Biosafety Regulations in México and the National Network for the Detection, Identification, and Quantitation of Genetically Modified Organisms (RNLD-OGM)

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Contents:
The Mexican Experience

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- National Regulatory Context:

  International environment, Mexican expertise on biosafety and current regulatory framework

  Installed capacities in México

- Experiences of GMO use and analysis.

  Responsibilities of the National Competent Authorities test labs for the detection of authorized and non authorized events.

  Taking advantage of local technical capacities for building-up the National Laboratory Network

- RNLD-OGM Current status, challenges and perspectives.

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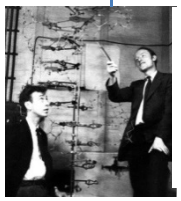
The National Regulatory Context in México

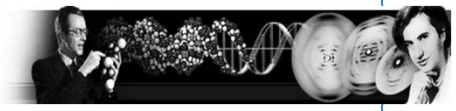
The Development of Modern Biotechnology and its Regulation

1950 1960 1970 1980 1990 2000 2010

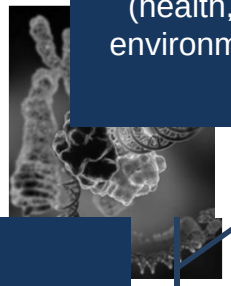
1976
NIH Guidelines for Genetic Engineering Research



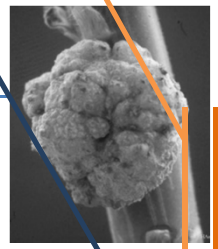
1953
DNA Structure
Watson-Crick
Wilkinson-Franklin



1990-2000
International Regulatory Frameworks began to develop intended for GMO products (health, phytosanitary and environmental risk analyses)

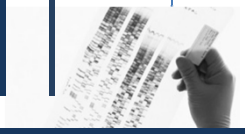


Recombinant DNA
Boyer-Cohen



1992
CBD: The International Community recognizes the importance of biotechnologies and recomends their cautiounary use for sustainable development

Genetic Improvement
Norman Borlaug
[Nobel 1970]



1998
Proposals on LMO international identification and harmonized regulation

978
grobacterium-Plant interaction
chell-Van Montagu

1980 GM mice

1988 First GM crop request for field release in México (approval 1995)

1994
Tomato FlavrSavr
FDA Approval

1995 GM Potato
(EPA Approval)

(USDA & FDA Approval)

1985-86 GM Tobacco
First transgenic plants

1995
México: Regulation Std
NOM-FITO-056-1995

2000; 2003
Cartagena Protocol on Biosafety (CPB)

1988
BT Maize

2002
Fast growth Salmon

2005
Mexican Law on Biosafety LBOGM

2003
GlowFish

Biosafety National Law

Development of the National Biosafety Framework

2000 | 2001 | 2002 | 2003 | 2004 | 2005

2000 May 24 — CPB Firm

2002 April 30 — CPB ratified

2003 Sept. 11 — CPB enters in force

2002 September
AMC presents the document : "*Basis and recommendations for the elaboration of the Mexican Law on GMO Biosafety*".

2002 November: The Senate takes AMC's proposal and presents a Law innitiative.

2005 May 4

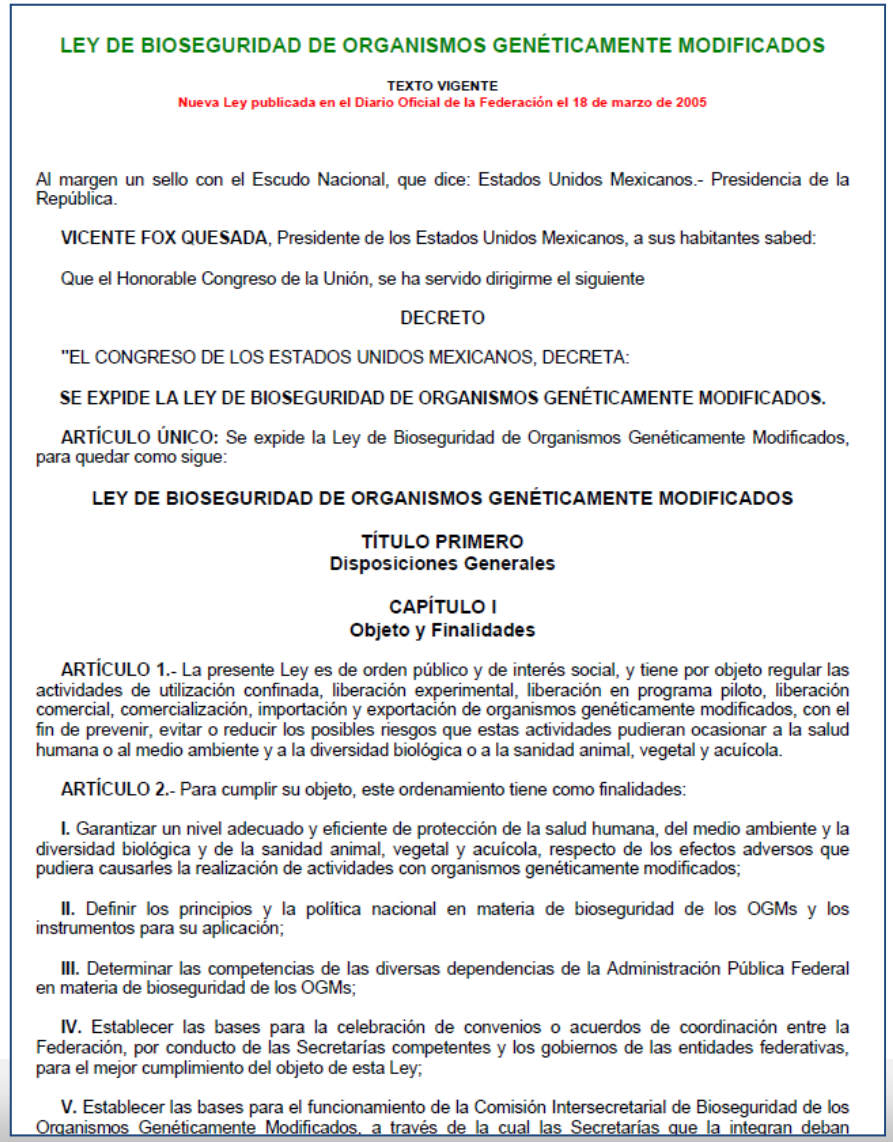
2003 Oct. 28 — CPB published at DOF

LBOGM published at DOF

2005 (March 18)

LBOGM enters in force

Biosafety Law in México



LEY DE BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS

TEXTO VIGENTE
Nueva Ley publicada en el Diario Oficial de la Federación el 18 de marzo de 2005

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República.

VICENTE FOX QUESADA, Presidente de los Estados Unidos Mexicanos, a sus habitantes sabed:

Que el Honorable Congreso de la Unión, se ha servido dirigirme el siguiente

DECRETO

"EL CONGRESO DE LOS ESTADOS UNIDOS MEXICANOS, DECRETA:

SE EXPIDE LA LEY DE BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS.

ARTÍCULO ÚNICO: Se expide la Ley de Bioseguridad de Organismos Genéticamente Modificados, para quedar como sigue:

LEY DE BIOSEGURIDAD DE ORGANISMOS GENÉTICAMENTE MODIFICADOS

TÍTULO PRIMERO
Disposiciones Generales

CAPÍTULO I
Objeto y Finalidades

ARTÍCULO 1.- La presente Ley es de orden público y de interés social, y tiene por objeto regular las actividades de utilización confinada, liberación experimental, liberación en programa piloto, liberación comercial, comercialización, importación y exportación de organismos genéticamente modificados, con el fin de prevenir, evitar o reducir los posibles riesgos que estas actividades pudieran ocasionar a la salud humana o al medio ambiente y a la diversidad biológica o a la sanidad animal, vegetal y acuícola.

ARTÍCULO 2.- Para cumplir su objeto, este ordenamiento tiene como finalidades:

I. Garantizar un nivel adecuado y eficiente de protección de la salud humana, del medio ambiente y la diversidad biológica y de la sanidad animal, vegetal y acuícola, respecto de los efectos adversos que pudiera causarles la realización de actividades con organismos genéticamente modificados;

II. Definir los principios y la política nacional en materia de bioseguridad de los OGMs y los instrumentos para su aplicación;

III. Determinar las competencias de las diversas dependencias de la Administración Pública Federal en materia de bioseguridad de los OGMs;

IV. Establecer las bases para la celebración de convenios o acuerdos de coordinación entre la Federación, por conducto de las Secretarías competentes y los gobiernos de las entidades federativas, para el mejor cumplimiento del objeto de esta Ley;

V. Establecer las bases para el funcionamiento de la Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados, a través de la cual las Secretarías que la integran deban

- Federal Law in force since 2005
- **Considers International Regulations**
- Defines national biosafety public policies
- Establishes regulatory instruments for its implementation
- Determines the attributions of Federal agencies involved
- Establishes mechanisms for communication and information
- Basis for setting national standards
- Instruments for promoting scientific and technical research
- 124 articles and 12 transitory

A Regulates Research Confined Use

B Regulates Experimental Release

C Regulates Environmental Commerical Release

D Regulates GM Product imports

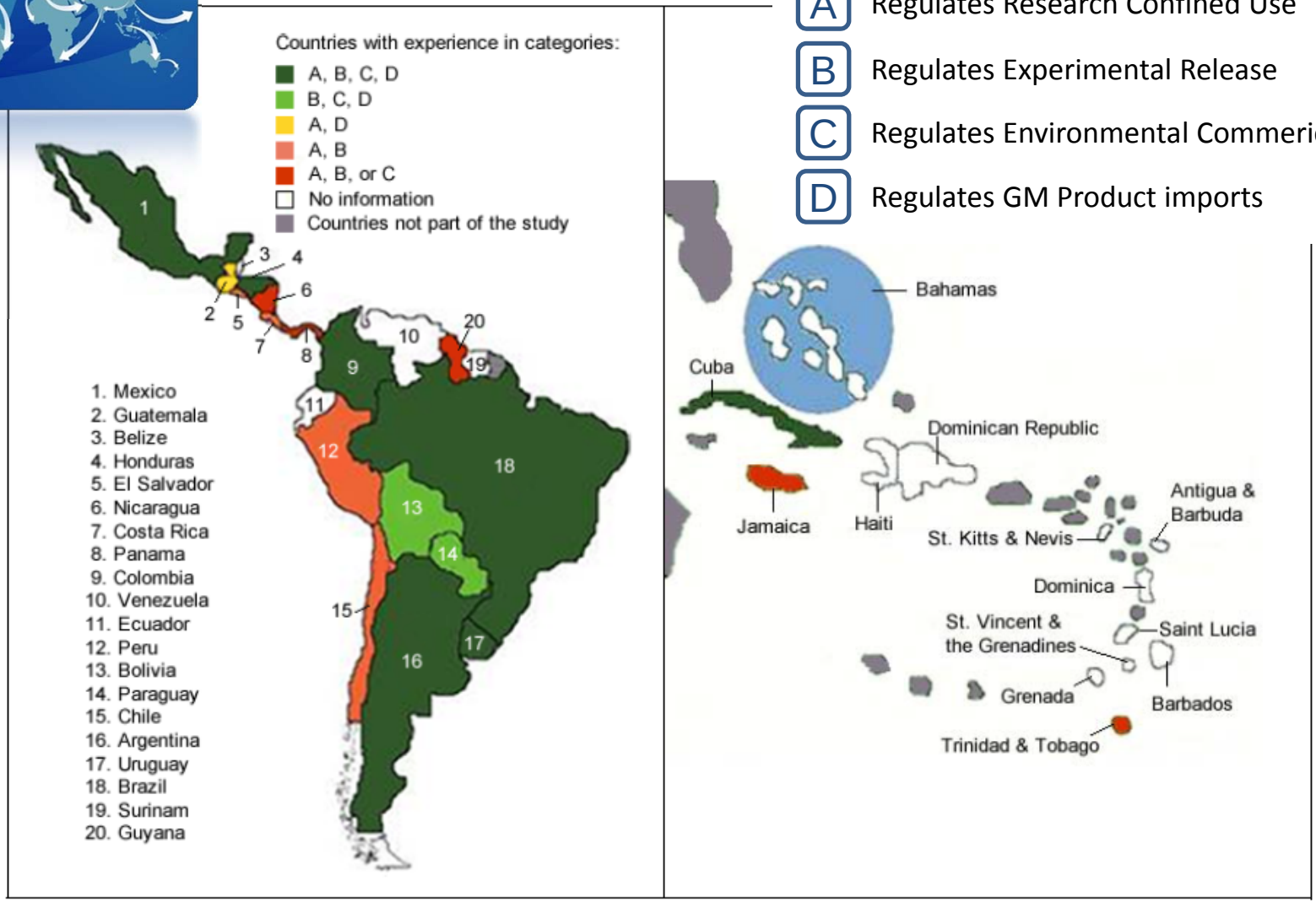


Figure 1. Biosafety regulatory experience in the LAC region according to the assessment of applications and process taken place in each country.

Note. Data compiled from: ICGEB LAC survey 2009-2011, Salazar and Montenegro (2009); USDA (2009a, 2009b); and Roca, Espinoza, and Panta (2004). Maps not to scale. Categories: A=regulating contained (laboratory & glasshouse) research; B=regulating confined field trial releases; C=regulating unconfined (commercial) releases; D=regulating the importation of GM products.

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Regulatory Instruments in México

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2005 **Federal Law on the Biosafety of Genetically Modified Organisms (LBOGM).**

2006 CIBIOGEM Reglament; modification of the Inner Reglament of National Competent Authoritie's according to LBOGM

2007 Operating Rules of CIBIOGEM

2008 **LBOGM Reglament**

2009 **LBOGM Reglament was reformed to include the special regime of maize protection (REPM) .**

Operation Rules of the Fund for Support and Promotion of Scientific and Technical reserarch on Biosafety and Biotechnology.

Operating Rules of the Mexican Network for GMO Monitoring RED-MEX-MOGMs.

2011 Unique Format for Notifications of Confined GMO Use

2012 Publication of a Centers of Origin and Genetic Diversity of Maize Agreement

Mexico Ratifies the Nagoya-Kuala Lumpur Protocol on Redress and Liability

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Mexican Biosafety Law (LBOGM)

CIBIOGEM

Article 1

The present Law is of public interest and has for an object **regulate the activities of confined use, experimental release, pilot program release, commercial release commercialization, import and export** of genetically modified organisms, with the purpose to **prevent, avoid or reduce the possible risks** that these activities might cause to **human health, environment and biological diversity, animal, vegetal and aquatic health**.

2005

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With the purpose to prevent, avoid or reduce the possible risks that activities involving GMO might cause to:

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- HUMAN HEALTH
- ANIMAL, VEGETAL AND FISH HEALTH
- ENVIRONMENT AND BIODIVERSITY

The LBOGM has the Objective of

Regulating GMO activities

- CONFINED USE
- RELEASE TO THE ENVIRONMENT
- COMERCIAL USE

- Experimental Field-trials
- Pilot Field-trials
- Comercial Release

Permits

- Imports
- Comercial use

Teaching and Research

Authorizations

Public Policy Interinstitutional Coordinating Mechanism

Health

Agriculture

Environment

SALUD
SECRETARÍA DE SALUD

SAGARPA
SECRETARÍA DE AGRICULTURA, GANADERÍA, DESARROLLO RURAL,

SEMARNAT
SECRETARÍA DE MEDIO AMBIENTE Y RECURSOS NATURALES

CONACYT

Science Council

SE
SECRETARÍA DE ECONOMÍA

SHCP
SECRETARÍA DE HACIENDA Y CRÉDITO PÚBLICO

SEP
SECRETARÍA DE EDUCACIÓN PÚBLICA

Economy

Finance

Education

CIBIOGEM

Intersecretarial Commission of Biosafety of Genetically Modified Organisms

Art 19, LBOGM

Interinstitutional Coordination

SALUD
SECRETARÍA DE SALUD

SEP
SECRETARÍA DE EDUCACIÓN PÚBLICA

SAGARPA
SECRETARÍA DE AGRICULTURA, GANADERÍA, DESARROLLO RURAL, PESCA Y ALIMENTACIÓN

SE
SECRETARÍA DE ECONOMÍA

SEMARNAT
SECRETARÍA DE MEDIO AMBIENTE Y RECURSOS NATURALES

SHCP
SECRETARÍA DE HACIENDA Y CRÉDITO PÚBLICO

Imports SHCP
Exports SE

National Competent Authorities:

GMO Destiny	Confined Use	Environmental Release	Comercialization
		Experimental Pilot Program Commercial	Human consumption Biorremediation Public Health
Legal Instrument	**NOTIFICATIONS**	**PERMITS**	**AUTHORIZATIONS**
National Competent Authority	**SAGARPA** **SEMARNAT**	**SAGARPA** **SEMARNAT**	**SALUD**

Biosafety in México

National Competent Authorities:

Ministry of Health

Ministry of Agriculture

Ministry of Environment

Decisions are sustained on the basis of risk analysis and scientific evidence, according to the use, receptor environment and GMO type.

Food and Feed consumption

AUTORIZATIONS

- **Human consumption**
- **Animal Feed**
- **Public Health**

Environmental Release

PERMITS

- **Experimental**
- **Pilot**
- **Commercial**

GMO Import and Authorizations

Since 1995, the Ministry of Health has evaluated the safety of 116 GM events, granting their import permits and authorizations for their use for human consumption and commercialization.

Cultivar	Número de solicitudes Autorizadas
Maíz (*Zea mays*)	55
Soya (*Glycine max*)	17
Jitomate (*Lycopersicum esculentum*)	3
Alfalfa (*Medicago sativa*)	2
Remolacha (*Beta vulgaris*)	1

Cultivar	Número de solicitudes Autorizadas
Algodón (*Gossypium* spp)	27
Canola (*Brassica napus*)	7
Papa (*Solanum tuberosum*)	3
Arroz (*Oryza sativa*)	1
Total	**116 Autorizaciones**

Resource: SSA, 2013

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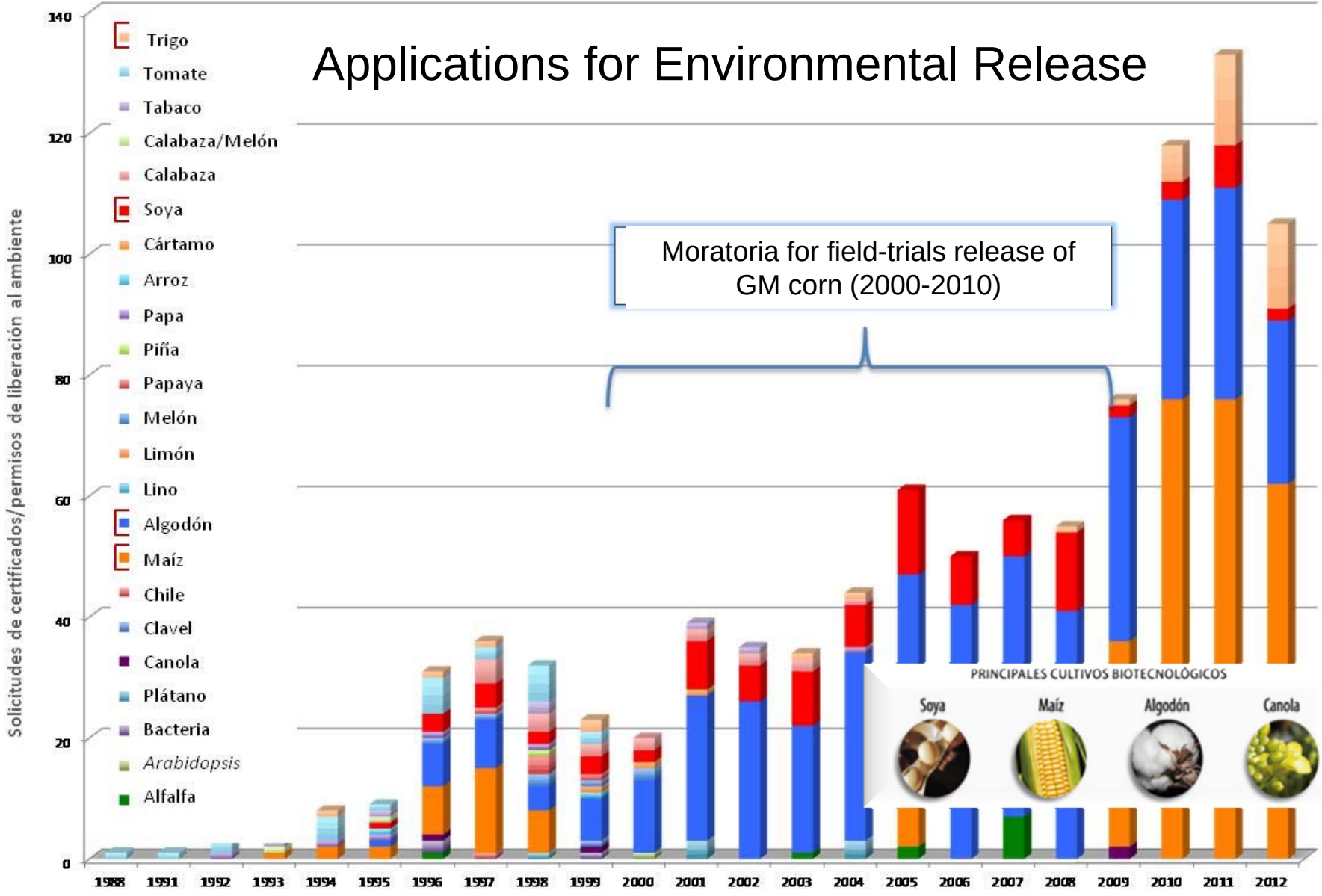
Permit Requests

Applications for Environmental Release



Article 112 Compliance to National Standards

The **application** of the Mexican Official Standards in Biosafety, as well as **inspection and surveillance measures will corrrespond eclusively to the Competent Ministries** in terms of this Law**.**

The fulfillment of such standards may be evaluated by certification organisms, verifying units or **test laboratories pproved by such Ministries** in conformity with regulatory dispositions deived from the present ordinance and with the Federal Law on Metrology and Normalization.

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Other Important Considerations

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Center of Origin and diversity of important crop species

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GM crop adoption

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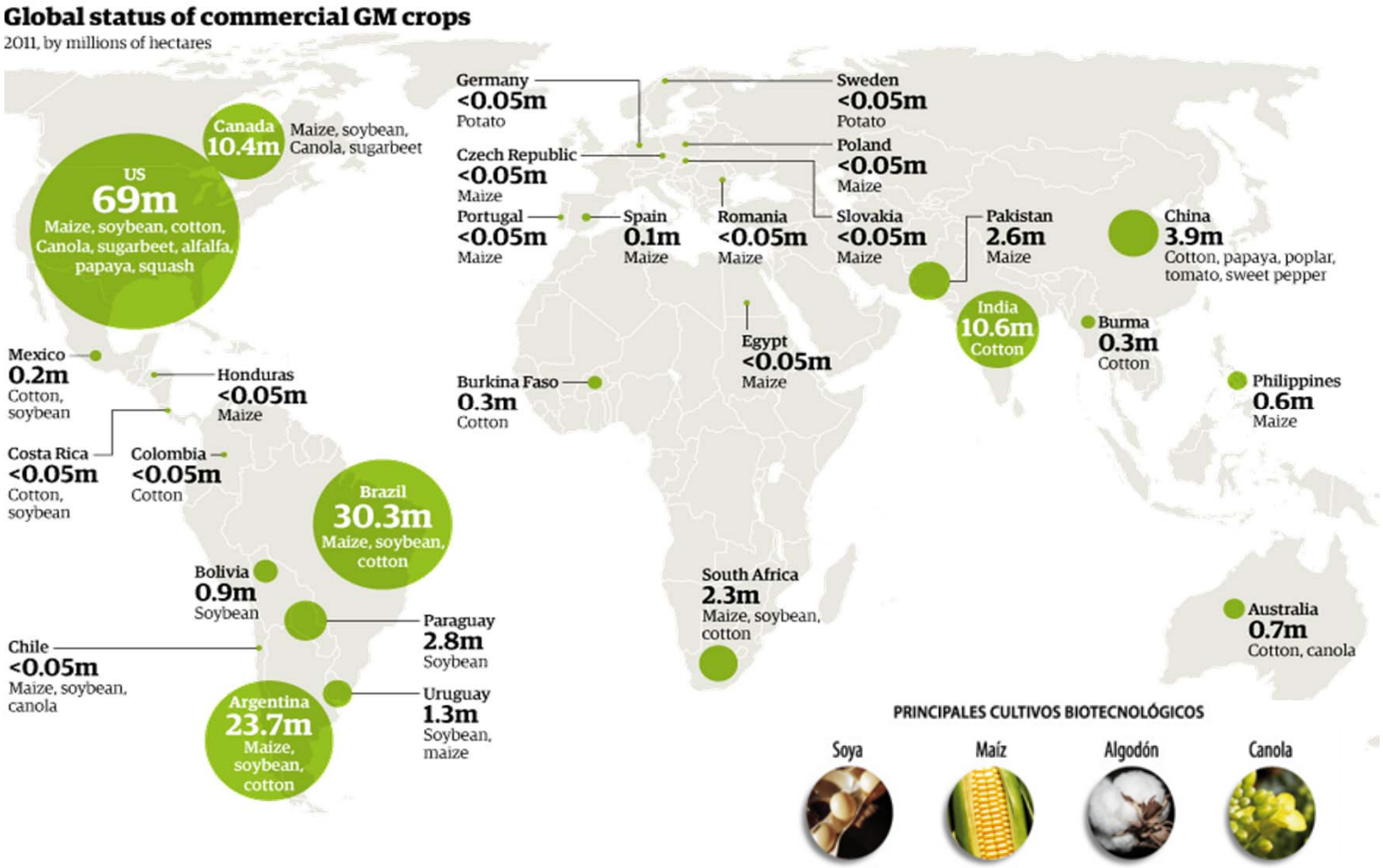

Four of the highest GMO producing countries are located in America: The United States, Brazil, Argentina and Canada, with whom MEXICO sustains active commercial trade.

Global status of Commercialized Biotech/GM Crops: 2012 (ISAAA, 2012)

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AP/LLP status

- Current legislation in Mexico has not yet established minimal tresholds for LLPs.
- CIBIOGEM and its federal agencies are working on the definition and technical aspects related to low level and adventitious presence of GMOs.
- Quality guidelines of the National Seed Certification System serve as a reference at the moment.

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National Detection, Analytical Installed Capacity and Expertise

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Capacities and Expertise

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CENICA-SEMARNAT
(Environment Ministry Test Lab)

- Operating since 2004
- First GMO Detection laboratory in the country to acquire formal Accreditation status.
- Performs Qualitative & Quantitative Analysis by PCR.
- Develops laboratory and field monitoring methods.
- Screening and Event-specific routine testing of several GM events dedicated mainly to environmental samples.
- Provides Training Courses and assistance.
- Actively participates in international proficiency testing and training (JRC, USDA-GIPSA, ISTA)

INECC
INSTITUTO NACIONAL DE ECOLOGÍA Y CAMBIO CLIMÁTICO

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Challenges for accurate GMO monitoring in the field

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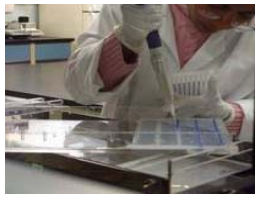
Particular Interests and on-going projects:

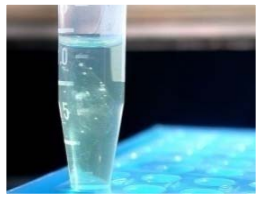
Monitoring the presence of GM events in the field and standardizing procedures for optimal performance
(conventional seed/tissue and polen sampling in several regions)

Detection **analysis of transgenes in wild relatives and local landraces**

Determinining **environmental effects** associated with GMOs

Novel strategies for emergent situations
Non-anauthorized GMO detection





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Capacities and Expertise

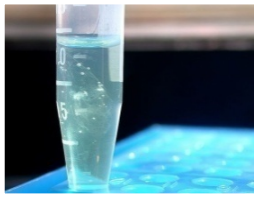
CIBIOGEM

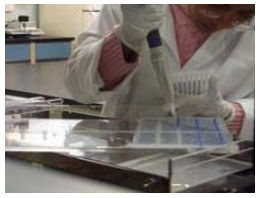
CNDROGM-SAGARPA (Agriculture Ministry Test Lab)

Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria

- National Reference laboratory for fitosanitary inspection and analyses
- High response laboratory, designed to comply fully to ISO17025
- Installed capacity to perform qualitative and quantitatie PCR, digital PCR and massive paralel sequencing analysis.
- Validates monitoring and inspection activities that observe field-release biosafety compliance measures.
- Provides specialized training and assistance to a wide range of users
- Collaborative development of Reference Materials (Flour and Plasmids).

Method Performance and Suitable Reference Material





Particular Interests and working projects:

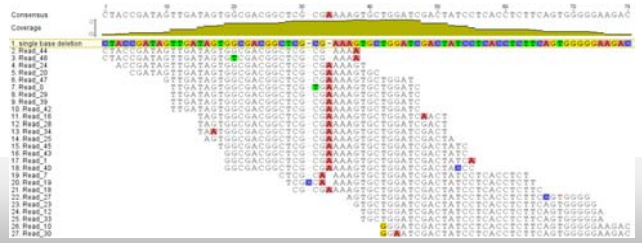
Method verification to fit our national regulatory context and demands as well as preparation of sampling guidelines.

Validation of **digital PCR methods** for absolute GMO quantitation.

Development of reference materials with higher concentration than commercially available MRCs.

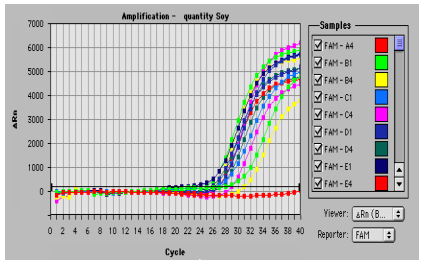
Plasmidic reference materials for easy sharing within network collaborations.

Massive paralel sequencing analysis and bioinformatics.



Capacities and Expertise

Comisión Federal para la Protección contra Riesgos Sanitarios



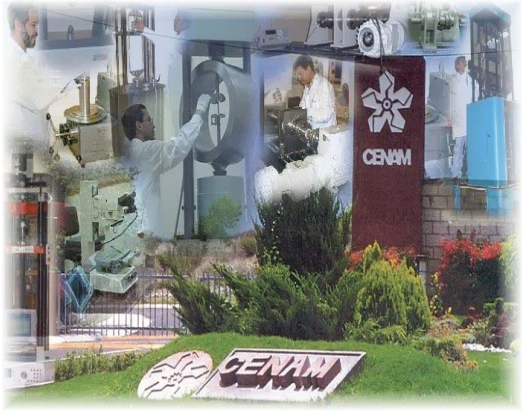
CCAyAC-SALUD
Health Ministry Reference laboratory

- Accredited laboratory in charge of sanitary risk analyses.
- Capacity for qualitative and quantitative analysis (ELISA, PCR and RT-PCR).
- Experience in molecular methods and analytical procedures for all types of food matrices.
- Adequate performance participating on collaborative studies.

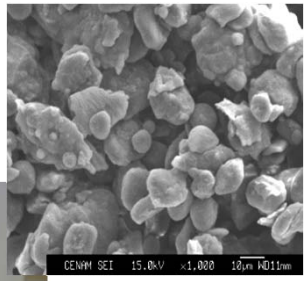
Capacities and Expertise

CENAM-SE
(National Metrology Laboratory)

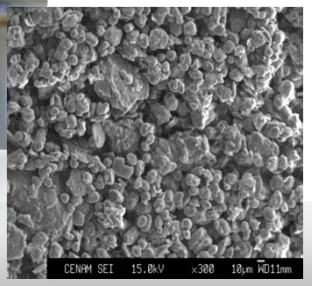
- National laboratory in charge of metrology and measuring refrence. Responsible for validating and developing all standards, methods and analytical measurement protocols in the country.
- Development, characterization, certification and preparation of Reference materials in several matrices of relevance in Mexico.
- Preparation of guidelines, method validation and harmonization guidelines.
- Uncertainty measurement and statistical support.
- Technical coordinator of collaborative studies.
- Capacity to perform quantitative PCR and digital PCR analysis.



DMR 436 Ia

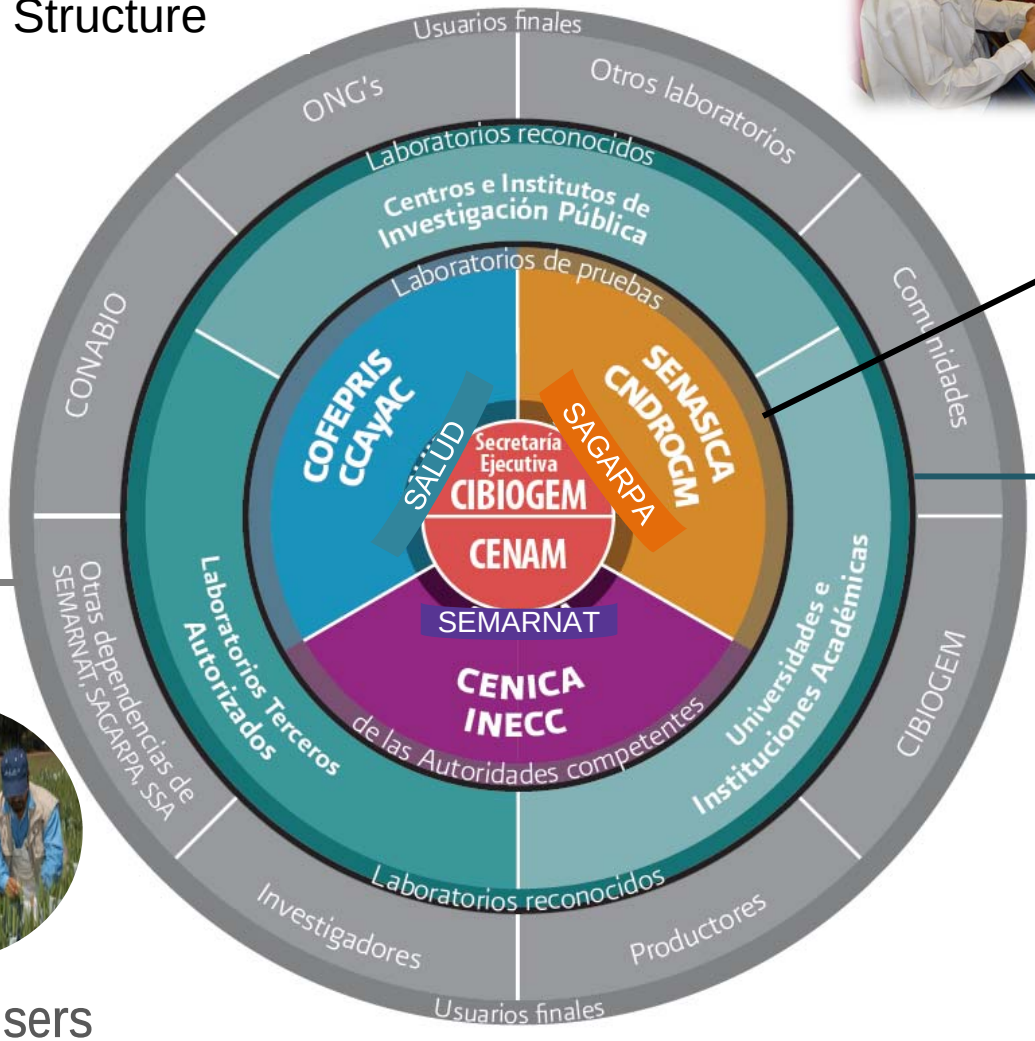


DMR 436 IIa



RNLD-OGM Network

RNLD-OGM Structure



Central Node
From the Competent Authoritie's reference laboratories.

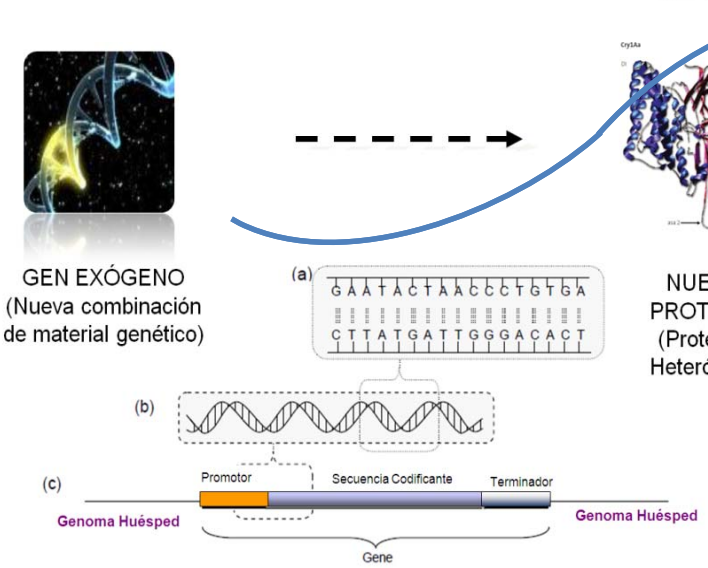
Network Laboratories
from Universities or Public Research Centers with demonstrated proficiency.

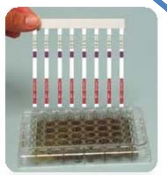
Final Users

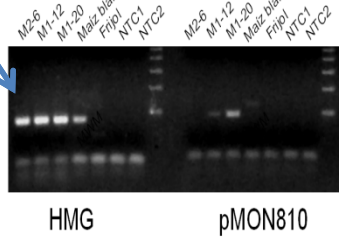
RNLD-OGM Network

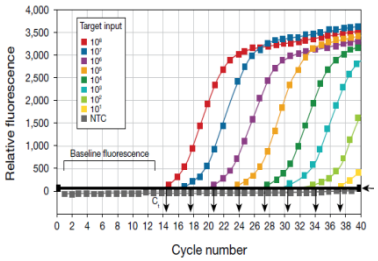
2008-2009 2009-2010 2010-2012

RNLD Proficiency Testing Scheme









The National Collaborative Essays allowed for:

a. A Technical diagnosis of the real lab capacities
b. Local proficiency testing protocols
c. Harmonization of Analytical Procedures
d. Reference Materials and Method Verification
e. Rich Technical and Scientific Exchange

National Laboratory Network for the Detection, Identification and Quantitation of GMOs (RNLD-OGM)

www. cibiogem.gob.mx

renalabmex@conacyt.mx

RNLD-OGM Network

- Formally recognized in 2012, the Network integrates experts and specialists on detection quantitation and identificacion of GMOs. Its members that have tested their proficiency and demonstrated analytical competence at high laboratory standards.

- The RNLD-GMO is regarded as a scientific and technical mechanism that can act as technical support as required:

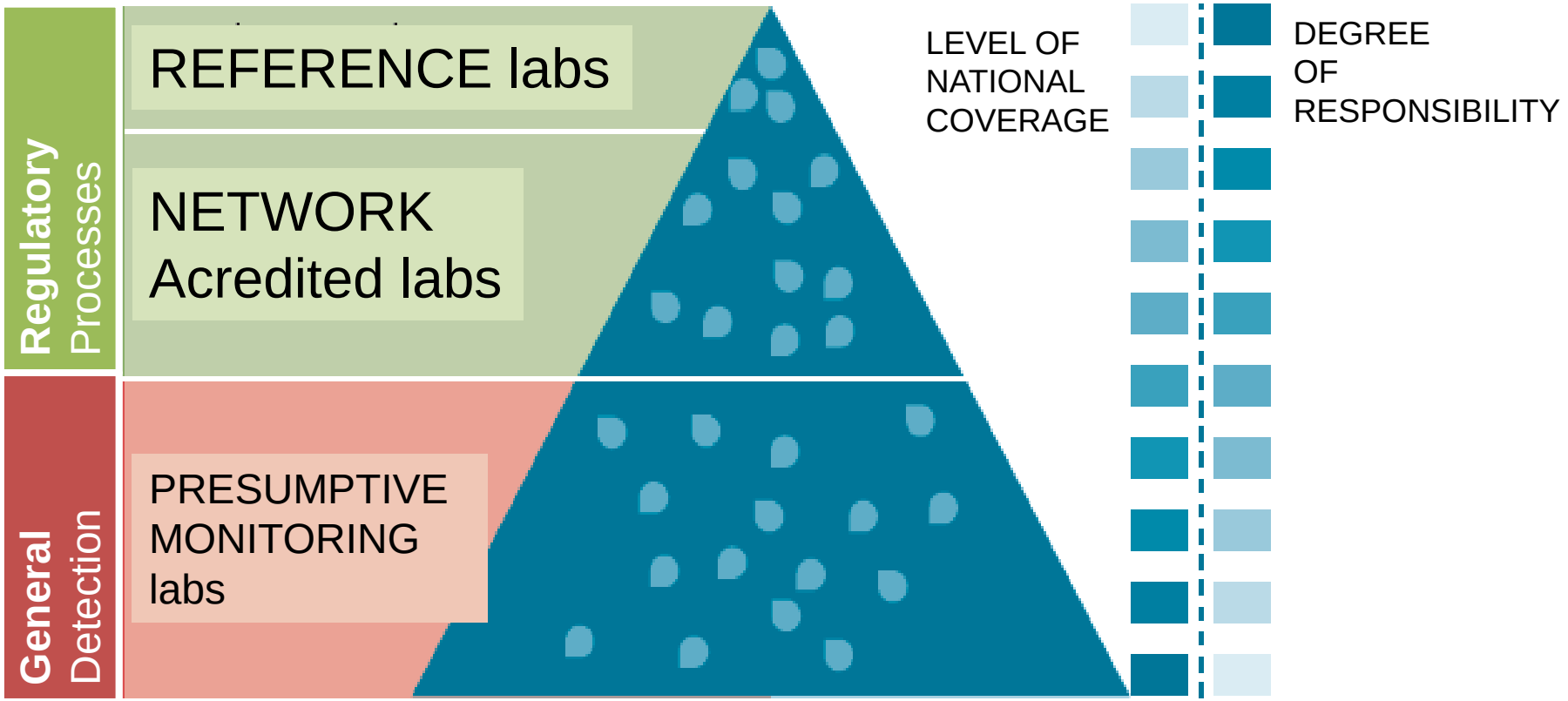
  - Metod validation according to international standards
  - Research and development of novel strategies

- The laboratories are taking part of international proficiency testing in order to enhance their capacities and validate the quality and reliability of their preformance.

- RNLD-OGM also collaborates, by means of its members in consolidating the regional innitiative for a Latin- America and the Caribeean Laboratory Network (RLAC-OGM).

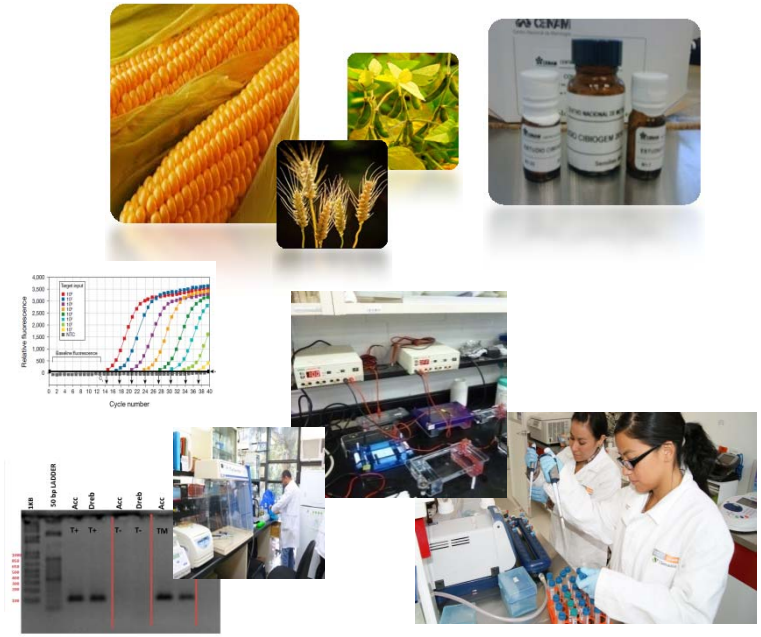
RNLD-OGM Network

Network Concept



PCB Strategic Plan

Capacity Building



Art. 22-CPB

Support and training for enhancing capacity of qualified human resources and institutional development

Conscience and Public Participation

http://www.cibiogem.gob.mx/

Art. 23-PCB

Promote conscience, education and public participation, including access to GMO and biosafety information.

SPECIFIC Objectives

1. **Promote the integration and coordination within national labs.** Enhance GMO detection and analytical capacities in the country by means of participative collaboration amongst specialists in the area.

2. **Support and strengthen the use of harmonized and validated methodologies for GMO analysis**, with the purpose that laboratories produce reliable and accurate results.

3. **Allow for scientific discussions amongst specialists** that are part of the RNLD network, creating a suitable environment for information exchange, addressing emergent topics on biosafety and GMO analysis.

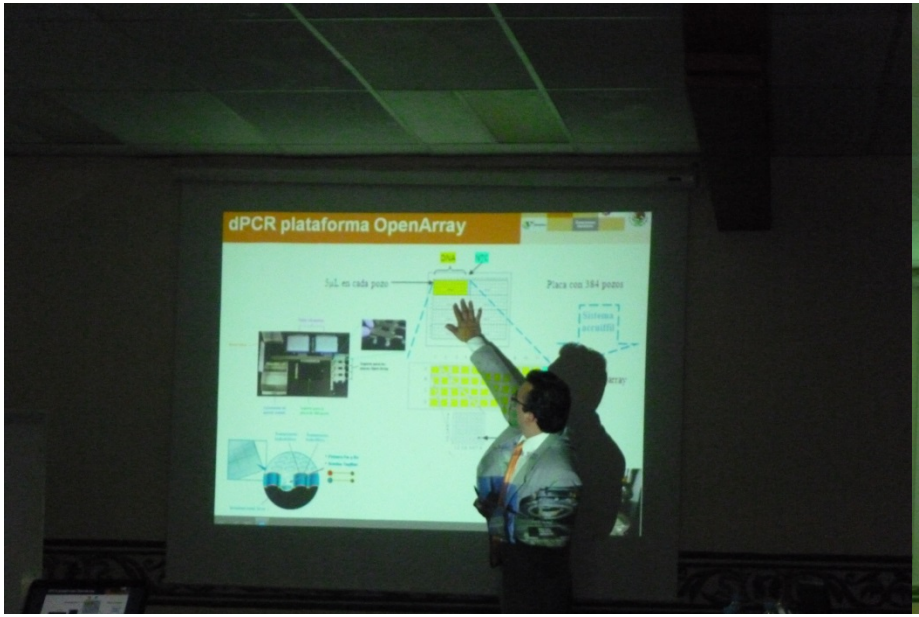
4. **Bring an excellent service on detection, identification and quantitation of GMOs**, as well as the necessary scientific support to the users of the network.

RED NACIONAL DE LABORATORIOS DE DETECCIÓN, IDENTIFICACIÓN Y CUANTIFICACIÓN DE ORGANISMOS GENÉTICAMENTE MODIFICADOS

SECOND INFORMATIVE MEETING , Feb 2011

National Collaborative Study for Validating Methodologies and Protocolos of Detection, Identification and Quantitation of GMOs

VISIT TO THE METROLOGY LABORATORY FACILITIES, CENAM March 2012



EXPERIENCE EXCHANGE AND REVISION OF TECHNICAL RESULTS,
Third National Collaborative Study, Sept 2012

TECHNICAL EXPERT MEETING [CENAM SAGARPA], Sept 2012
D4 Project: Soy, Weath & Maize Reference Material Certification

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RNLD-OGM Network

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General Challenges

- Availability of Reference Materials
- Detection protocols for wild relatives and local landraces
- Transit and import commodities used as seeds
- Import study-GM material

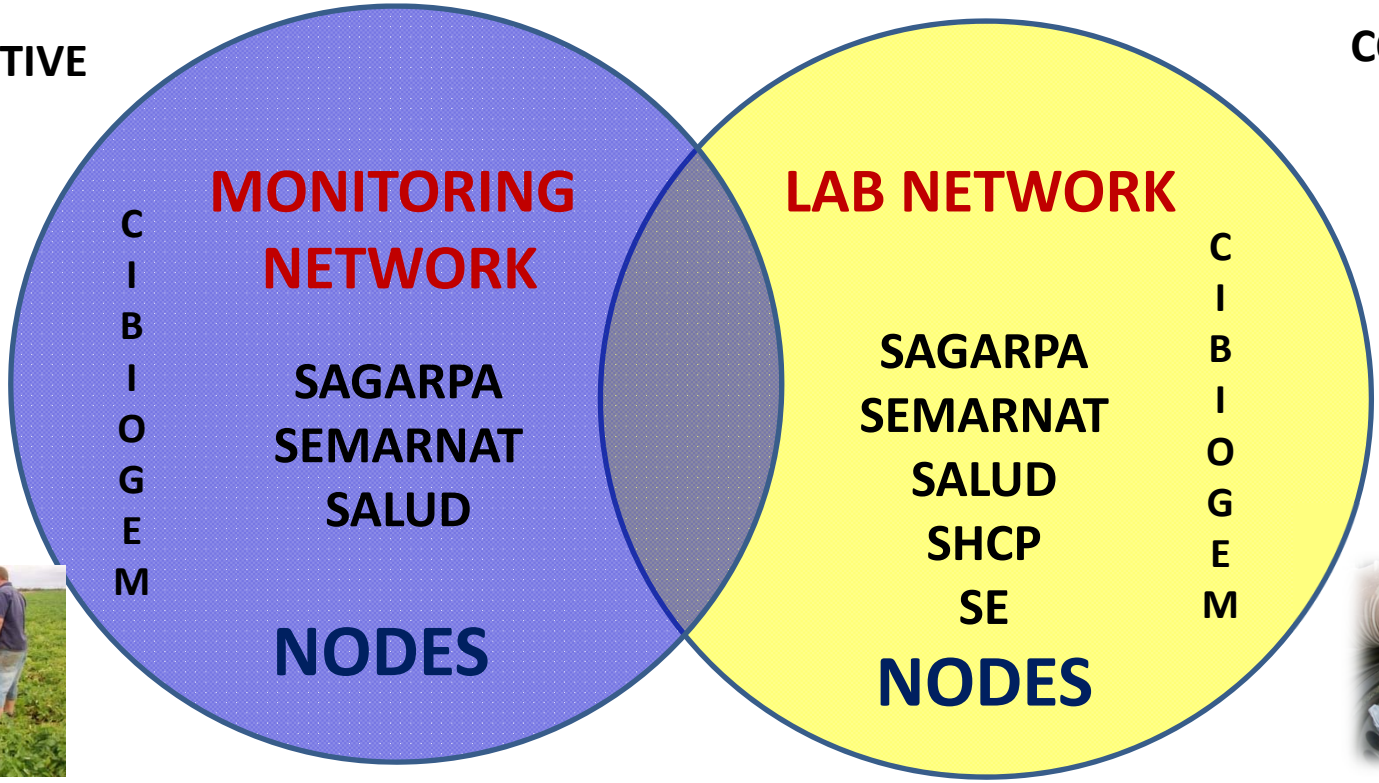
Network Challenges

- Differential capacities = different needs
- Continuous Training and experience exchange
- Infrastructure improvement
- Limited Human Resources

Interaction of Biosafety GMO Networks in México

PRESUMPTIVE

CONCLUSIVE



Effects derived from GMO use :

- environmental,
- biological diversity
- human health, vegetal and auatic.
- socioeconómic effects.

Presumptive Identificaction of GMO presence/absence.

Final Identification of the presence, type and quantity of GM material with aims to:

- Support monitoring activities
- Assist inspection and surveillance activities
- Evaluate control, mitigaiton and management measures
- Support reliable data for legal procedures and sanctions

Latin America & Caribeean Network (RLAC-OGM)

3rd International Workshop on Harmonisation of GMO Detection and Analysis for Central and South America

Cartagena, Colombia 4-5-May 2012

Recommendations

- Provide Relevant Training Courses and Capacity Building Activities.
- Maintain periodic communication and relevant information exchange among players.
- Promote continuous participation in National and International Proficiency Testings.
- Facilitate the identification of common problems and Technical collaboration opportunities.
- Effective interaction with the Monitoring Networks (Eg. RED MEX-MOGM) for the standarization of methods of GM detection and effects that might be associated with GMOs in environment.

www.cibiogem.gob.mx/redes/RNLD-OGM

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Special Thanks to RNLD-GMO

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LABORATORIO DE BIOLOGÍA MOLECULAR, Centro Nacional de Investigación y Capacitación Ambiental, Instituto Nacional de Ecología y Cambio Climático (CENICA, INECC-SEMARNAT)


CENTRO NACIONAL DE REFERENCIA EN DETECCIÓN DE ORGANISMOS GENÉTICAMENTE MODIFICADOS, Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA), SAGARPA


SEGUNDA SESIÓN INFORMATIVA, Febrero 2013
Estudio Nacional Colaborativo para la [illegible] de Metodologías y Protocolos de Detección, Identificación y Cuantificación de Organismos Genéticamente Modificados


LABORATORIO DE GENÉTICA MOLECULAR DEL DESARROLLO SEXUAL Y ASEXUAL, CINVESTAV Unidad Irapuato


LABORATORIO DE INTERACCIÓN MOLECULAR PLANTA MICROORGANISMO, Centro de Biotecnología Genómica, IPN Reynosa

LABORATORIO DE DIAGNÓSTICO MOLECULAR, Dirección General de la Comisión de Recursos Naturales, Secretaría del Medio Ambiente, GDF.


LABORATORIO DE BIOTECNOLOGÍA AGRÍCOLA, CINVESTAV Unidad Saltillo

LABORATORIO DE BIOLOGÍA MOLECULAR Y CULTIVO DE TEJIDOS VEGETALES, Universidad de Colima.


CICY
GRUPO DE ESTUDIOS MOLECULARES APLICADOS A LA BIOLOGÍA, Centro de Investigaciones Científicas de Yucatán.


LABORATORIO 4, Instituto de Biotecnología, Facultad de Ciencias Biológicas, Universidad Autónoma de Nuevo León.


RED NACIONAL DE LABORATORIOS DE DETECCIÓN, IDENTIFICACIÓN Y CUANTIFICACIÓN DE ORGANISMOS GENÉTICAMENTE MODIFICADOS


LABORATORIO DE BIOTECNOLOGÍA, Facultad de Química, Universidad Nacional Autónoma de México.

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Muchas Gracias!

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