)

- Pesticides and plant nutrients require sanitary registration.
- Registration is a shared process between the agricultural (**SAGARPA**), environmental (**SEMARNAT**) and health (**SALUD**) Mexican authorities.



General Health Act (Article 376)

- Therefore it is a joint evaluation and only with the approval of the agricultural and environmental authorities, the Ministry of Health (SALUD) would grant the registration.
- The registration will be valid for 5 years, and may be renewed for equal periods, if the person concerned so requests.



Basic documents

“Regulation for Registration, Export and Import Permits and Certificates for Export of Pesticides, Fertilizers and Toxic and Hazardous Substances”

- Specific Regulation that establishes the general registration procedure and the specific requirements by pesticide type.
- Published on the Official Gazette of the Federation on December 28th, 2004

www.cofepris.gob.mx

<http://www.salud.gob.mx/unidades/cofepris/bv/mj/REGLAMENTOS/12/REGLAMENTORegAutImpoExpoCertPlagui.doc>

“Agreement by which the procedures, services and formats registered in the Federal Register of Procedures and Services are released and used by the Ministry of Health, through the COFEPRIS”

- Procedures guide that contains the official formats and the specific procedures that correspond to each pesticide type.
- Published on the Official Gazette of the Federation on January 28th, 2011

<http://www.cofepris.gob.mx/nom/acuerdos/salud2a28ene11.pdf>

<http://www.cofemer.gob.mx/BuscadorTramites/BuscadorGeneralHomoclave.asp>





Biological Pesticide (Biopesticide) classification

On the Mexican pesticide regulation (General Health Act and specific Regulation), the biopesticides category is not defined, and the pesticides are grouped on:

Chemical

Microbial

Botanical

Biochemical



Microbial pesticide (Procedure 06-006)

Product formulated with microorganisms such as bacteria, viruses, fungi or yeast, nematodes or protozoa, used for pest control purposes.

Botanical pesticide (Procedure 06-007)

Substances extracted directly from plants and are conditioned to be exploited for pest control.

Biochemical pesticide (Procedure 06-005)

Substance that occurs naturally and is used for pest control through non-toxic mechanisms, including insect sex pheromones that interfere with reproduction.



Before submitting the application...

- Sanitary license for pesticide manufacture, formulation, mixing or packaging. (Procedure 05-022-B)
 - Floor blueprint
 - Worker training program
 - MSDS
 - Worker health surveillance program
 - Special security systems (sprinklers, smoke detectors, leakage detection alarm)
 - Technical information about production lines (raw materials, residues, process description, flow diagram, etc.)
 - Fee (Fee Federal Law 2011, art. 195-K-8, \$15,944.93 MXP)
- Biological efficacy opinion (SAGARPA)



General data requirements although there are specific for each pesticide type

- Administrative data (Off.form, Leg. pers. acredit., Current registry in country of origin, License)
- Product identity and composition (name, IUPAC, CAS, ai content, etc.)
- Physico-chemical characteristics (physical state, colour, pH, etc.)
- Physical characteristics related to use (foam persistence or stability)
- Analytical Methods (ai quantification and purity)
- Toxicological information (DL50 oral & dermic, irritation, patogenicity, etc.)
- Target pests (pests scientific name)
- Product Label (Regulations NOM-045-SSA1-1993 before April 2012 or NOM-232-SSA1-2009 after April 2012)
- Biological efficacy opinion (SAGARPA)
- Ecotoxicological information





Accepted data

- For physicochemical and toxicological studies, COFEPRIS considers valid studies made under international guidelines (OECD, EPA, etc.) and under Good Laboratory Practices statement.
- In the case that an specific requirement does not apply to a particular product presentation, then the specific Regulation considers the waiving of this requirement with the respective technical justification (article 5).





Total requirements, Current registries & Fees

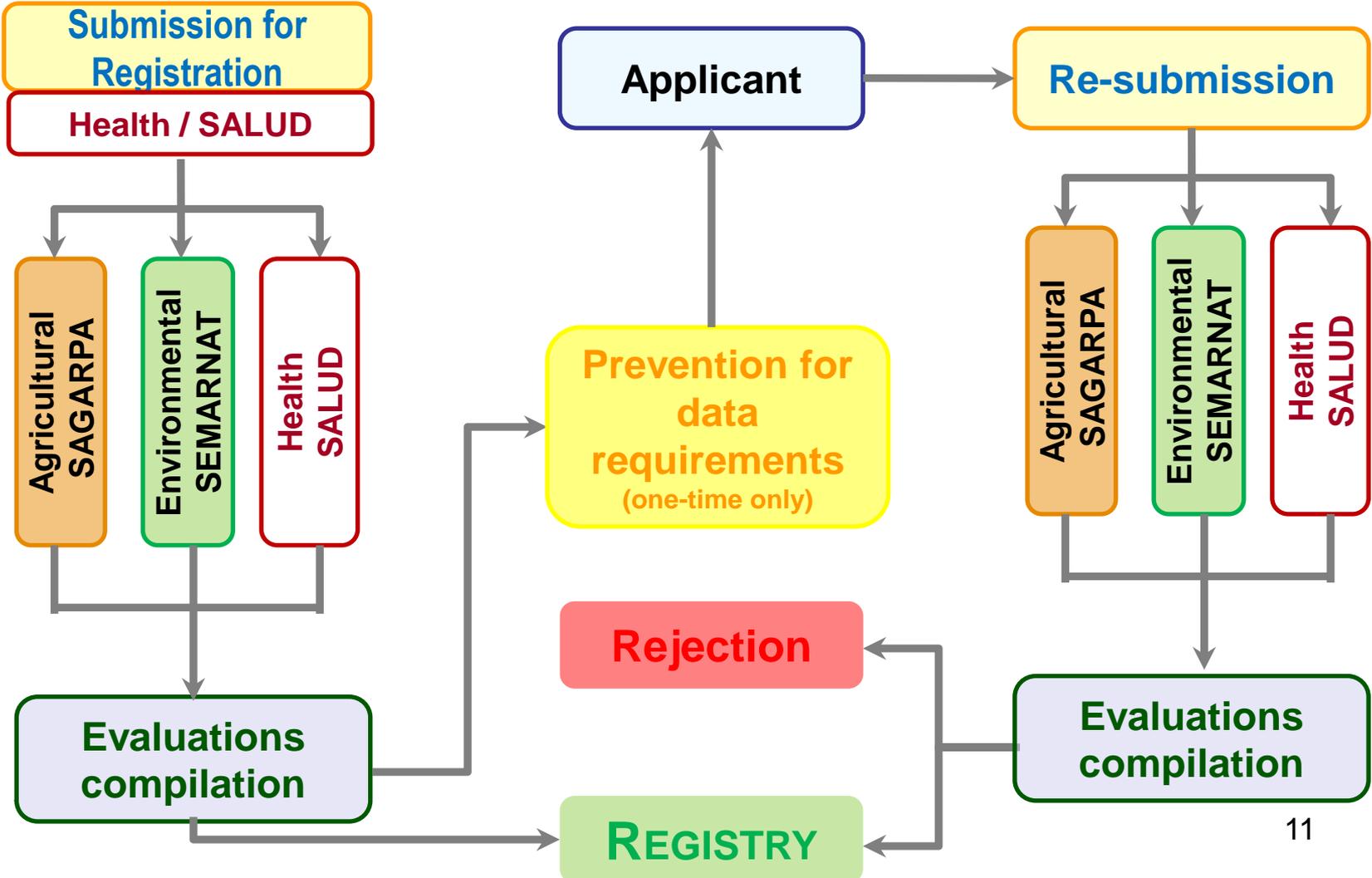
	Total requirements (of which are toxicological data)	Current registries		Cost Right Federal Law 2011, article 195-A-IV
Microbial	20 (5)	bacteria	77	Toxicological category V: \$15,713 MXP
		fungi	13	
		virus	2	
		nematods	19	
Botanical	19 (2)	21		
Biochemical	12 (2)	39		

for example

- *Chrysanthemum extract*
- *Euphorbia extract*
- Nuclear polyhedrosis virus
- *Trichoderma lignorum*
- Torula dry yeast
- *Cydia pomonella granulosis virus*
- *Bacillus subtilis*
- *Bacillus thuringiensis*
- *Beauveria bassiana*
- *Trichoderma harzianum*

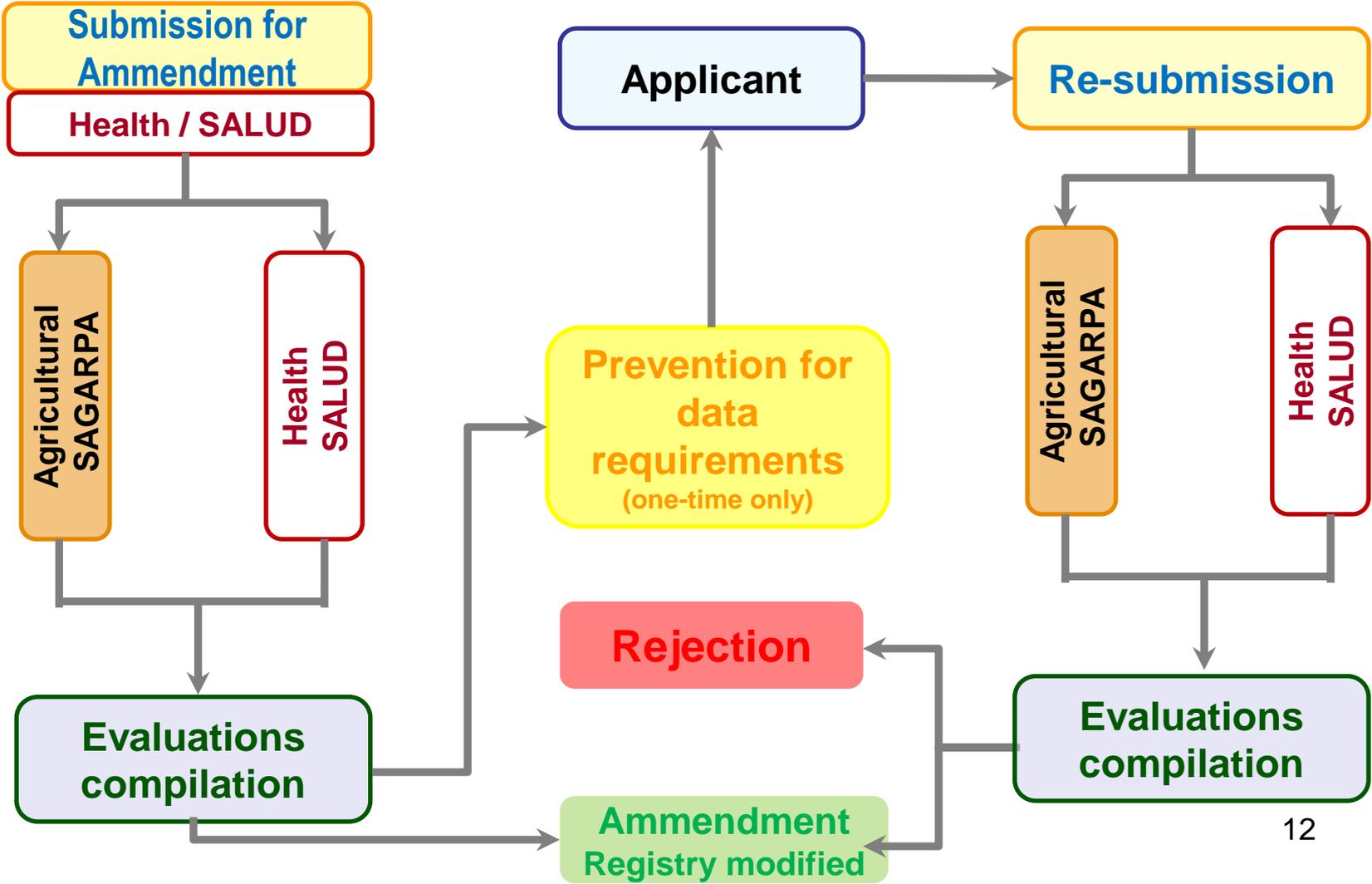


Registration process





Registration's ammendment (i.e. add culture use)





NEW Regulation

“Regulation for Registration, Export and Import Permits and Certificates for Export of Pesticides, Fertilizers and Toxic and Hazardous Substances” (RPLAFEST)

- Specific Regulation that establishes the general registration procedure, requirements and pesticide classification.
- Published on the Official Gazette on December 28th, 2004.
- After six years of implementation, we found out fields of opportunity to improve this regulation.



Proposed amendments

- Incorporation of biocides (currently called industrial pesticides), with a harmonization perspective.
- The register in the origin country will be not longer requested.
- A new rule has been proposed to allow Mexico to participate in a regular basis in the Joint Review Program.
- For microbial, biochemical and botanic pesticides (biopesticides), a list of reduced risk products will be generated. The products in the list will be exempt for the major requirements. The inclusion criteria is currently under development.



Proposed amendments

- For fertilizers the requirements have changed with a harmonization perspective.
- The requirements for equivalent pesticides are amended to be harmonized with the latest version of FAO's rules.
- A new set of rules has been included to allow Mexico to establish its own pesticides specifications.



Proposed amendments

- The current regulation for microbial, biochemical and botanic pesticides (biopesticides), despite being less strict than the typical pesticide, efforts to streamline the process are being done. There are several amendments that include:

- For biochemical
 - The requirements hydrolysis and photolysis were withdrawn.
 - The toxicological data may be from the literature.
- For microbial
 - The methodology to assess purity and identity were withdrawn



Proposed amendments

- For Botanic:
 - The requirements hydrolysis and photolysis were withdrawn.
- For all of them, a list of reduced risk products will be generated. The products in the list will be exempt for the major requirements (toxicological and ecotox).
- The inclusion criteria is currently under development. The products evaluated for EPA and CODEX may be considered.



**GOBIERNO
FEDERAL**

SALUD

Thank you

