Overview of Mexico’s Biopesticide Regulation

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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.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)
  o Floor blueprint
  o Worker training program
  o MSDS
  o Worker health surveillance program
  o Special security systems (sprinklers, smoke detectors, leakage detection alarm)
  o Technical information about production lines (raw materials, residues, process description, flow diagram, etc.)
  o Fee (Right Federal Law 2011, art. 195-K-8, $15,944.93 MXP)

• Biological efectiveness 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

<table>
<thead>
<tr>
<th>Total requirements (of which are toxicological data)</th>
<th>Current registries</th>
<th>Cost</th>
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<tbody>
<tr>
<td>Microbial</td>
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<tr>
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<td>bacteria 77</td>
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<td>fungi 13</td>
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<td></td>
<td>nematods 19</td>
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<td>Botanical</td>
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<td>19 (2)</td>
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<tr>
<td>Biochemical</td>
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<tr>
<td>12 (2)</td>
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</tbody>
</table>

Toxicological category V: $15,713 MXP

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

Submission for Registration

Agricultural SAGARPA
Environmental SEMARNAT
Health / SALUD

Applicant

Prevention for data requirements (one-time only)

Rejection

Evaluations compilation

Registry

Re-submission

Agricultural SAGARPA
Environmental SEMARNAT
Health / SALUD

Evaluations compilation
Registration's amendment (i.e. add culture use)

- Submission for Amendment
  - Health / SALUD
  - Agricultural SAGARPA
  - Health SALUD
  - Evaluations compilation

- Prevention for data requirements (one-time only)
- Rejection
- Ammendment Registry modified
- Evaluations compilation
- Re-submission
- Agricultural SAGARPA
- Health SALUD

Applicant
Thank you

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

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