

US EPA ARCHIVE DOCUMENT



Overview of Mexico's Biopesticide Regulation

M. Sc. Jose Herrera

Federal Commission for the Protection
from Sanitary Risk (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.
- 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 Journal 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 Journal 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 purposes of pest control.

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 to pest control by nontoxic mechanisms, including insect sex pheromones that interfere with intercourse.





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 (Right Federal Law 2011, art. 195-K-8, \$15,944.93 MXP)
- Biological effectiveness opinion (SAGARPA)



General data requirements although are specifics 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, odor, pH, etc.)
- Physical characteristics use related (foam persistence or stability)
- Analytical Methods (ai quantification and purity)
- Toxicological information (DL50 oral & dermic, irritation, patogenicity, etc.)
- Pests controlled (pests scientific name)
- Product Label (Regulations NOM-045-SSA1-1993 before April 2012 or NOM-232-SSA1-2009 after April 2012)
- Biological effectiveness 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 to waive this requirement with the respective technical justification (article 5).



Total requirements, Current registries & Fees

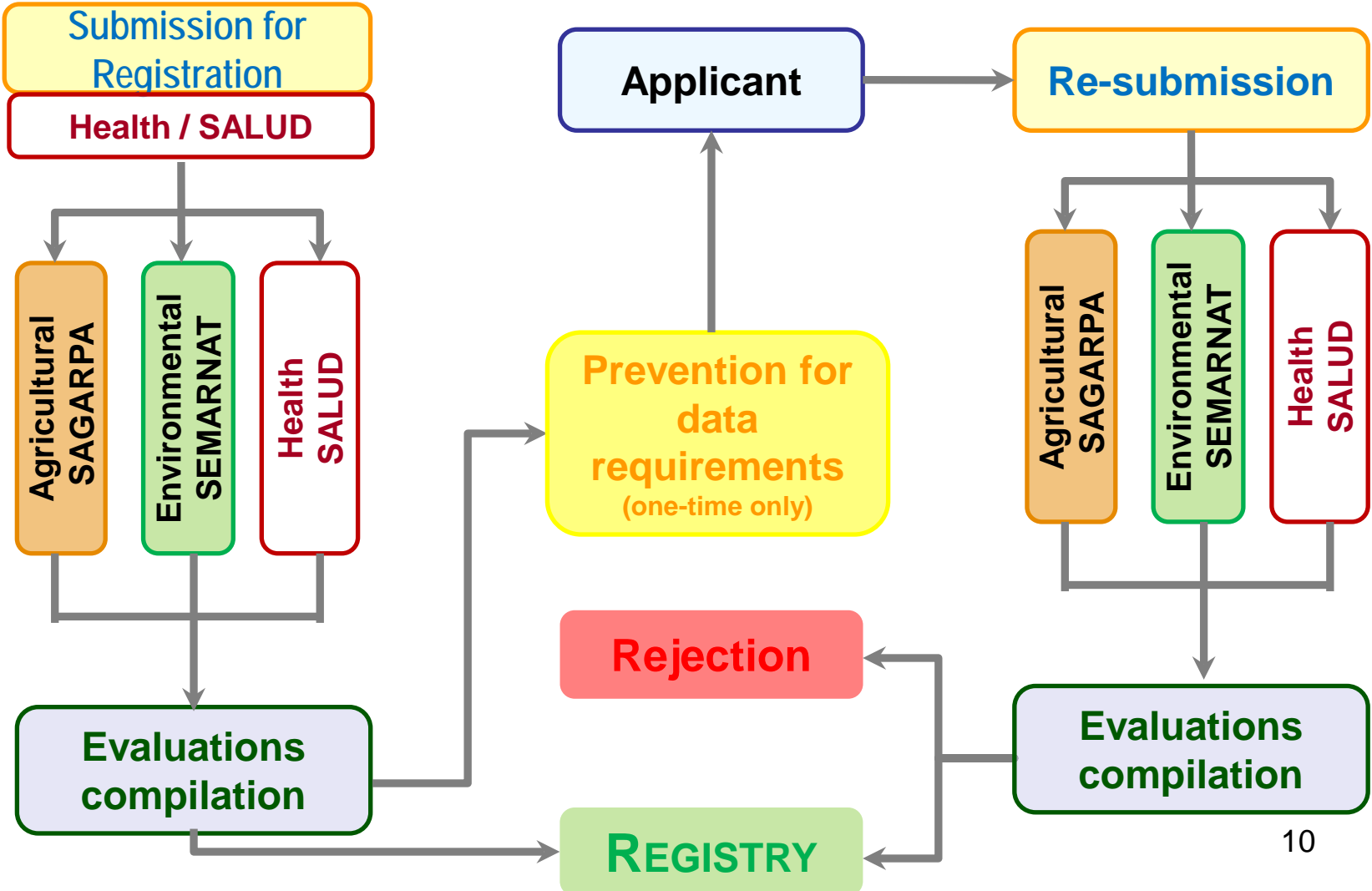
	Total requirements (of which are toxicological data)	Current registries		Cost Right Federal Law 2011, article 195-A-IV
Microbial	20 (5)	bacteria	77	Toxicological category V: \$15,713 MXP
		fungi	13	
		virus	2	
		nematods	19	
Botanical	19 (2)	21		
Biochemical	12 (2)	39		

for example

- *Chrysanthemum* extract
- Garlic extract
- Tea tree extract
- *Capsicum* extract
- Soybean oil
- *Euphorbia* extract
- Nuclear polyhedrosis virus
- *Cydia pomonella* granulosis virus
- *Bacillus subtilis*
- *Bacillus thuringiensis*
- *Beauveria bassiana*
- *Trichoderma harzianum*
- *Trichoderma lignorum*
- *Torula* dry yeast

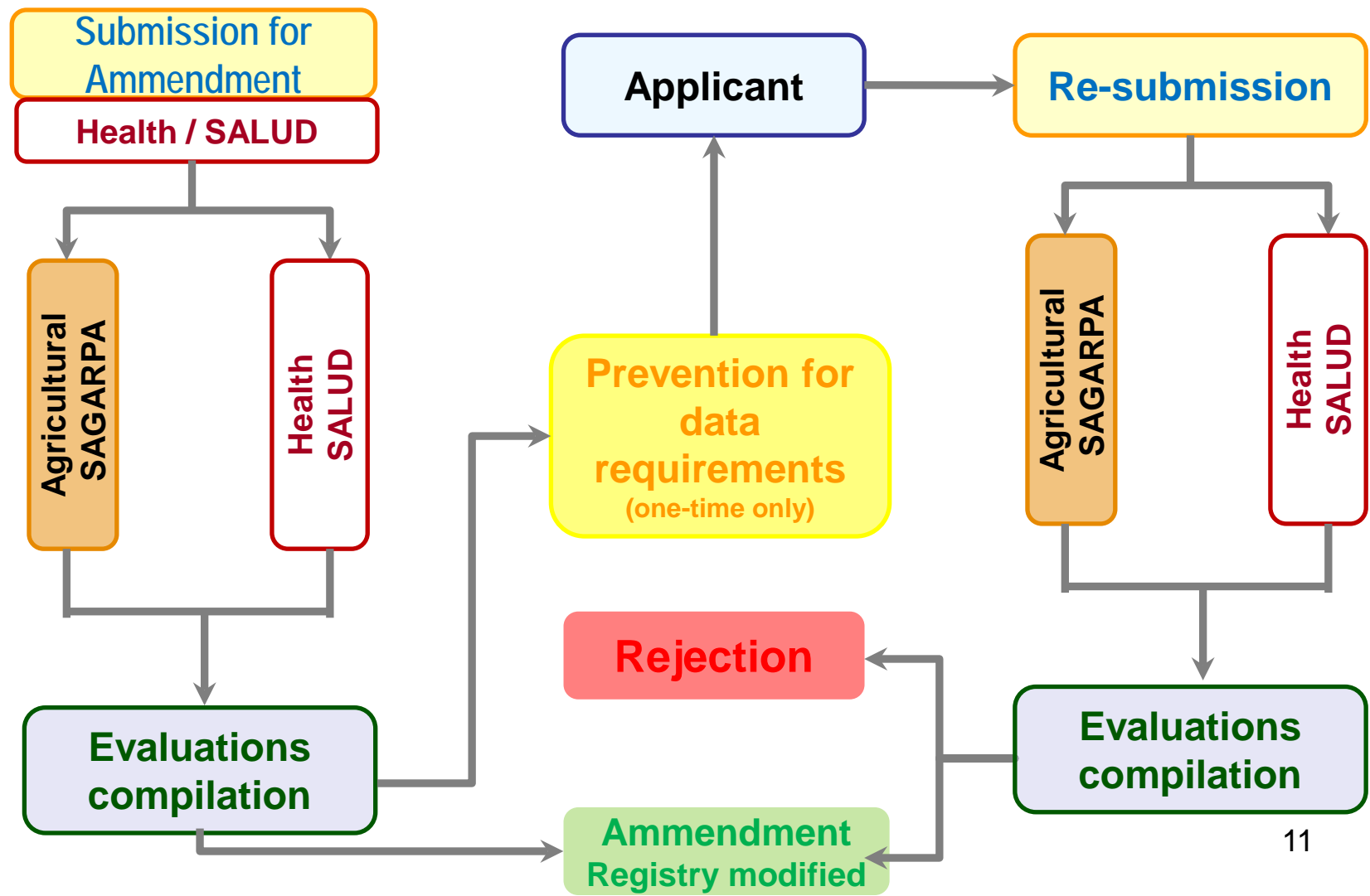


Registration process





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





GOBIERNO
FEDERAL

SALUD

Thank you

Jose Herrera-Bazan

Comisión de Evidencia y Manejo de Riesgos /
Commission of Evidence and Risk Management

Comisión Federal para la Protección contra Riesgos Sanitarios /
Federal Commission for the Protection from Sanitary Risk
Monterrey No. 33, Col. Roma, Delegación Cuauhtémoc, C.P. 06700, México, D.F.

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<http://www.cofepris.gob.mx/wb/cfp/plaguicidas02>

http://www.cofepris.gob.mx/work/sites/cfp/resources/LocalContent/931/8/4preguntas_frec_PLAGNV_261108.pdf

jjherrera@cofepris.gob.mx



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