



# Purpose and aim of the new Maximum Residue Limit (MRL) regulation project in Mexico

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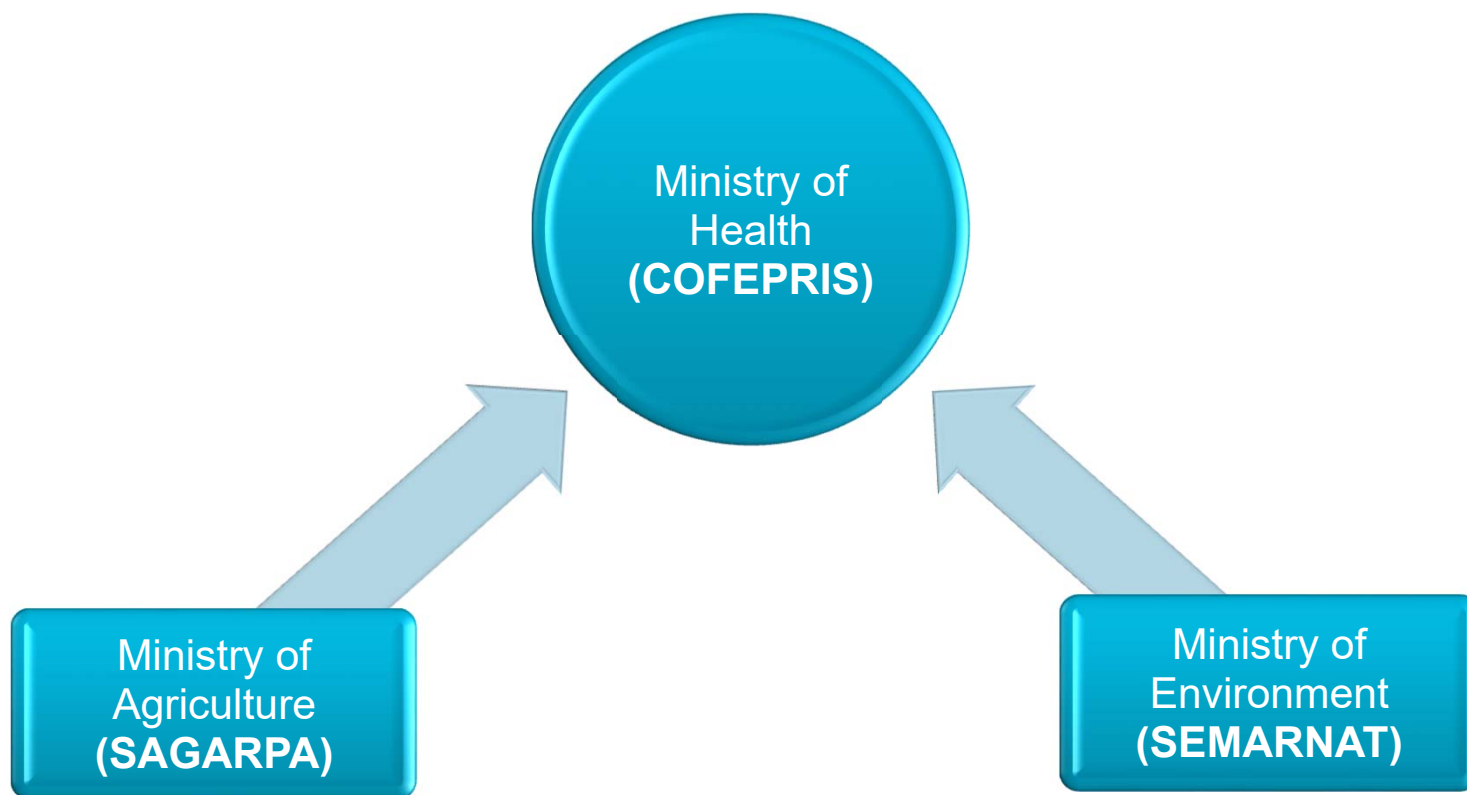
## Background

- According to the General Law of Health: “It is considered contaminated the product or raw material containing microorganisms, hormones, bacteriostatic, pesticides, radioactive particles or foreign matter as well as any other substance which exceed the permissible limits established by the Ministry of Health”.
- By the other hand, Regulation of products and services (Fruits and vegetables) declares: “Fruits and vegetables should not exceed the MRLs of pesticides, toxic substances and microorganisms established in the corresponding rules”.
- Regulation for the registration of a pesticide establishes that all submissions should include a MRL.

## Background cont.

- This MRL shall be determined in accordance with the guidelines established in the corresponding rule.
- While the MRL rule is established, COFEPRIS accepts, previous analysis, MRLs set by EPA, Codex Alimentarius, EU and Brazil.

# Authorities that participate in Mexican Regulation



## MRL Regulation Project

- SAGARPA and COFEPRIS elaborated the draft -PROY-NOM-000-SAG-FITO/SSA1-2013.
- The aim of this regulation is to establish and review of MRL's of chemical pesticides for agricultural usage for purposes of registration and use in Mexico.
- This project contains the technical guidelines and procedures for authorization of an MRL, and laboratory methods for risk analysis.
- This regulation will be mandatory for all Mexican territory and will apply to all entities.
- This regulation will enforce the agreements done in the Technical Working Group for the harmonization of MRLs and minor uses.

## Criteria to establish a MRL in Mexico

- Pesticides use for ornamentals, tobacco, soil applications (pre-seedling) and the ones applied in warehouses, vans and empty containers are exempt of this rule.
- Criteria to establish an MRL will be according to domestic regulations and considering international parameters like the ones published by FAO and WHO, through the CODEX Alimentarius, EPA, and others.
- Authorities may rely on the MRL of the following sources:

CODEX, EPA, PMRA, EU, Br, Argentina or a MRL established by a OECD country.

MRL's based on Mexican residues studies

MRL's based on residues studies of other countries

## Criteria to establish a MRL in Mexico cont.

- For all cases, the pattern of use should be similar to the one proposed on the label.
- MRLs from other sources should be valid and should match with the pesticide/crop or pesticide/crop group declared on the label.
- Regarding the local MRL, it is established through a dietary risk assessment. This assessment is based on local consumption (national data) and residue studies.

## Requirements to establish a MRL in Mexico

Requirement	Source of MRL		
	Local	EPA, EU, PMRA, Brazil or Argentina	CODEX
MRL proposed	YES	YES	YES
Local dietary risk assessment	YES	YES	YES
GLP residue studies	YES	-----	-----
Local use pattern analysis	YES	YES	-----



## Authorized MRL

- COFEPRIS will publish the approved MRLs including the pattern of use.
- Published MRL are valid for all submissions with similar pattern of use.
- Approved MRLs before this regulation will continue to be valid and will be also published by COFEPRIS.

## Situation of the MRL regulation project

- MRL regulation project was published for comments on August 2014.
- SAGARPA has received them and is working on the publication of the agreements.
- It has been identified that concept of import tolerance and the guidelines for authorization are missing in this rule.
- Government and Industry are working together in order to have a list of MRLs already approved.
- Once the new rule is finished, it comes into force 180 days after its publication in the Official Journal of the Federation.

Thanks you for your attention