

ERA of LMOs for food, feed and processing in Mexico: the case of genetically modified maize

24 May 2013

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Biosafety regulatory framework in Mexico

- 1995. Standard for field trial evaluation of genetically engineered plants NOM-FITO 056 (Cancelled).
- 1999. Presidential agreement for the creation of the Inter-ministerial Commission for Biosafety of Genetically Modified Organisms (CIBIOGEM)
- 2003. Ratification of the Cartagena Protocol on Biosafety
- 2005. Biosafety Law of Genetically Modified Organisms
- 2006. Ruling (bylaw) for the Inter-ministerial Commission for Biosafety of Genetically Modified Organisms
- 2008. Ruling (bylaw) for the Biosafety Law of Genetically Modified Organisms

Scope of the law

The safe use of GMOs obtained through the application of modern biotechnology techniques

Genetically modified organism

Any living organism, with exception of human being, which has acquired a novel genetic combination, generated through the use of modern biotechnology.

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

- Published in 2005
- Takes into account international commitments
- Defines the principles for the public policy on biosafety of GMOs
- Creates legal instruments for its implementation
- Establish attributions and competence to different Ministries
- Mechanisms for interministerial coordination and public communication and information sharing
- Instruments for biotech and biosafety research
- 124 articles plus 12 "transitorios"

Biosafety Law of Genetically Modified Organisms

- Entry into force in 2005
- According to the Cartagena Protocol provisions
- Intended use for the specific GMO defines the Competent authorities:

- I. Ministry of Environment (SEMARNAT)
- II. Ministry Agriculture (SAGARPA)
- III. Ministry Health (SSA)
- IV. Ministry of Treasury (SHCP)

Coordinated
By CIBIOGEM

+

SEP

SE

CONACYT

Application
for **Commercialization**
for human consumption
and food processing

Articles 91 to 97 of the Biosafety Law complement previous regulation in the General Law of Health



Competent Authority
Ministry of Health
COFEPRIS

Food safety evaluation

Decision

Authorization:
Authorized GMOs may be freely commercialized and imported for their trading, as well as products containing such organisms and products derived from them, can be used for food, feed and processing.
They are not intended for environmental release.

The Ministry of Health issues authorization for:

- Human use and consumption, including grains*
- Food processing for human consumption
- Public health, and
- Biorremediation

* The Law also consider GMOs for human use and consumption, those that are for animal consumption and could be directly consumed by humans (Art. 91).

Commercialization of transgenic crops in Mexico, started in 1995, to date the Ministry of Health and its Federal Commission for the Protection against Sanitary Risks (COFEPRIS), have approved **116** LMOs for use and human consumption.

| Crop | Approved LMO | Crop | Approved LMO |
|-------------|---------------------|-------------|---------------------|
| Tomato | 3 | Maize | 53 |
| Potato | 3 | Cotton | 28 |
| Alfalfa | 2 | Soybeans | 17 |
| Sugar Beet | 1 | Canola | 7 |
| Rice | 1 | | |

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

Intentional release into the environment

The Biosafety Law establishes three modalities according to the intended use with a step by step approach:

- Experimental*

- Pilot Program**

- Commercial**

**Require previous authorization from Ministry of Health (*maize)

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Confined use

Notification

Application
for **ENVIRONMENTAL
RELEASE**

Articles 32 to 71 of the Biosafety Law and article 16 of the bylaw.

Competent Authority
SAGARPA

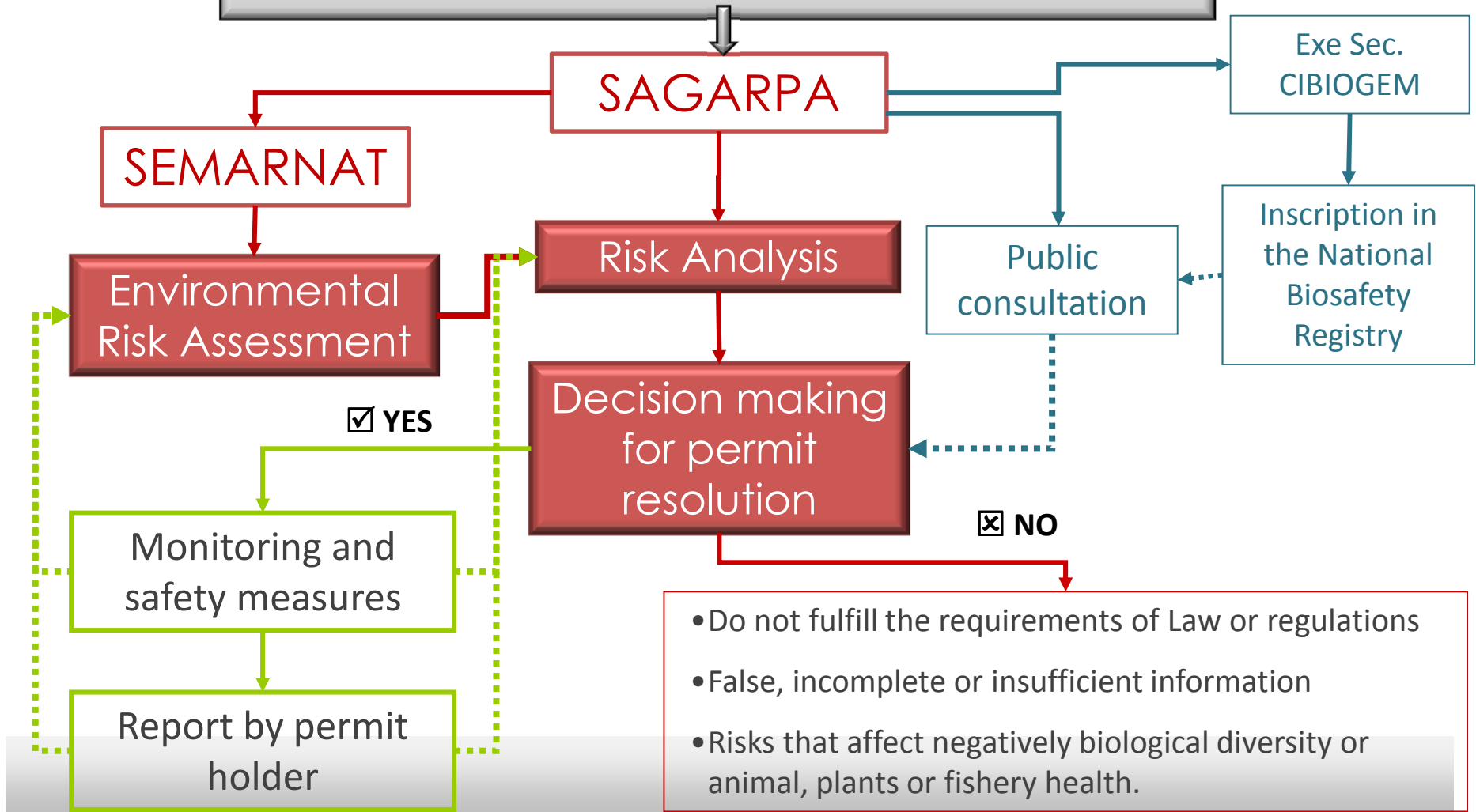
Risk Analysis

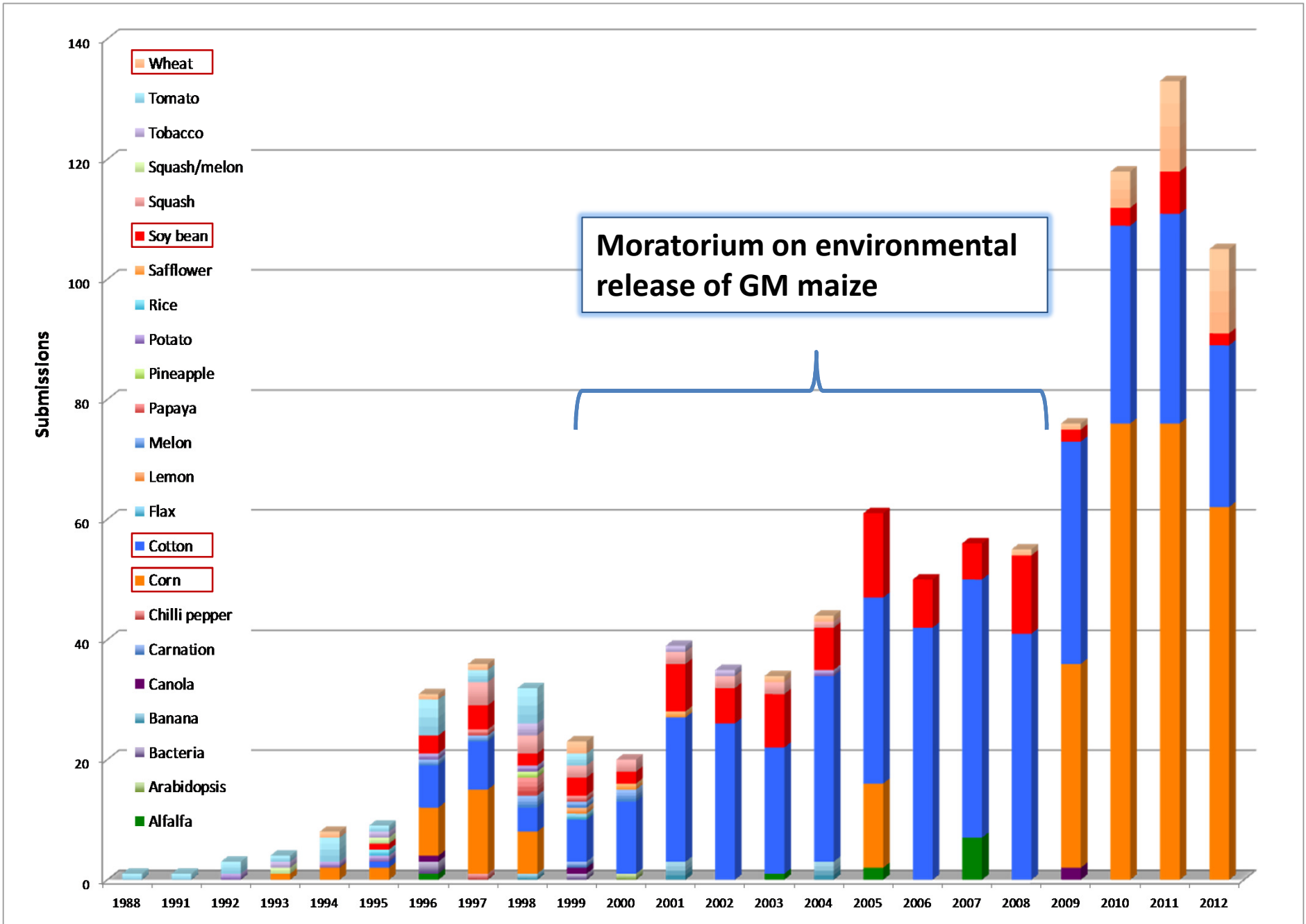
← Decision →

Permit /License:

Issued by SAGARPA or SEMARNAT for allowing the experimental release, release within a pilot program or commercial release to the environment and importation of GMOs to carry out such activities.

Application for Environmental release of GM crops, including importation







Family Poaceae
Tribe Maydeae
Section ZEA

Zea (5)

Tripsacum (12)

Clasificación by Iltis & Doebley (1980)
and Doebley & Iltis (1980)

ZEA

Zea mays ssp. *mays*

Z. mays ssp. *mexicana*

Z. mays spp. *parviglumis*

Z. mays *huehuetenanguensis*

LUXURIANTES

Z. luxurians (Guatemala)

Z. diploperennis

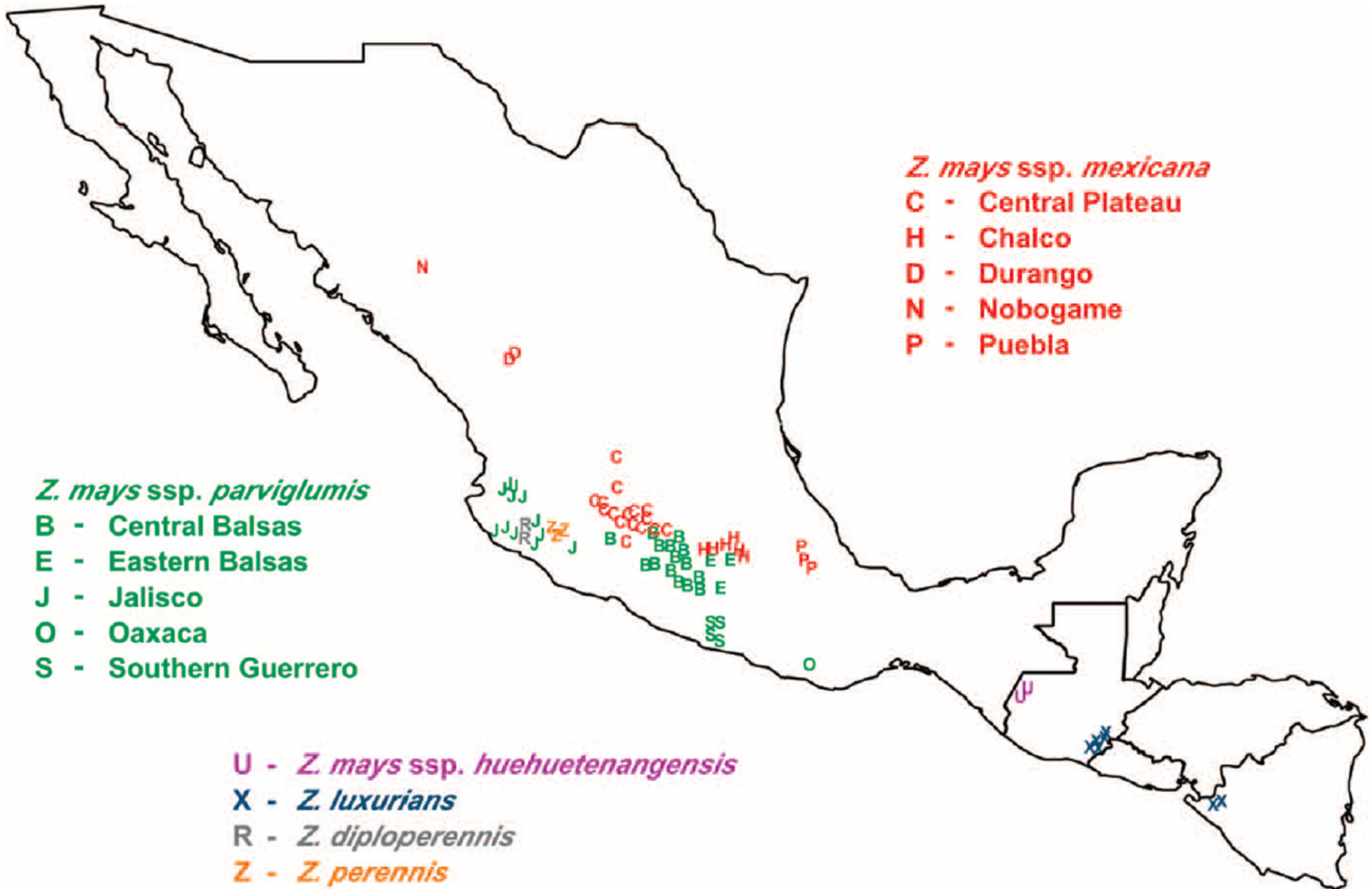
Z. perennis

Z. nicaraguensis (Iltis & Benz, 2000)

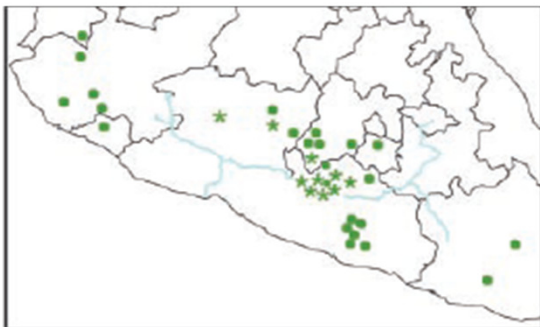
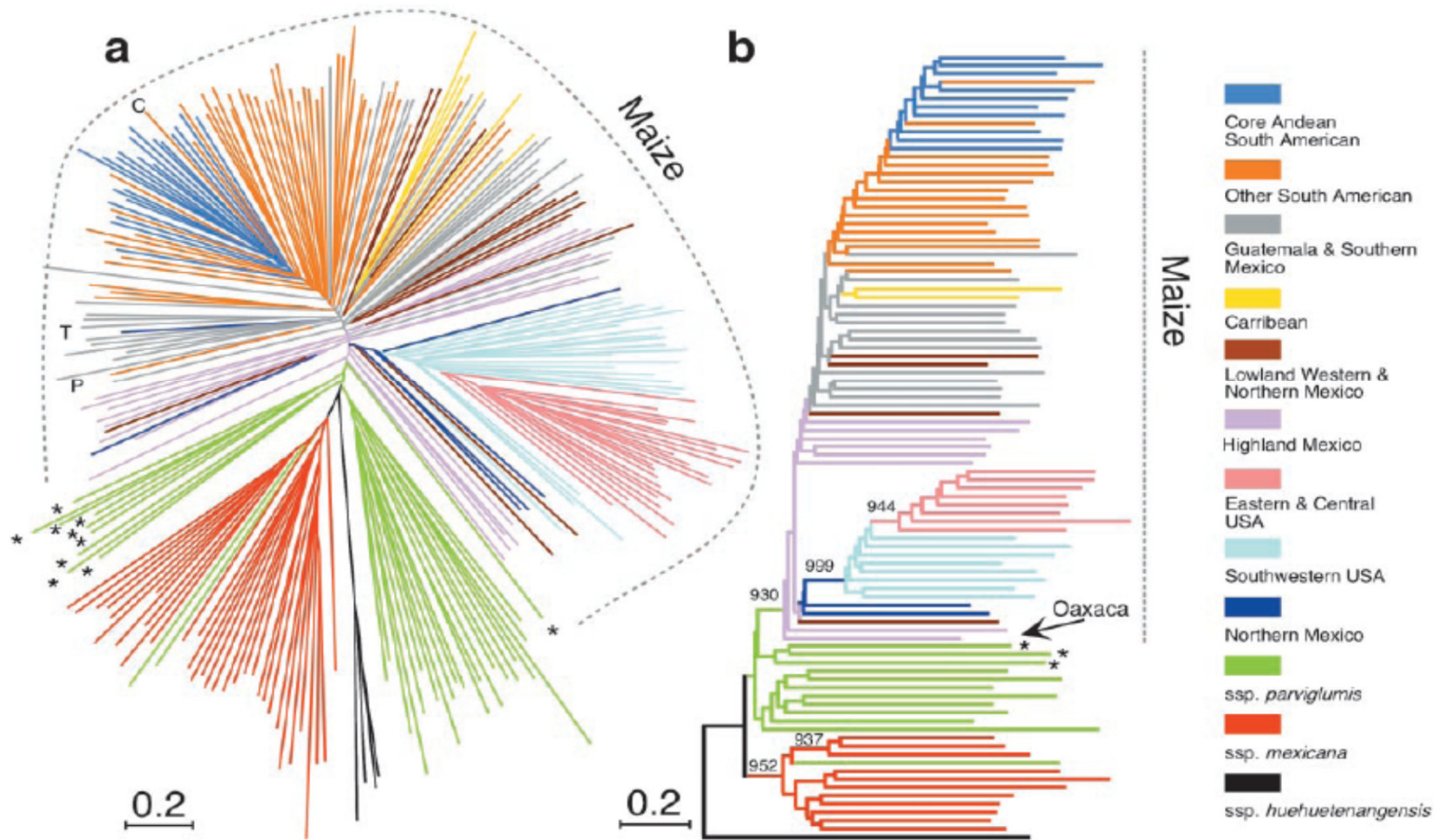
Geographic Distribution of teosinte populations

2242

K. Fukunaga *et al.* 2005



Domestication and origin of maize



Matsuoka et al, (2002), present evidence of a single domestication event for cultivated maize from *Z. mays parviglumis*

Zea mays ssp. mays ~ 60 land races in Mexico
the most cultivated cereal
53 commercial events /stacks approved for FFP
different agricultural systems
small farmers select and save seeds each season
compatibility with some teosintes
Mexico is part of its center of origin and diversification



MÉXICO

GOBIERNO DE LA REPÚBLICA



CIBIOGEM



Maize also has cultural, religious and nutritional values in Mexico

Tortillas, elotes, tamales, pinole, atole , pozole, pozol, huitlacoche, etc.



Maize as a special case

- ✓ Mexico does not allow the commercialization or the environmental release of any maize with a genetic modification that compromises its use as food (i.e. vaccines, pharmaceuticals).
- ✓ There is a special regime for the protection of landraces of maize, as well as its wild relatives.
- ✓ Current centers of high maize diversity should be identified and maintained free of GM maize



GRACIAS
(thank you)

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www.cibiogem.gob.mx

<http://www.cibiogem.gob.mx/RegistroOGMs.html>