



**Comisión Intersecretarial de Bioseguridad de los
Organismos Genéticamente Modificados**

Towards a National Laboratory Network for Detection and Analysis of GMOs: The Mexican Experience



Inter-Ministerial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM), México.

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Executive Secretariat, CIBIOGEM

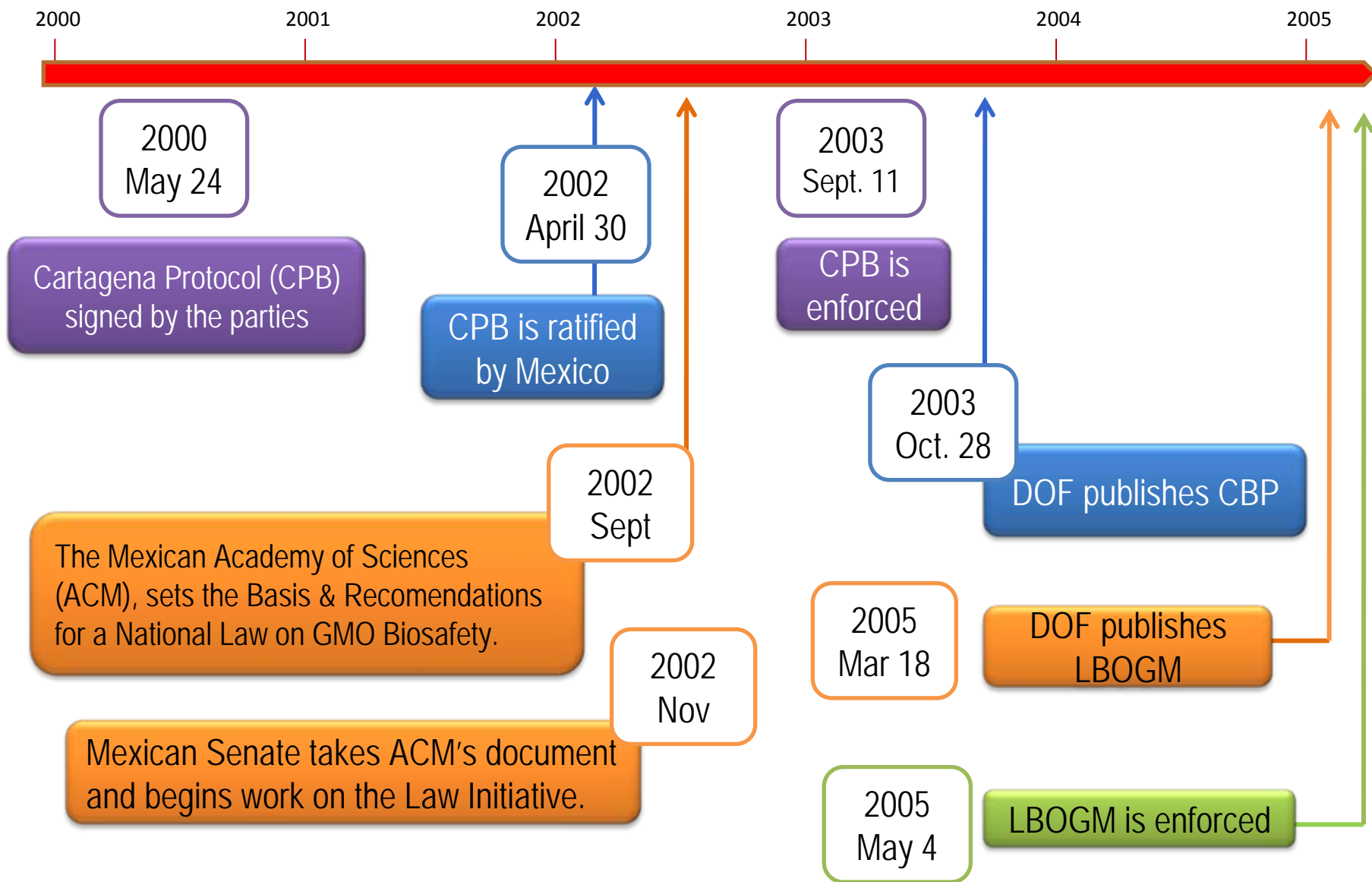
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Overview



- Legal Aspects
 - Regulatory background in Mexico
 - The necessity of a Laboratory Network
- Network Conceptualization
- Progress on the establishment of the Mexican Laboratory Network for D&A of GMOs and perspectives





Law on the Biosafety of Genetically Modified Organisms

Main Purpose:

Regulate the activities of confined usage, experimental release, release within a pilot program, commercial release, trading, importation and exportation of GMOs in order to prevent, avoid or reduce the possible risks that these activities might entail to human health, environment, biological diversity, or on the health of animals, plants and aquatic organisms.

**Ley de Bioseguridad de Organismos
Genéticamente Modificados (LBOGM), 2005**



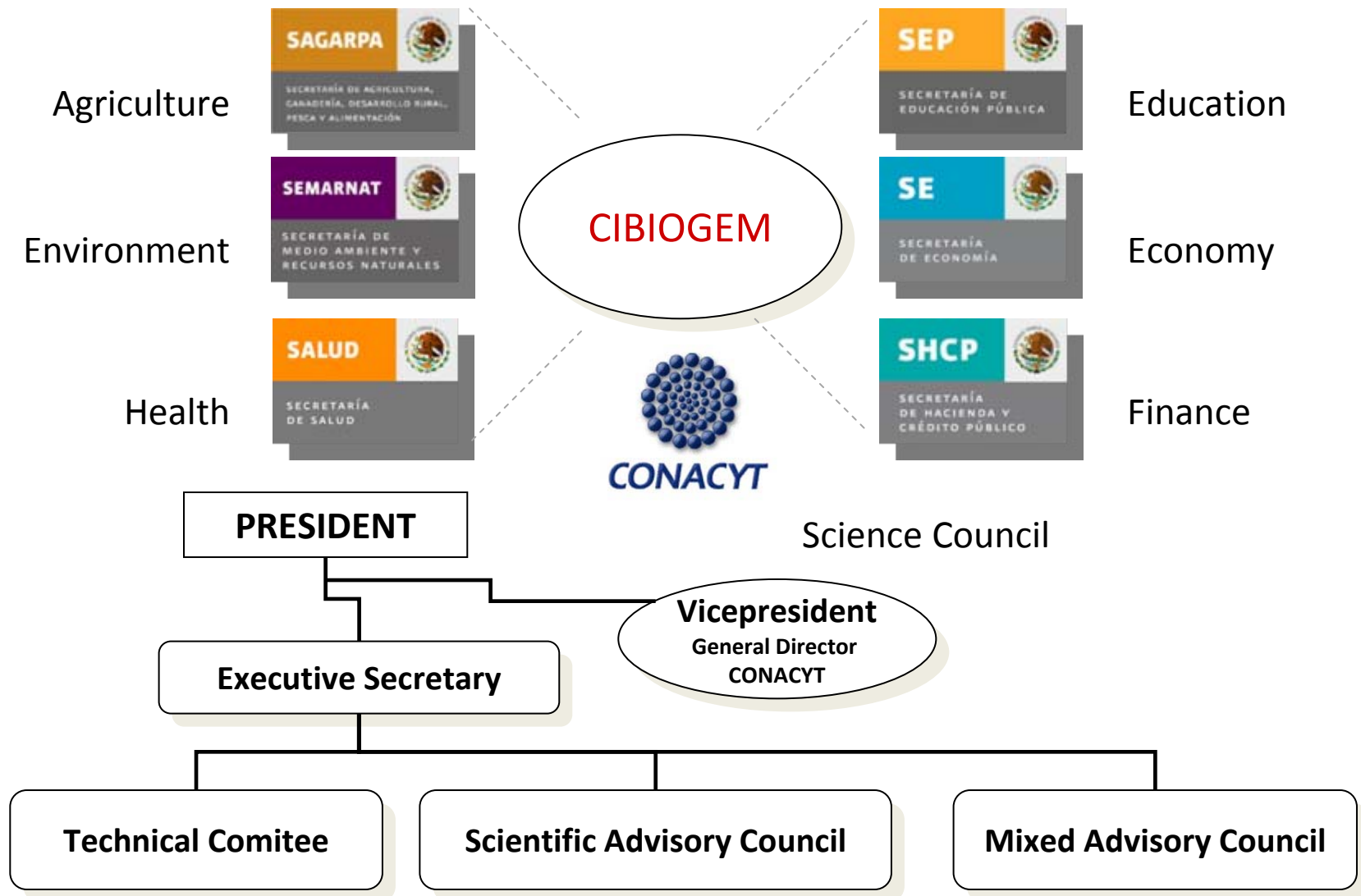
Law on the Biosafety of Genetically Modified Organisms

Article 19:

The Inter-Ministerial Commission on Biosafety of GMOs will be the entity in charge to coordinate all federal public policies on Biosafety and GMO-activities in México.

**Ley de Bioseguridad de Organismos
Genéticamente Modificados (LBOGM), 2005**

The Inter Ministerial Commission: CIBIOGEM





Agreements reached by CIBIOGEM



CIBIOGEM/ORD/02/2008-08 La Comisión instruye a la Secretaría Ejecutiva para que coordine los trabajos de las Instancias que conforman la CIBIOGEM, para que a su vez en coordinación con el Centro Nacional de Metrología, se lleven a cabo las gestiones necesarias para el establecimiento y mantenimiento de un Laboratorio Nacional de Referencia que coadyuve en la detección, identificación y cuantificación de OGMs, así como a promover el desarrollo de metodologías armonizadas y protocolos para la identificación y detección OGMs.

CIBIOGEM/ORD/02/2008-09 La Comisión instruye a la Secretaría Ejecutiva, a efecto de que coordine a las instancias que conforman la CIBIOGEM, para que se lleven a cabo las gestiones necesarias para el establecimiento de una Red de Laboratorios de Detección, Identificación y Cuantificación de Eventos de Transformación de OGMs.

Environment and
Biological Diversity

Animal, Plant and Aquatic
Organisms Health

Human Health

1. To support activities for GMO monitoring.
2. To support Inspection and Surveillance activities:

Confined use: Check up confinement conditions

Commercialisation: Verify compliance with authorised events.

Survey intentional and non authorized environmental release.

Evaluate proper control and handling of GM material as well as mitigation measures,

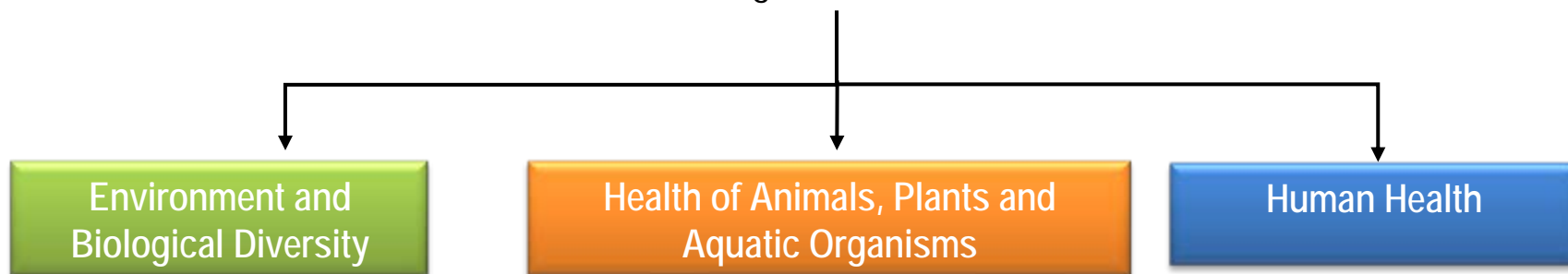
Provide support to legal actions and if necessary sustain administrative sanctions.

Confined use

Environmental Release

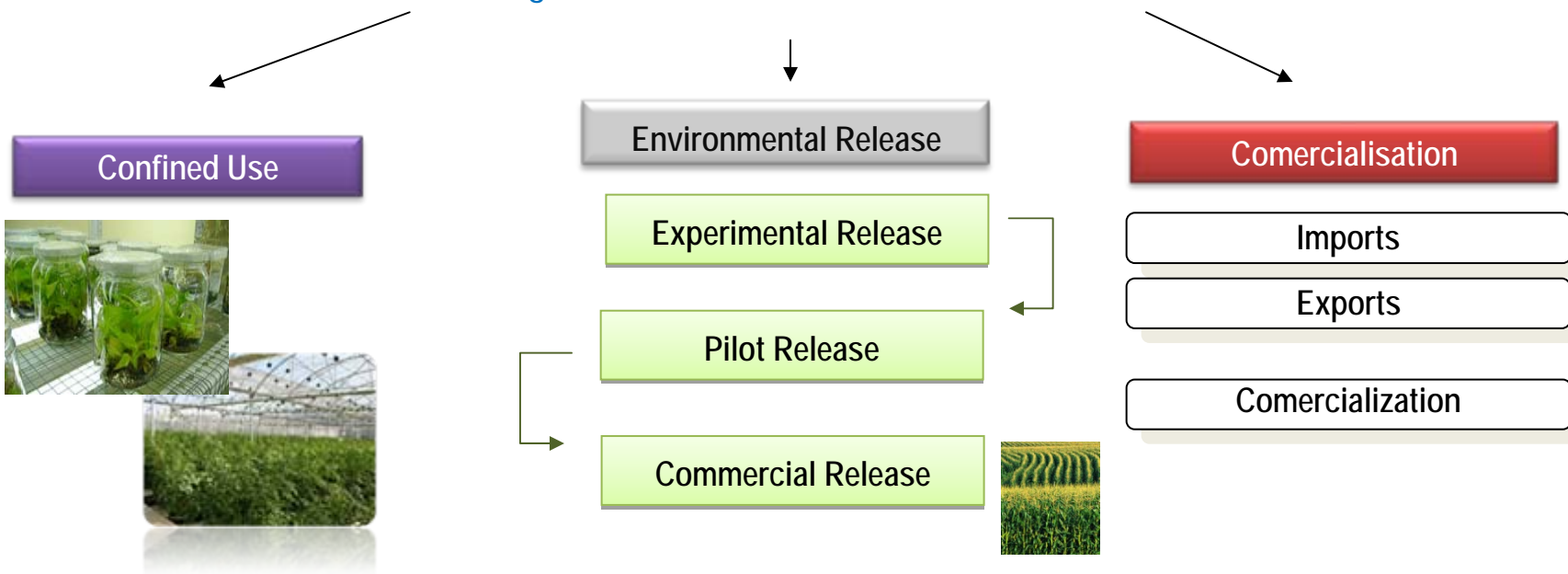
Comercialisation

Prevent, avoid or reduce possible risks that activities with GMOs might entail on:



Purpose of LBOGM

Regulate activities that involve GMOs





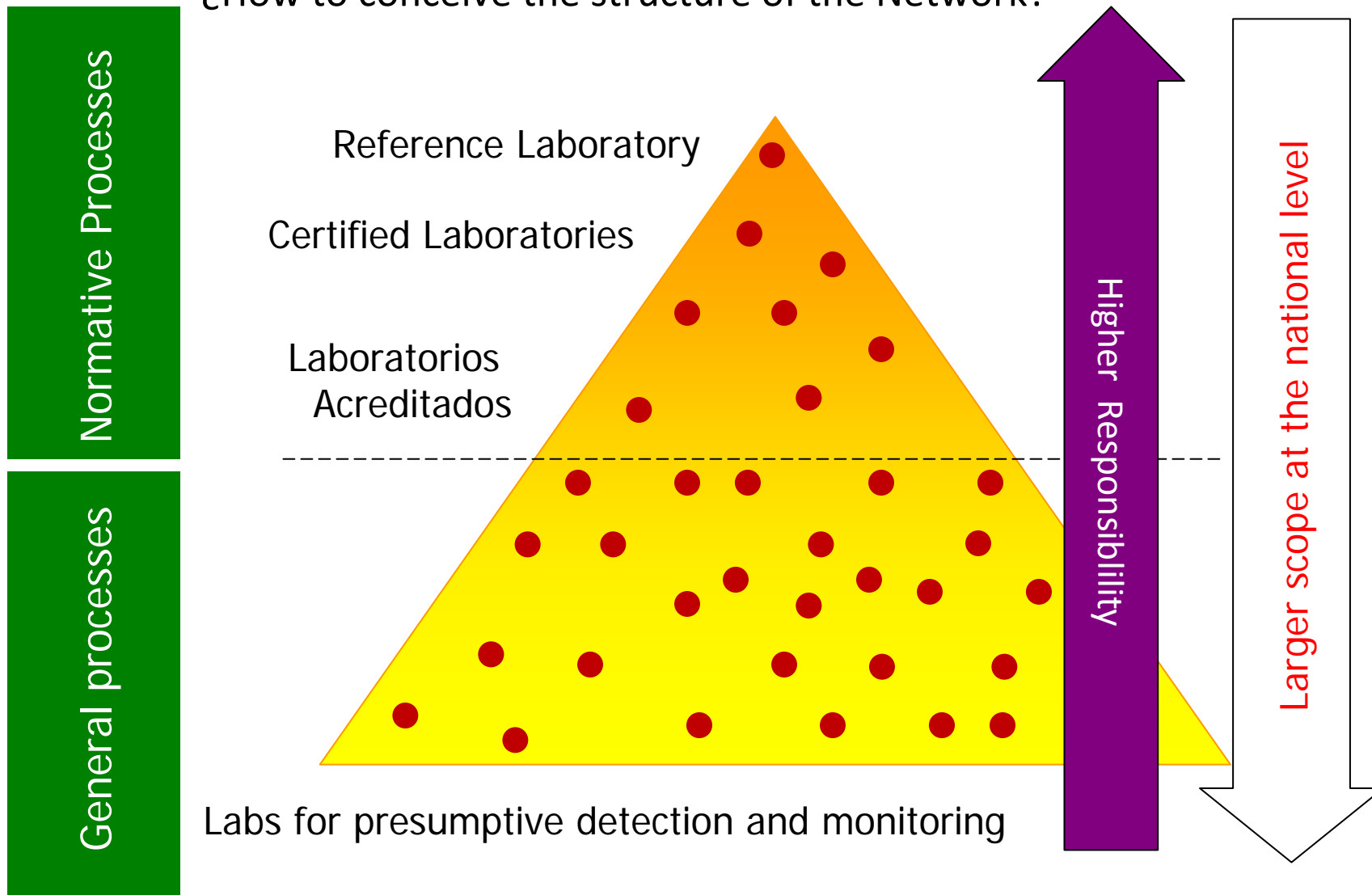
Network Conceptualization

LBOGM - Article 112

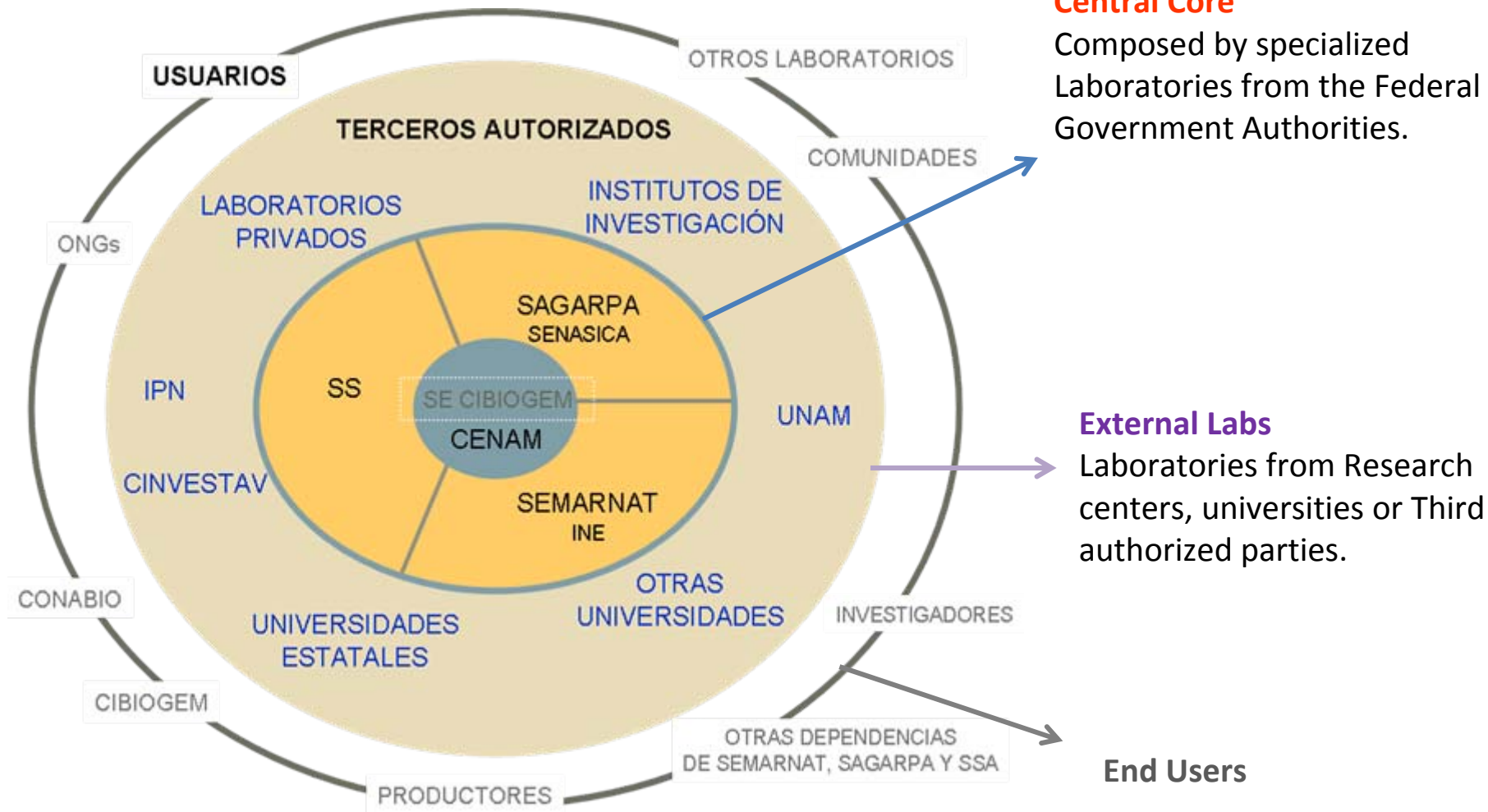
The application of the Mexican Official Norms in the matter of biosafety, as well as **inspection and surveillance measures will correspond exclusively to the competent Ministries** in the terms of this Law. **The fulfillment of such norms may be evaluated by** certification organisms, verifying units **or test laboratories approved by such Ministries** in conformity with the regulatory dispositions derived from the present ordinance and with the Federal Law on Metrology and Normalization.

Network Concept: Laboratories with different capacities

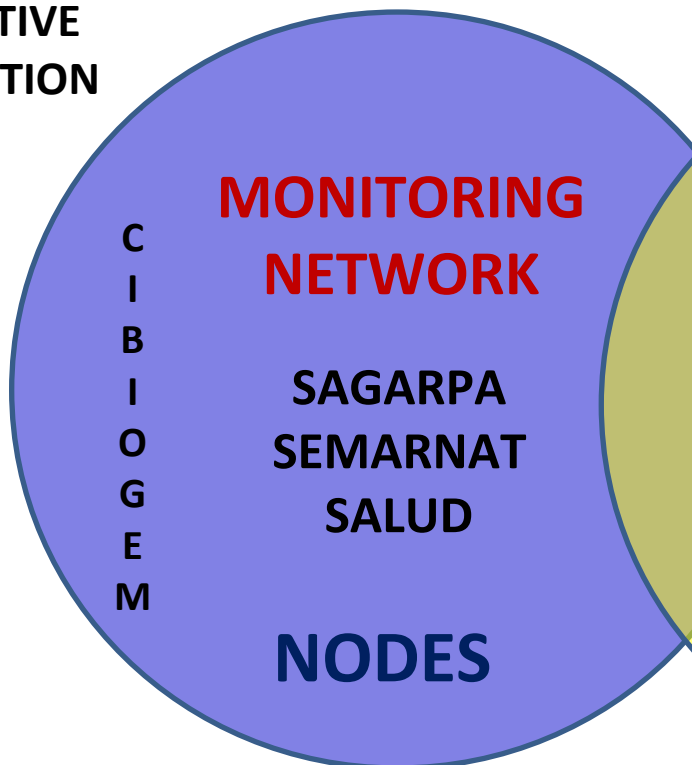
¿How to conceive the structure of the Network?



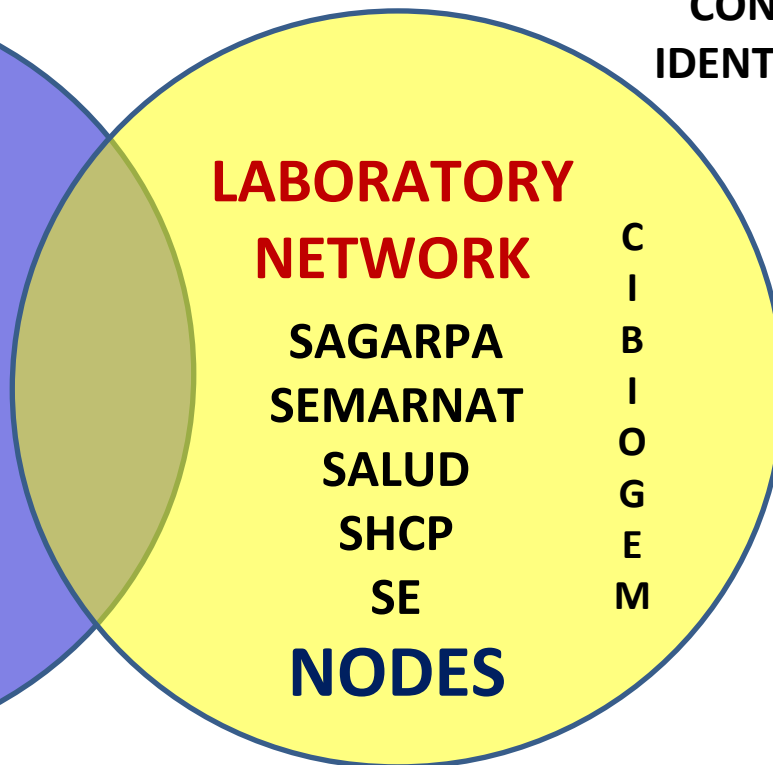
Proposed Structure Lab Network



**PRESUMPTIVE
IDENTIFICATION**



**CONCLUSIVE
IDENTIFICATION**



Monitoring of effects derived from GMO use :

- to the environment,
- to biological diversity
- effects on human, plants, animals and aquatic animal health.
- socioeconomical impact

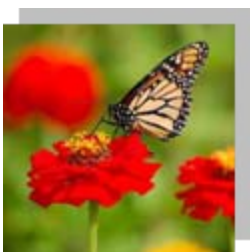
Presumptive identification of the presence or absence of GMOs

Conclusive Identification of the presence, type and amount of GM material with the purpose of:

- Support GM Monitoring Activities
- Assist Inspection and Surveillance activities
- Evaluate control, handling and mitigation procedures
- Sustain legal actions and sanctions

Red Mexicana de Monitoreo de Organismos Genéticamente Modificados

<http://www.cibiogem.gob.mx/RedMexOGMs>



Artículo 9, Fracción V, X, XVI LBOGM

Officially installed on: 23 june 2009



Establishing the Lab Network

Establishment Committee

Committee for the Establishment of the Mexican Laboratory Network

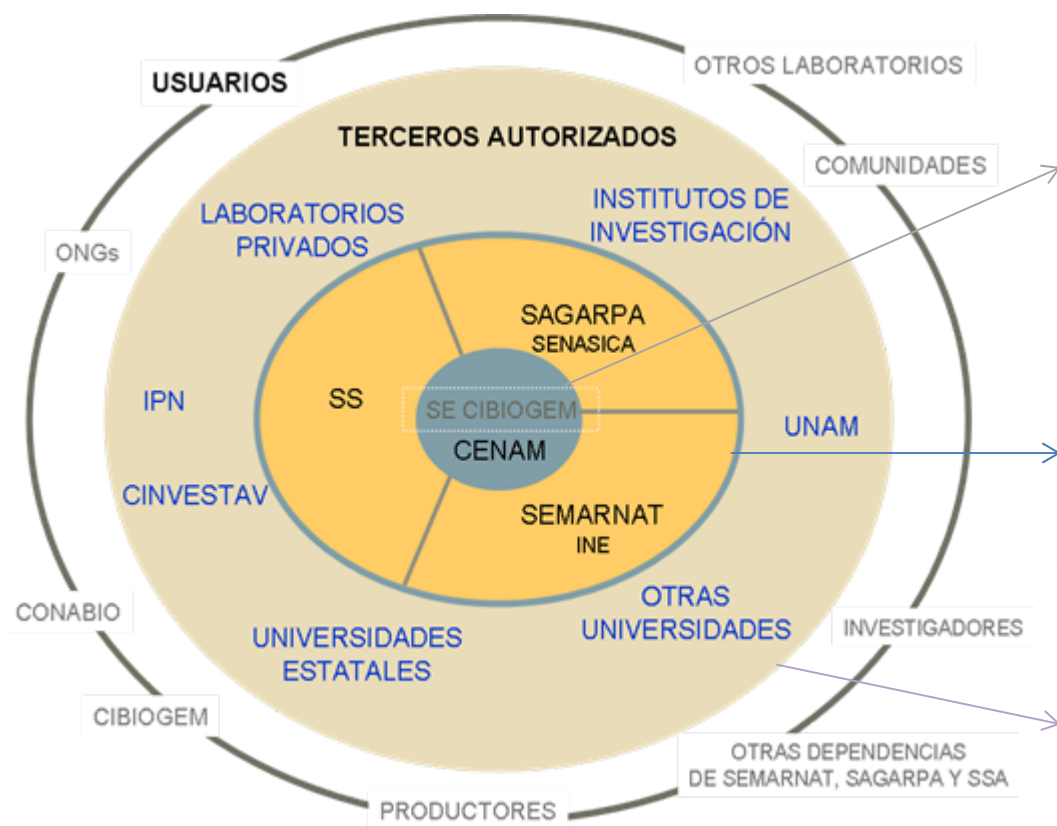
SAGARPA, SEMARNAT, SALUD, ECONOMIA, SHCP, Ex Secr CIBIOGEM

Technical Working Group:

- Methodologies
- Detection and Quantification Protocols
- Harmonization and standardization.
- Collaborative studies
- ID the technical requirements that the labs will have to fulfill in order to provide reliable and accurate results. (Based on ISO/IEC/17025 and current practices)

Legal Working group:

- Legal instruments that will allow the integration of the network and official recognition of potential members by competent authorities:
 - Certification / Accreditation
 - Third Parties (Terceros Autorizados)
 - Legal Agreements / Contracts
- Legal instruments for adequate network performance (Operations, structure and working flow) which might be NOMs, NMXs, Authorized Certified Protocols, etc.



STAGE 1

Establish the National Reference lab for reference methods and certified materials.

STAGE 2

Consolidate the capabilities for detection and analysis of GMOs in the test labs of the Federal Government Authorities.

STAGE 3

Integrate laboratories which are recognized by the ministries and Federal Accreditation Entities, which comply with the necessary quality standards for accurate and reliable detection and analysis of GMOs.



Where are we now?

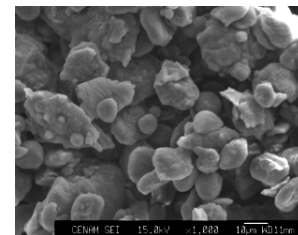
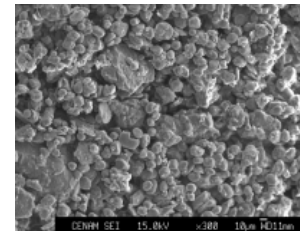
Establecimiento de la Red Nacional de Laboratorios



STAGE 1.

Establish the National Reference lab for procedures, methods and certified materials.

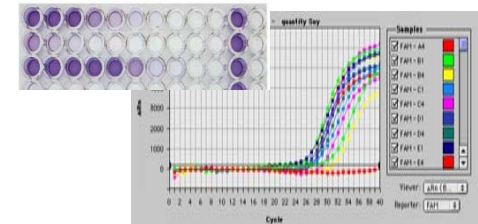
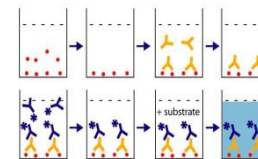
- ✓ Validates and Standardizes Protocols and Methods
- ✓ Prepares and Characterizes Reference Materials
- ✓ Coordinates Collaborative Studies



<http://www.cenam.gob.mx/>

STAGE 2

Consolidate the capabilities for detection and analysis of GMOs in the test labs of the Federal Government Authorities.



Infraestructure for analysis and QC

- ✓ Specialized Laboratories
- ✓ Skilled Personnel with strong background in Biomol. Science
- ✓ Acreditados/Certificados

Detection capacity

- ✓ Standardized Methodologies
- ✓ Rigorous QC and process management
- ✓ Tests for Certifying RM

Assay Validation

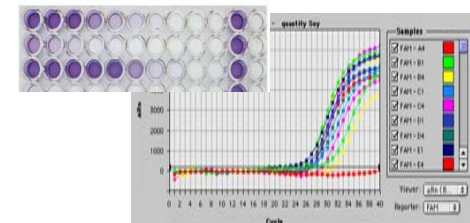
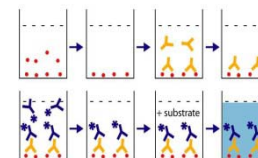
- ✓ Participation in National and International Collaborative Studies for validating and harmonizing methodologies.

STAGE 2

Consolidate the capabilities for detection and analysis of GMOs in the test labs of the Federal Government Authorities.



Comisión Federal para la Protección
contra Riesgos Sanitarios



CENICA, INE-SEMARNAT
CNRDOGM, SENASICA-SAGARPA
CCAYAC, COFEPRIS-SALUD

2009 – 2010

Engaged in a Inter-laboratory Proficiency Test.

Validated in a collaborative trial study, methods for detection of GM events in maize (35S and event-specific) according to ISO and JRC guidelines, and were coordinated by CENAM and SEj.



*"2010, Año de la Patria.
Bicentenario del Inicio de la Independencia y
Centenario del Inicio de la Revolución"*

Protocolo para el Estudio Nacional Comparativo en la Validación de Métodos y Procedimientos para la Detección y Cuantificación de Organismos Genéticamente Modificados.

Introducción

Un estudio de la factibilidad técnica para la normalización en materia de detección y cuantificación de Organismos Genéticamente Modificados (OGM) es la tarea principal que se propuso la Comisión Intersecretarial de Bioseguridad de Organismos Genéticamente Modificados (CIBIOGEM) en el inicio de 2008. A través de la colaboración de los laboratorios del Centro Nacional de Metrología (CENAM), el Centro Nacional de Investigación y Capacitación Ambiental (CENICA) y el Centro Nacional de Referencia en Detección de Organismos Genéticamente Modificados (CNRDOGM), así como de una de las empresas desarrolladoras de la tecnología, se generó una serie de Materiales de Referencia que permitiera cuantificar la fracción masa de eventos de modificación genética en maíz, mismos que podrían ser empleados para la validación de los métodos de PCR. La PCR en tiempo real es actualmente el método de medición más aplicado a nivel internacional para identificar y cuantificar las secuencias de ADN puesto

STAGE 3

Integrate laboratories which are recognized by the ministries and Federal Accreditation Entities, which comply with the necessary quality standards for accurate and reliable detection and analysis of GMOs.

2010

The Establishment Committee decided to **test the capacities** of external labs interested in taking part of the network.

Agreement RML/ORD/01/10 – 5

We are currently developing a collaborative trial at the national scale for Validating Procedures and Methods for Detection and Quantification of GMOs with several institutes and universities, using the CRMs prepared by CENAM and certified by the core labs as a blind study.

Purpose of the National Study

Establish the comparability of measurements of genetic modification events available in Mexico, amongst detection and quantification techniques at diverse organizations, as well as evaluating the performance within different laboratories.

IDENTIFY labs that are interested to take part of the Laboratory Network for D&A of GMOs

DETERMINE LEVELS OF PARTICIPATION according to performance, capacities to develop detection/quantification methods and accuracy

EXPLORE THE POTENTIAL SCOPE of the network.

CONTRIBUTE to the scientific consolidation of the network.

ESTUDIO NACIONAL COMPARATIVO EN LA VALIDACIÓN DE MÉTODOS Y PROCEDIMIENTOS PARA LA DETECCIÓN Y CUANTIFICACIÓN DE ORGANISMOS GENÉTICAMENTE MODIFICADOS (ENC CIBIOGEM 2010- 2011)

15 Labs from Research Centers and Public Institutions were invited.
10 Labs took part in the First Informative Session of the study.

2010 – Oct 19

Participants were provided with:

- ✓ A unique ID code per lab
- ✓ Three samples for analysis
(2 flasks flour powder + 1 flask corn seed)
- ✓ General Protocol and guidelines.





ENC 2010 -2011 Survey

- In addition, participants were asked to provide info about:
 - Sample Processing
 - Extraction procedure
 - Number of Independent replicates
 - Purity and Quality fo DNA.
 - Type of Controls used
 - Endogenous Gene
 - Standards of Reference Material available
 - Metodology used
 - Detection, Quantification
 - Rxn Conditions (ELISA, PCR, Real Time PCR)



ENC 2010 -2011 Survey

- In addition, participants were asked to provide info about:
 - Results
 - Presence or absence of transgenic material on the provided samples
 - If positive, Estimated Concentrations and variation coefficients
 - Detection Limits
 - Quantification Limits
 - Precision (Repeatability and Reproducibility of the Method).

ENC 2010 -2011



February 28, 2011

Second Meeting ENC-CIBIOGEM for Discussion and Analysis of Results.

ENC 2010 -2011

Results are being processed for statistical analyses, and the preliminary report should be available in the next month.

METHOD USED	% Labs
Strip detection	10 %
Qualitative PCR	80 %
Quantitative PCR	50%

Limitations encountered:

- Availability of Reference Materials
 - Few Crossed-Contamination
 - Uniformity among laboratories
- Methods (Extraction, References and Standards)*
- Reporting Units (Copy numbers vs. % (w/w))*

Perspectives

- Technical Working group:
Phase 2 of the ENC for 2011
Harmonisation activities in concert with Monitoring Network
Capacity Building and Training
- Legal Working Group:
Follow up on the essential topics for integrating the network



More information @

WWW.CIBIOGEM.GOB.MX



GRACIAS !

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