Alicia Gutierrez Gonzalez

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List of Abbreviations

AIA	Advance Informed Agreement
AMC	Mexican Science Academy
ASERCA	Agricultural Marketing Support Services
BCH	Bio-safety Clearing House
BINAS	Biosafety Information Network and Advisory Service
BSP	Biosafety Protocol/Cartagena Protocol on Biosafety
BT	Bacillus Thuringiensis
CAC	Codex Alimentariux Commission
CBD	Convention on Biological Diversity
CBM	Biological Mesoamerican Corridor
CEC	Commission for Environmental Cooperation
CENICA	National Environmental Research and Training Centre
CHM	Clearing House Mechanism
CIBIOGEM	Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms
CGIAR	Consultative Group on International Agriculture
CIMMYT	International Centre for Maize and Wheat Improvement
CINVESTAV	Centre for Research and Advanced Studies
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CNBA	National Commission for Agricultural Biosafety
COD	Centre of Origin and Diversity
CODEX	Codex Alimentarius Commission
COFEMER	Federal Commission for the Regulatory Improvement
COFEPRIS	Federal Commission for Protection against Health Risks
CONABIO	National Commission for the Use and Knowledge of Biodiversity
CONACYT	National Council on Science and Technology
CONANP	National Commission of Protected Areas
CONASUPO	National Company of Popular Subsistence
COP	Conference of the Parties to the Convention on Biological Diversity

COP/MOP	Conference of the Parties serving as the Meeting of the Parties to the Protocol
DGIAAP	Plant Health General Directorate
DGIF	General Directorate for Phytozoosanitary Inspection
DGIRA	General Directorate of Environmental and Impact Assessments
DGSV	General Directorate on Plant Health
DICONSA	Food Distribution Agency
DNA	Deoxyribonucleic Acid
DPH	Directorate of Plant Health
DR	Delayed Ripening
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EC	European Communities
EU	European Union
EIA	Environmental Impact Assessment
EIS	Environmental Impact Statement
FAO	Food and Agriculture Organisation of the United Nations
FDA	Food and Drug Administration
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GE	Genetic Engineering
GEF	Global Environment Facility
GTI	Global Taxonomy Initiative
GM	Genetically Modified
GMOs	Genetically Modified Organisms
HT	Herbicide Tolerance
ICCP	Intergovernmental Committee for the Cartagena Protocol
ICGEB	International Centre for Genetic Engineering and Biotechnology
IEL	International Environmental Law
IGTC	International Grain Trade Coalition
INE	National Institute for Ecology
INEGI	National Statistics Geography and Informatics Institute
INIFAP	National Institute of Forestry and Agriculture Research

IRRO	Information Resource for the Release of Organisms
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
LGEEPA	General Law for Ecological Balance and Environmental Protection
LMO	Living Modified Organism
LMO-FFPs	Living Modified Organism for Food, Feed and Processing
MEA	Multilateral Environmental Agreement
MFN	Most Favoured Nation Treatment
MSDN	Microbial Strain Data Network
NAAEC	North American Agreement on Environmental Cooperation
NABI	North American Biotechnology Initiative
NAFTA	North American Free Trade Agreement
NBSAP	National Biodiversity Strategy Action Plan
NDP	National Development Plan
NGOs	Non Governmental Organizations
NIHRAC	National Institute of Health rDNA Advisory Committee
NOM	Mexican Official Standard
NMX	Voluntary Mexican Standards
OECD	Organisation for Economic Cooperation and Development
PAN	National Action Party
PCR	Polymerase Chain Reaction
PIC	Prior Informed Consent
PRI	Institutional Revolutionary Party
PVEM	Mexican Green Environmental Party
PROFEPA	Federal Attorney for Environmental Protection
REMIB	Mexican Network on Biodiversity
SAGARPA	Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food
SBS	State-level biodiversity Strategies
SBSTTA	Scientific Advisory Body
SCJN	Supreme Court of Justice of the Nation
SE	Secretariat of Economy
SEA	Specialised Subcommittee on Agricultural
SEMARNAT	Secretariat of Environment and Natural Resources

SENASICA	National Food Health, Safety and Quality Service
SEP	Secretariat of Education
SHCP	Secretariat of Finance and Public Credit
SIOVM	Information System of Living Modified Organisms
SNIB	National Biodiversity Information Network
SPS-Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
SRE	Ministry of Foreign Relations
TBT-Agreement	Agreement on Technical Barriers to Trade
TRQ´s	Tariff-Rate Quotas
UAM	Metropolitan Autonomous University
UACH	Chapingo Autonomous University
UN	United Nations
UNAM	National Autonomous University of Mexico
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation
USA	United States of America
USDA	United States Department of Agriculture
USDA-APHIS	United States Department of Agriculture-Animal and Plant Health Inspection Service
VR	Virus Resistance
WHO	World Health Organisation
WTO	World Trade Organization
WWF	World Wildlife Fund

PREFACE

This doctoral thesis has been written from July 2007 to June 2009 under the supervision of Prof. Dr. Peter-Tobias Stoll, from the Department for International Economic and Environmental Law of the Institute for International and European Law at the Faculty of Law at Georg-August University of Göttingen.

I would like to highlight that this investigation began in October 2004, when I came to Germany to study my PhD in International Economical and Environmental Law. In 2007 I received the Magister Iuris degree in European and Mexican Environmental Law for my work on "The Regulation of Genetically Modified Organism (GMOs) both in Europe and in Mexico". In July 2007 I began with my doctoral thesis on the same topic, "Genetically Modified Organisms", which represents the continuation of my previous studies. However, this investigation expands the points at issue including international economic and environmental law. The bibliography cited in this doctoral thesis ends in April 2009.

Alicia Gutiérrez González

Göttingen, June 2009

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The Protection of Maize under the Mexican Biosafety Law: Environment and Trade

Introduction

Genetically Modified Organisms (GMO's) or Living Modified Organisms (LMO's) are the result of biotechnology. The use of biotechnology in sectors such as medicine (red biotechnology) and agriculture (green biotechnology) has produced a growing number of GMO's and products derived from them. This doctoral thesis focuses only on the green biotechnology. During the last two decades both the adoption of bio-crops, and countries, crops, traits and area cultivated has increased rapidly. Thus, during the period from 1996 to 2008, there was a large increase in the area grown with transgenic crops worldwide, from 1.7 million hectares in 1996 – the first year of commercialization – to 125 million hectares in 2008. To date, the USA continues to lead with 62.5 million hectares follows by Argentina 21.0, Brazil 15.8, India 7.6, Canada 7.6, China 3.8, Paraguay 2.7, and South Africa 1.8. This doctoral thesis will chronologically illustrate the development of biotechnology, its uses in the agricultural sector and its regulation in Mexico, in the United States of America (USA), in Germany and in the European Union (EU). This study will briefly compare the differences between the regulation of biotechnology in the USA and in the EU. It is known that the use of biotechnology does not come without risks and uncertainty. There are discussions about its benefits and risks at national and international levels. Hence, this research will also analyse the international instruments addressing biotechnology such as: Agenda 21, the Convention on Biological Diversity (CBD), the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (BSP), and the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO).

The perception of the risks associated with the use of GMO's differs from country to country. While developed countries have a legal framework of biotechnology and may implement its national regulations to minimize the possible risks associated with GMO's, developing countries, which regularly lack such regulation or lack financial resources in order to implement its national regulations appropriately, may not be in a position to minimize the potential effects GMO's may cause to human, animal, and plant health, as well as to the biodiversity and to the environment.

Mexico as a developing country and as a centre of origin and diversity (COD) of different crops such chilli pepper, beans, squash, papaya, cotton, tomato, guayaba, cacao, agave, amaranth, and especially maize faces this problem. On the one hand Mexico has to comply with its international environmental commitments and hence has the obligation to protect, conserve and preserve its biodiversity and its maize, since maize is not only the staple food of Mexican but it has cultural, nutritional, historical, environmental, symbolic, religious, social, and economic significance. On the other hand Mexico has to comply with its international commercial commitments i.e. with the provisions provided in the North American Free Trade Agreement (NAFTA) and in the World Trade Organization (WTO) regimes. Thus, this doctoral thesis will analyse the provisions of NAFTA and of the WTO Agreements with regard to imports of GM maize, import bans, and labelling of GMO's. Another crucial international instrument which will be also analyzed and described is the inter-institutional agreement and its addendum signed by the NAFTA trading partners at the end of October 2003. They were signed with the aim of implementing Article 18.2 of the BSP.

This research is divided into three main chapters. The first chapter focuses on the description and analysis of the development of biotechnology. It also analyses the importance of maize worldwide and for Mexico being a COD. The second chapter provides a descriptive and analytical insight into the Mexican legal framework of biotechnology and biosafety. It also briefly describes and analyses the regulation of biotechnology in the USA, in Germany, and in the EU. It also analyses the diverse international instruments addressing biotechnology mentioned above. The third chapter illustrates the process of economic liberalization in Mexico from 1980´s until the inception of NAFTA in 1994. It also analyses the impact that GM maize imports from the USA may have in Mexico as COD of maize. By adopting a comparative approach, the analysis focuses on how developed and developing countries operate in relation of imports of GMO's. In doing so, the research outlines the problematic of complying with two perspectives: environmental, and trade commitments. This research analyses the environmental and the commercial commitments of Mexico regarding biotechnology, and the protection of biodiversity, especially maize. The final part of this doctoral thesis gives an overall view of the main findings in this investigation.

Chapter I

Biotechnology and Biodiversity: Developments, Potentials and Concerns

Introduction

This chapter provides an overview of the developments, potentials and concerns of biotechnology and of the protection of biodiversity in Mexico with regard to Genetically Modified Organisms (GMO's)[1], especially maize.

[1] Genetically Modified Organisms (GMO's) are living organisms that possess a novel combination of genetic material and have been produced using the techniques of modern biotechnology. The terms GMO, Genetically Engineered Organism (GEO), Transgenic Organism and Living Modified Organism (LMO's) are widely used in this doctoral thesis. However, it must be said that all transgenics are GMO's but not all GMO's are transgenic i.e. transgenics are organisms which have inserted DNA that originated in a different species. Thus, some GMO's contain no DNA from other species and are therefore not transgenics.

It is divided into two main sections: the first section will briefly describe the development of biotechnology in general and its current uses. This investigation only focuses on agricultural biotechnology or green biotechnology. It will briefly show the commercial use of GMO's in agriculture[2] and it will also describe the increase of GMO's in the world from 1996 to 2008.

The second section provides an overview of the protection of biodiversity in Mexico. It will explain the most important core elements concerning the protection, conservation and use of the biological diversity in a sustainable way and will also analyze the challenge that a country like Mexico faces by being both a developing country and a centre of origin and diversity (COD)[3] of different crops and especially of maize. Furthermore, this section explains why maize is important both worldwide and for Mexico. It describes the differences between the use of maize in developed and in developing countries.

At the end of this chapter the contamination of maize in the north of Oaxaca in 2001 will be explained. Also, the Star-Link event in the United States of America (USA) will be mentioned.

A. Development of Biotechnology

I. Historical Development

For centuries farmers have been using selective breeding to improve both crops and stock by breeding from the plants or animals that have the qualities they want to bring out and strengthen.[4] The storage of the best of the agricultural production for future use as seed for sowing, or animals for breeding, has been the key for the enhancement over the ages. In this way farmers have developed animals and crops to obtain desired characteristics

[2] The commercial use of GMO's in agriculture is currently limited aLMO'st exclusively to different varieties of four crop species: soybeans, maize (corn), oilseed rape (canola) and cotton.

[3] Vavilov Nikolai 1887-1943 defined a centre of origin and diversity of crops as a biogeographic region where the crop has its largest diversity and a close relationship exists with its wild relatives. Online: http://www.vir.nw.ru.

[4] Genetic Modification: an overview for non-scientists, Report of the New Zealand Royal Commission on Genetic Modification, Wellington, 2001, page 363.

such as resistance to disease or ability to cope better with extremes of climate and in order to increase production.[5]

The development of biotechnology began towards the end of the 18th century[6]. The first event took place in 1796 when Edward Jenner developed the first vaccine by injecting a healthy boy with cow pox in order to build immunity to the deadly scourge of smallpox. In the 19th century, the most important contributors were Charles Darwin and Gregor Mendel. Darwin made known his theory of evolution in his monumental publication "The Origin of Species" in 1859. It ignited intense controversy over the role of natural selection in evolution. Darwin wrote:

> *All the organic beings which have ever lived on this earth have descended from some one primordial form.*

However, it took almost a century to find common ground between evolutionary theory and genetics. Gregor Mendel, breeding his garden peas, published his "Rules of Inheritance"[7] in 1865 and demonstrated that "factors" in pea plants that will later be called genes, do not blend together i n successive generations, but instead are inherited independently from one another. His experiments went largely unnoticed. Around 1900, Mendel's experiments on pea plants were rediscovered by the Dutch botanist Hugo de Vries. Even though they did not offer support for Darwin's theory, they bolstered the view that species originate through sudden transformation or "mutations", from one generation to the next. Thus, the natural selection and adaption became irrelevant. Mendel became the father of genetics. In 1869 the very first isolation of deoxyribonucleic acid (DNA) was performed by Frederich Mieschner. Luis Pasteur also contributed, with the development of the vaccine against rabies in 1885. August Weismann postulated in 1892 that a substance in chromosomes within the cell's nucleus, which he calls the

[5] Mackenzie, Ruth, Burhenne-Guilmin, Francoise, La Viña, Antonio G. M. and Werksman, Jacob D. in cooperation with Ascencio, Alfonso, Kinderlerer, Julian, Kummer, Katharina and Tapper, Richard (2003). An Explanatory Guide to the Cartagena Protocol on Biosafety, IUCN, Gland, Switzerland and Cambridge, UK, Xvi + 295pp.

[6] Bolivar Zapata Francisco G., compilador y editor: autores Carlos F. Arías Ortíz... et al. – 2da Ed. México, D.D. El Colegio Nacional, 2007. 718 p. Co-edición con: Academia Mexicana de Ciencias; UNAM, Instituto de Biotechnología: CONACTY: CIBIOGEM. "Fundamentos y casos exitosos de la biotechnología moderna".

[7] Mendel Georg, Versuche über Pflanzenhybriden, vorgelegt in den Sitzungen vom 8. Februar und 8. März 1865, gedruckt in den Verhandlungen des Naturforschenden Vereins in Brünn. IV. Band. Abhandlungen 1865, Brünn, 1866. Im Verlage des Verein. S. 3-47. Online: http://www.biologie.uni-hamburg.de/b-online/d08_mend/mendel.htm

germ plasm, is responsible for the inheritance of traits. The germ plasm was later identified as the material basis of the gene. By the end of the century, a German physician, Robert Koch, made significant discoveries toward the validation of the germ theory of disease.[8]

In the early 20th century, the seeds of prosperity in the modern biotechnology movement were sown. New sciences continued to emerge, particularly immunology and genetics. Thomas Hunt Morgan, and his group of fruit fly researchers, made significant contributions to genetics by showing that the basic units of Mendel's heredity, genes, were physically located on chromosomes. Thus, by studying multiple generations of fruit flies, they are able to infer the existence of genes, link them to inheritance, and map their locations on chromosomes. In the 1920s advances in genetics proved that mutations cannot transform species, but instead provide the raw material to enable variation through natural selection. Population geneticists Ronald Fisher., J. B. S. Haldane, and Sewall Wright developed models showing how small, favourable mutations can spread throughout a population. In 1928, Alexander Fleming discovered the mold penicillin which inhibited the growth of a human skin disease-causing bacterium called Staphylococcus aureus, leading to the purification of the first antibiotic, penicillin. In 1943, Oswald Avery and others provided definitive evidence that DNA is the material that constitutes the make up of genes. In 1949, Linus Pauling demonstrated that sickle cell anaemia is a disease that can result from a single mutation in a protein.

However, the knowledge on which the techniques of genetic modification are based dates from the 1950s[9] when James Watson, Francis Maurice Wilson and Rosalind Franklin discovered the structure of DNA.[10] In 1953[11] Watson and Crick discovered the double helix of nucleotides that bears the genetic information for the biosynthesis of proteins like enzymes, certain hormones (e.g. insulin) and whole parts of the body (e.g. nails, hair). They unlocked the mystery of how genetic information is passed from one generation to the next. What they found was that every organism carries a chemical code for its own creation inside its cells, a text written in a language common

[8] Ibid, Bolivar Zapata, supra note 6
[9] Ibid Mackenzie Ruth, supra note 5
[10] DNA is present in almost all living cells and contains information coding for cellular structure, organisation and function. DNA not only confirms the reality of evolution, it also shows, at the most basic level, how it reshapes living things.
[11] Watson, J. D. y F. H. C. Crick, 1953, Molecular Structure of Nucleic Acids. A structure for Deoxyribonucleic Acid", Nature, 171, pp. 737-738

to all life: the simple, four-letter code of DNA. This new understanding opened up the possibility of altering the genetic coding of organisms to give them new characteristics that natural evolution or selective breeding cannot produce.[12] In the 1960s Marshall W. Nirenberg established the universal genetic code founded in the works of F. Crick. In the early 1970s, researchers discovered molecular scissors, or DNA restriction enzymes, that can cut segments of DNA, ushering in an era of genetic engineering and cloning.

In the 1970s, it became possible to isolate individual genes, refashion them and subsequently copy them in cells, opening up huge commercial possibilities. Ways of applying this new technology to medicine were developed quite rapidly. The technology could also be used in industry to produce new fine chemicals and pharmaceuticals using living modified organisms as factories.[13]

By 1973 Paul Berg, Herbert Boyer and Stanley Cohen performed the first successful recombinant DNA experiment, stitching together different bacterial genes from the common human gut bacterium, E. coli. Thus, they conceived the concept of recombinant DNA. With the success of this experiment, other researchers continued to make progress in genetic engineering, and the 1970's also witnessed the birth of the biotechnology industry. In addition, new lab methods such as DNA sequencing and protein analysis, and later the polymerase chain reaction (PCR)[14], which makes unlimited copies of genes, led to a future revolution in forensics and biomedicine.

In the 1980s, the maturation and growth of the biotech industry continued unabated, with the first genetically engineered products being approved by the Food and Drug Administration (FDA). Genentech's Humulin, became the first new treatment for diabetes that was produced from genetically engineered bacteria. Soon after, methods to genetically engineer plants were discovered and the first field tests of genetically engineered tobacco plants were performed. Later, the Flavr Savr, a genetically engineered tomato resistant to rotting, was approved for sale. In the late 1980s, what has been referred to as the biological equivalent of the Apollo program, the Human Genome Project, was launched. This international effort resulted in a fifteen year goal to map and sequence the 3 billion letters of the human genetic DNA code. The 1990s also offered the tantalizing promise of DNA sequence applications toward health and medicine, as genes responsible for

[12] Ibid Mackenzie Ruth, supra note 5

[13] Ibid, Bolivar Zapata, supra note 6

[14] Polymerase Chain Reaction (PCR) amplifies the DNA target sequence, which is subsequently detected via fluorescence labelled hybridization probes in real time

cystic fibrosis, breast cancer and Huntington's disease were identified. The end of the twentieth century drew to a close as the world was introduced to Dolly, the first sheep to be cloned from DNA derived from adult cells. One year later, John Gearhart and James Thomson, published independent results showing their ability to isolate human stem cells. [15]

II. Overview of Biotechnology

Biotechnology is a general term that relates to the harnessing of living or dead cells, or cell components, to undertake specific processes with applications in medicine,[16] industry, agriculture, conservation and the provision of food and fuel energy.[17]

Currently, scientists isolate[18] single genes that control particular characteristics; they copy them with modifications and splice them with other control elements from genes to form a gene construct[19] so that they work well within the target organism. The next step is to insert them, usually in a random position, within that organism. The techniques used for genetic modification (GM) or genetic engineering (GE)[20] involve steps that take place in vitro, i.e. they take place outside any organism. Through genetic modification, genes are transferred and modified in ways that are not possible in nature, i.e. between different species and between animals and plants and micro-organisms. The use of genetic modification techniques allow very large evolutionary barriers to be crossed, and allows for one or a

[15] Ibid, Bolivar Zapata, supra note 6

[16] The medical applications include for instance an anticancer agent, and human insulin.

[17] Mannion A. M. and Bowly S.R., Chapter 9 "Biotechnology and Genetic Engineering: New Environmental Issues" in: Environmental Issues in the 1990s, pp147-160, Ed by John Wiley Sons Ltd, England 1995.

[18] The objective is to isolate components of chromosomal DNA (deoxyribonucleic acid) which confer specific, preferred characteristics and transfer them into other species. These should then produce offspring that express the characteristics.

[19] The gene construct is built from genetic material isolated from several different organisms, for example, a promoter from the Cauliflower Mosaic Virus, a bacterial DNA vector (Agrobacterium plasmid), one or more genes that may have been modified artificially in the laboratory, termination and signalling sequences, and a selectable marker gene, for example for resistance to the antibiotic kanamycin.

[20] In genetic modification, scientists take individual genes from one plant or animal and put them into the DNA of the cells of another. They may also make changes to modify an existing gene. Genetic modification provides a way of giving a plant or animal new, inheritable qualities much faster than traditional breeding methods; these qualities may themselves be entirely new. Genes can be transferred in ways that are not found in nature, between different species and even between animals and plants.

few genes to be moved between organisms, including organisms which have not been known to have genetic contact.[21] Some examples of genetic modification are GM bacteria, GM agricultural crops, GM trees, GM animals, GM fish and GM insects.

The proliferation of biotechnology and its growing commercial use have given rise to policy and legislative initiatives that aim to address the potentially hazardous effects on human, animal or plant health and on the environment".[22] Biotechnology is defined as:

> *The application of in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.*[23]

Biotechnology is used to modify organisms by creating a novel combination of genetic material in order to generate a variety of products and applications, including pharmaceuticals, food and animal feed.[24] Sometimes, as is the case with seeds, food or feed crops, these Living Modified Organisms (LMO's) are directly used for human consumption. This "revolutionary technology offers humanity the power to change the characteristics of living organisms by transferring the genetic information from one organism, across species boundaries, into another organism".[25]

Biotechnology continues the tradition of selection and improvement of cultivated crops and livestock developed over the centuries. However, it identifies desirable traits more quickly and accurately than does conventional plant and livestock breeding and allows gene transfers that would be impossible with traditional breeding. The use of biotechnology in sectors such as agriculture and medicine has produced a growing number of GMO's and

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[21] Wright, S. Molecular Politics – Developing American and British Regulatory Policy for Genetic Engineering 1972-1982, University of Chicago Press, 1994, p.76.

[22] Stoll Peter Tobias, "Controlling the Risks of Genetically Modified Organisms: The Cartagena Protocol on Biosafety and the SPS Agreement, In: Yearbook of International Environmental Law 10 (1999), pp. 82-119.

[23] The definition of biotechnology means the same for the Biosafety Protocol (BSP) at Art 3 (i) and for the Mexican Biosafety Law (LBOGM) Article 3 (VI).

[24] Ibid Stoll Peter Tobias, supra note 22

[25] Zarilli Simonetta, "International Trade in Biotechnology Products and Multilateral Legal Frameworks". –In: Biological Resource Management in Agriculture, "Challenges and Risks of Genetically Engineered Organisms", OECD Paris, 2004, pp. 29-45

products derived from them. Changing the characteristics of organisms may provide benefits to society, including new drugs and enhanced plant varieties and food. However, biotechnology does not come without risks and uncertainty. Its potential effects on the environment, human health and food security are currently being debated at national and international levels. Following this, "there is a sharp contrast at present between the widespread international acceptance of the benefits of biotechnology in pharmaceuticals and industrial products and the widespread concerns about its possible dangers to agriculture and food production". [26]

III. Categorisation of Biotechnology

1. The Colours of Biotechnology

In his Article "The Colours of Biotechnology"[27] Edgar J. DaSilva, former Director Division of Life Sciences UNESCO, Paris, France, provided a guide with the colours of biotechnology with the purpose of promoting public perception and understanding of biotech applications, see table 1.1. He divided it into 10 different colours and areas that are defined as follows: red is the colour for the medicine sector, yellow shows the food biotechnology and nutrition science, blue represents aquaculture, coastal and marine biotech, brown shows the arid zone and desert biotechnology, dark indicates bioterrorism, bio-warfare, bio-crimes, and anti-crop warfare, purple is the colour for patents, publications, inventions and international property rights; white belongs to the gene-based bio-industries, gold is the colour given for bioinformatics and nanobiotechnology, grey represents the classical fermentation and bioprocess technology and the last colour, green, is used for the agricultural, environmental biotechnology i.e. bio-fuels, bio-fertilizers, bioremediation and geo-microbiology. As aforementioned, this investigation will focus only on the green biotechnology.

[26] Ibid, Zarilli Simoneta, supra note 24

[27] Dasilva, Edgar J. "The Colours of Biotechnology": Science, Development and Humankind. Electron. J. Biotechnol. dic., 2004, vol. 7, no. 3, pp-01-02. ISSN 0717-3458.

Table 1.1 Colours of Biotechnology

Colour Type	Area of Biotech Activities
Red	Health, Medical, Diagnostics
Yellow	Food Biotechnology, Nutrition Science
Blue	Aquaculture, Coastal and Marine Biotech
Green	Agricultural, Environmental Biotechnology – Biofuels, Biofertilizers, Bioremediation, Geomicrobiology
Brown	Arid Zone and Desert Biotechnology
Dark	Bioterrorism, Biowarfare, Biocrimes, Anticrop warfare
Purple	Patents, Publications, Inventions, IPRs
White	Gene-based Bioindustries
Gold	Bioinformatics, Nanobiotechnology
Grey	Classical Fermentation and Bioprocess Technology

Currently, the three most important activities related to biotechnology are: green biotechnology, which describes research on plants and plant varieties; red biotechnology, which refers to the development of drugs for treatment and diagnostic purposes; white biotechnology which uses the cell tissues to create and breakdown substances in technical processes, in particular in the chemical, food, and textile industry.

2. The Green Biotechnology: Agricultural Biotechnology

As aforementioned, the green biotechnology describes research on plants and plant varieties. The commercial use of GMO's in agriculture is currently limited to five main types of traits:[28] herbicide tolerance (HT),[29]

[28] Clives James, 2007. Global Status of Commercialized Biotech/GM Crops: 2007. ISAAA Briefs No. 37-2007

[29] Herbicide tolerance includes soybean, maize, rapeseed and cotton. And it can be defined as the insertion of an herbicide-tolerant gene into a plant and enables farmers to spray wide-spectrum herbicides on their fields to control weeds without harming the crop.

virus resistance (VR),[30] delayed ripening (DR), stacked traits[31] (IR/HT, IR/IR, IR/IR/HT) and insect resistance (IR).[32] Under this last type of trait, there is Bacillus thuringiensis, commonly known as (Bt). It is not harmful to mammals, including humans, to birds or fish or to beneficial insects. Bt is not effective against all insects; however, different Bt strains are effective against specific species. The major families of insects that respond to Bt are: Lepidoptera (caterpillars; e.g. European corn borer or cotton bollworm), Coleoptera (beetles; e.g. Colorado potato beetles) and Dioptera (flies and mosquitoes). With the emergence of biotechnology, the development of insect resistant plants by transferring the gene that produces the Bt toxin became possible and this procedure is now well established.[33]

The agricultural applications include crop improvement, the engineering of disease – and drought-resistant crops, and the biological control of pests. There is a range of bacteria, fungi and viruses which can produce fatal infections in many insect species and can supplement pesticide applications, or reduce them in integrated pest management strategies. For example many strains of Bacillus thuringiensis produce insecticidal chemicals and are thus insect pathogens. This bacterium can produce crystalline spores which are natural insecticides. As mentioned above, these are known as Bt toxins. The gene that controls Bt production can be cloned into tobacco plants, conferring resistance to tobacco budworm and the large white butterfly. Advances have also been made in engineering crop plants that are resistant to herbicides. This facilitates the treatment of field crops with a broad-spectrum herbicide that would kill the weeds but not the crop. There is also a possibility that crops could be engineered to combat environmental hazards such as frost, drought and high salinity.

[30] Virus resistant genes have been introduced in tobacco, potatoes, papaya and squash.

[31] Stacked events are transgenic crops which involve two or more traits. The most common stacked events at present are combinations of herbicide tolerance (HT) and insects resistance (e.g. Bt.).

[32] Insect resistant transgenic crops are used as a way of controlling specific pests. Insect-resistant crops have been developed by integrating genes derived from various strains of a bacterium Bacillus thuringiensis (Bt), which produces toxins that kill certain insect pests. Insect-resistance genes have been introduced in maize and cotton.

[33] Insect Resistance in Crops: A Case Study of Bacillus thuringiensis (Bt) and its Transfer to Developing Countries. No. 2 – 1997.
Online: http://www.isaaa.org/Resources/Publications/briefs/default.html

3. The Generations of Transgenic Plants

Biotechnology is being use as a tool to give plants new traits that benefit agricultural production, the environment, and human nutrition and health. As mentioned above, the manipulation of DNA of organisms achieves the acceleration of the process of plant improvement. Genes are found within the genome and serve as the "words" of the instruction manual. When a cell reads a word, or in scientific terms "expresses a gene", a specific protein is produced. Proteins give an individual cell, and therefore the plant, its form and function. [34]

Genes (words) are written using the four letter alphabet A (Adenine), C (Cytosine), G (Guanine) and T (Thymine). The letters are abbreviations for four chemicals called bases, which together make up DNA. It is universal in nature, meaning that the four chemical bases of DNA are the same in all living organisms. Consequently, a gene from one organism can function in any other organism.[35]

a) The First Generation of Transgenic Plants

The first generation of transgenic plants also known as: Input-traits[36] have already been approved for cultivation and placement on the market. An input trait helps producers by lowering the cost of production, improving crop yields, and reducing the level of chemicals required for the control of insects, diseases, and weeds.[37] Examples include herbicide resistance in a range of crops, insect resistance in maize and cotton, fungal resistance in potatoes, rapeseed and wheat, and virus resistance in sugar beet and potatoes.[38] Input traits that are commercially available or being tested in plants provide resistance to destruction by insects, tolerance to broad-spectrum herbicides, resistance to diseases caused by viruses, bacteria, fungi, and worms, protection from environmental stresses such as heat, cold, drought, and high salt concentration.[39]

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[34] Gálvez Mariscal Amanda, "Principios básicos de biología molecular y biotecnología" pp. 87-112 en: "Bioseguridad en la aplicación de la biotecnología y el uso de los organismos genéticamente modificados", CIBIOGEM, PNUD, GEF, primera edición, México, 2008

[35] Ibid

[36] German Federal Agency for Nature and Conservation (BfN)
Online: www.bfn.de/0301_transgen+M52087573ab0.html

[37] Vines Randy, Plant Biotechnology, publication 443-002 in: Virginia Cooperative Extension, Virginia Polytechnic Institute and State University

[38] Ibid, German Federal Agency for Nature and Conservation, supra note 36

[39] Ibid, Vines Randy, supra note 37

b) The Second Generation of Transgenic Plants

The second generation of transgenic plants describes an advanced stage of development which is close to being approved and is also know as Output-traits. An output trait helps consumers by enhancing the quality of the food and fiber products they use.[40] Output-traits or use traits refer to all downstream factors such as streamlining of and cost-cutting in production, transportation and storage processes, optimisation of feed and of raw materials for industry and medicine, and traits that produce functional foods. Plants with new output traits include the anti-sense tomato with a longer shelf-life, rapeseed with higher lauric acid content, potatoes with a different starch composition, poplars with lower lignin content (designed to simplify production of wood-free paper) and the production of substances for use in pharmaceuticals (gene pharming). GMO's for use in the production of functional foods have yet to reach market maturity. Current research and development includes the creation of vitamin-enriched potatoes, rice containing beta-carotene (known as 'golden rice'), and apples and strawberries containing protein that acts as a prophylactic to reduce dental caries. These GMO's and others like them raise hopes that public acceptance of agro-genetic engineering can be increased because their altered use traits should mean tangible benefits for consumers.[41]

c) The Third Generation of Transgenic Plants

The third generation of transgenic plants are those used in research or which are in the very early stages of development.[42]

IV. Benefits and Risks of Biotechnology

1. Benefits

Advocates argue the following benefits from the application of genetic modification: It can help to provide increased food needs in the future and offer higher quality foods[43] as well as better health care possibilities;[44] new pharmaceuticals[45] better targeted towards particular diseases, and chemi-

[40] Ibid

[41] Ibid, German Federal Agency for Nature and Conservation, supra note 36

[42] Ibid

[43] Herrera Estrella Luis and Martinez Trujillo Miguel, "Plantas Transgénicas: Potencial, uso actual y Controversias. " En ciencia, ambiente y mercado: un debate abierto, pp. 29-50, siglo xxi S.A. de C.V. en coedición con el Centro de Investigaciones Interdisciplinarias en Ciencias y Humanidades, UNAM, primera edición 2004.

[44] Agenda 21, at Chapter 16

[45] Bolivar Zapata Francisco G., " Biotecnología Moderna para el Desarrollo de México" En ciencia, ambiente y mercado: un debate abierto, pp. 261-267, siglo xxi S.A. de C.V. en co-

cals produced with few environmental pollutants in a more controlled fashion; it also provides beneficial changes to agricultural and industrial practice, including diminution of environmental pollution, conservation of soil, water and energy, friendly bio-herbicides and bio-insecticides, significant environmental benefits[46] and new possibilities for monitoring and controlling environmental effects.[47] The benefits in animals are: increased resistance, productivity and feed efficiency; better yields of meat, eggs and milk and improved animal health and diagnostic methods. The benefits in crops are: improved resistance to disease, pests and herbicides; increased nutrients, yields, and stress tolerance and reduced maturation time among others. Other potential benefits from using transgenic plants include: reduced crop production costs and increased yields; healthier, more nutritious foods; reduced environmental impact from farming and industry and increased food availability for underdeveloped countries. [48]

2. Risks

Critics argue that there is currently little evidence to support the claim of increased agricultural yield and that the consequences of the release of GMO's into the environment are likely to be significant. In particular, the effects on biological diversity and changes to agricultural and industrial practices, including an increase in environmental pollution, may be so severe that they should not be permitted.[49] The potential human health impacts, like allergens transfer of antibiotic resistance markers, and unknown effects. Socio-economic consequences are potentially severe,[50] e. g. through displacement of cash crops or traditional crops and disruption of small scale

edición con el Centro de Investigaciones Interdisciplinarias en Ciencias y Humanidades, UNAM, primera edición 2004.

[46] Alvarez Morales Ariel y Jofre Garfias Alba E, „Manejo y Control de Riesgos Aplicado a los OGMs en: Bioseguridad en la aplicación de la biotecnología y el uso de los organismos genéticamente modificados, pp. 145-159, CIBIOGEM/PNUD/GEF, primera edición 2008.

[47] Ibid, Mackenzie Ruth, supra note 5

[48] Ibid, Vines Randy, supra note 37

[49] Alvarez-Buylla Roces Elena, "Aspectos ecológicos, biológicos y de agrobiodiversidad de los impactos del maíz transgénico" En ciencia, ambiente y mercado: un debate abierto, pp. 181-218, siglo xxi S.A. de C.V. en coedición con el Centro de Investigaciones Interdisciplinarias en Ciencias y Humanidades, UNAM, primera edición 2004.

[50] Ribeiro Silvia, "Cultivos Transgénicos: Contexto Empresarial y Nuevas Tendencias" En ciencia, ambiente y mercado: un debate abierto, pp. 67-87, siglo xxi S.A. de C.V. en coedición con el Centro de Investigaciones Interdisciplinarias en Ciencias y Humanidades, UNAM, primera edición 2004.

farming systems that are prevalent in developing countries. There is a small number of companies involved in agricultural biotechnology; for critics, the grouping of seed-stock and chemical control agents in these companies is unacceptable as well as their patents on living organism, genes and/or genetic resources. It is particularly important that farmers are able to keep seed from one season to the next. And finally, intellectual property claims on gene or nucleic acid sequences without a true invention being made should not be permitted.[51]

The main environmental risks are related to genetic crosses with non-transgenic crops, leading to the appearance of new weeds, plagues and/or the disappearance of landscape important crops. Nevertheless, the major concern is about the effects on health, allergies and toxicity. The risk element must be minimized. This requires close cooperation between industry, governments and regulatory organizations. Other potential risks associated with transgenic plants include: introduction of allergenic or otherwise harmful proteins into food, transfer of transgenic properties to viruses, bacteria or other plants, detrimental effects on non-target species and the environment.[52]

To sum up, there are many applications of biotechnology, which can influence environmental quality. There is also a wide range of medicinal and industrial applications, such as the production of enzymes and antibodies. In a broader context biotechnology can be used to produce food. Biotechnology is extending the process of plant and animal manipulation for human benefit by exploiting further ranges of organisms - bacteria, viruses and fungi. This, in turn has lead to a greater understanding of genetic operation that is currently being developed to produce engineered organism with advantageous traits.

V. Biotechnology and its Commercial Use from 1996 to 2008.

1. Background of the Commercialization of Biotech/GM Crops.

The first genetically modified organisms or transgenic crops became commercially available in the mid-1990s. Since then, their uptake has been rising. During the period from 1996 to 2003[53] there was a large increase in the area used for the growth of transgenic crops worldwide, from 1.7 million hectares in 1996 to 67.7 million hectares in 2003. So far, adoption has been uneven across countries and commercialisation has involved only a few crops

[51] Ibid, Mackenzie Ruth, supra note 5

[52] Ibid, Vines Randy, supra note 37

[53] OECD 2005, Agriculture, Trade and the Environment: "The Arable Crop Sector", Chapter 2, p. 84, Paris.

(soybean, cotton, maize and rapeseed) and two traits (insect resistance and herbicide resistance). In 2003, two thirds of the transgenic crop area worldwide was found in six developed countries. The United States grew 63% of the global total, followed by Argentina (21%), Canada (6%), Brazil (4%), China (4%) and South Africa (1%). Genetically engineered crops such as maize, soybean, rapeseed and cotton have been approved for commercial use in an increasing number of countries. From 1996 to 2005, for instance, there was a more than fifty-fold increase in the area used for the growth of transgenic crops worldwide, reaching 90 million hectares in 2005. Such approvals usually follow a science-based risk/safety assessment.[54] 2. Global Status of Commercialized Biotech/GM Crops 2008

The global area of biotech crops continues to increase. The International Service for the Acquisition of Agri-biotech Applications (ISAAA) published that in 2008,[55] the number of biotech countries planting biotech crops has increased rapidly from 6 in 1996, the first year of commercialization, to 18 in 2003 and 25 in 2008.

In 2008, the global hectare of biotech continued to grow strongly reaching 125 million hectares, up from 114.3 million hectares in 2007. As mentioned before, the number of countries planting biotech crops increased to 25, comprising 15 developing countries and 10 industrial countries. The top eight countries each grew more than 1 million hectares. In decreasing areas of cultivation they were: "USA (62.5 million hectares), Argentina (21.0), Brazil (15.8), India (7.6), Canada (7.6), China (3.8), Paraguay (2.7), and South Africa (1.8 million hectares)".[56] The remaining 17 countries which grew biotech crops in 2008 in decreasing order of hectare were: Uruguay, Bolivia, Philippines, Australia, Mexico, Spain, Chile, Colombia, Honduras, Burkina Faso, Czech Republic, Romania, Portugal, Germany, Poland, Slovakia and Egypt.

It is important to note that the growth rate between 1996 and 2008 was an unprecedented 74-fold increase making it the fastest adopted crop technology in recent history. In 2008, a new biotech crop, RR® herbicide

[54] Clive James, 2005. International Service for the Acquisition of Agro-biotech Applications. Online: http://www.isaaa.org/.

[55] ISAAA Brief 39-2008: Executive Summary Global Status of Commercialized Biotech/GM Crops: 2008. The First Thirteen Years, 1996 to 2008

Online:http://www.isaaa.org/resources/publications/briefs/39/executivesummary/default.html

[56] Ibid

tolerant sugar beet, was introduced for the first time globally in the USA plus a small hectare in Canada.[57]

In 2008, 17 (or two-thirds) of the 25 biotech countries planted biotech maize (same as 2007), 10 countries planted biotech soybean (up from 9), 10 countries planted biotech cotton (up from 9) and 3 countries planted biotech canola (up from 2 in 2007). In addition two countries, the USA and China, grew virus resistant papaya; two countries, Australia and Colombia, grew biotech carnation. In China a few hectares of Bt poplar was grown and, in die USA, biotech squash and alfalfa. Biotech soybean continued to be the principal biotech crop in 2008, occupying 65.8 million hectares or 53% of the global biotech area, followed by biotech maize (37.3 million hectares at 30%), biotech cotton (15.5 million hectares at 12%) and biotech canola (5.9 million hectares at 5% of the global biotech crop area).[58]

From the genesis of commercialization in 1996 to 2008, herbicide tolerance has consistently been the dominant trait. In 2008, herbicide tolerance deployed in soybean, maize, canola, cotton and alfalfa occupied 63% or 79 million hectares of the global biotech area of 125 million hectares. For the second year running in 2008, the stacked double and triple traits occupied a larger area (26.9 million hectares, or 22% of global biotech crop area) than insect resistant varieties (19.1 million hectares) at 15%. The stacked trait products were by far the fastest growing trait group between 2007 and 2008 at 23% growth, compared with 9% for herbicide tolerance and -6% for insect resistance. Stacked traits are an increasingly important feature of biotech crops. 10 countries planted biotech crops with stacked traits in 2008. Stacked products are a very important feature and future trend, that meets the multiple needs of farmers and consumers and these are now increasingly deployed by ten countries – USA, Canada, Philippines, Australia, Mexico, South Africa, Honduras, Chile, Colombia, and Argentina, (7 of the 10 are developing countries), with more countries expected to adopt stacked traits in the future. A total of 26.9 million hectares of stacked biotech crops were planted in 2008 compared with 21.8 million hectares in 2007. In 2008, the USA led the way with 41% of its total 62.5 million hectares of biotech crops stacked, including 75% of cotton, and 78% of maize; the fastest growing component of stacked maize in the USA was the triple stacks conferring resistance to two insect pests plus herbicide tolerance. Double stacks with pest resistance and herbicide tolerance in maize were also the fastest growing component in 2008 in the Philippines doubling from 25% of biotech maize in 2007 to 57%

[57] Ibid

[58] Ibid, ISAAA Brief 39-2008, supra note 55

in 2008. Biotech maize with eight genes, named Smartstax™, is expected to be released in the USA in 2010 with eight different genes coding for several pest resistant and herbicide tolerant traits. Future stacked crop products will comprise both agronomic input traits for pest resistance, tolerance to herbicides and drought plus output traits such as high omega-3 oil in soybean or enhanced pro-Vitamin A in Golden Rice.[59]

The first biotech maize hybrids with a degree of drought tolerance are expected to be commercialized by 2012, or earlier in the USA in the more drought-prone states of Nebraska and Kansas where yield increases of 8 to 10% are projected. Drought tolerance is expected to have a major impact on more sustainable cropping systems worldwide, particularly in developing countries where drought is more prevalent and severe than industrial countries. Drought tolerance conferred through biotech crops is viewed as the most important trait that will become available in the second decade of commercialization, 2006 to 2015, and beyond, because it is by far the single most important constraint to increased productivity for crops worldwide. Drought tolerant biotech/transgenic maize, is the most advanced of the drought tolerant crops under development, and is expected to be launched commercially in the USA in 2012, or earlier. Notably, a Private/Public sector partnership hopes to release the first biotech drought tolerant maize by 2017 in Sub Saharan Africa where the need for drought tolerance is greatest.[60]

Maize has the most events approved (44) followed by cotton (23), canola (14), and soybean (8). The event that has received regulatory approval in most countries is the herbicide tolerant soybean event GTS-40-3-2 with 23 approvals (EU=27 counted as 1 approval only), followed by insect resistant maize (MON810) and herbicide tolerant maize (NK603) both with 21 approvals, and insect resistant cotton (MON531/757/1076) with 16 approvals worldwide.

Rice is unique even amongst the three major staples (rice, wheat and maize) in that it is the most important food crop in the world and more importantly, it is the most important food crop of the poor in the world. The second decade of commercialization, 2006-2015, is likely to feature significantly more growth in Asia and Africa compared with the first decade, which was the decade of the Americas, where there will be continued vital growth in stacked traits, particularly in North America, and strong growth in Brazil".[61]

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[59] Ibid, ISAAA Brief 39-2008 supra note 55
[60] Ibid
[61] Ibid, ISAAA Brief 39-2008 supra note 55

Figure 1.1 Global Status of GM Crops in 2008

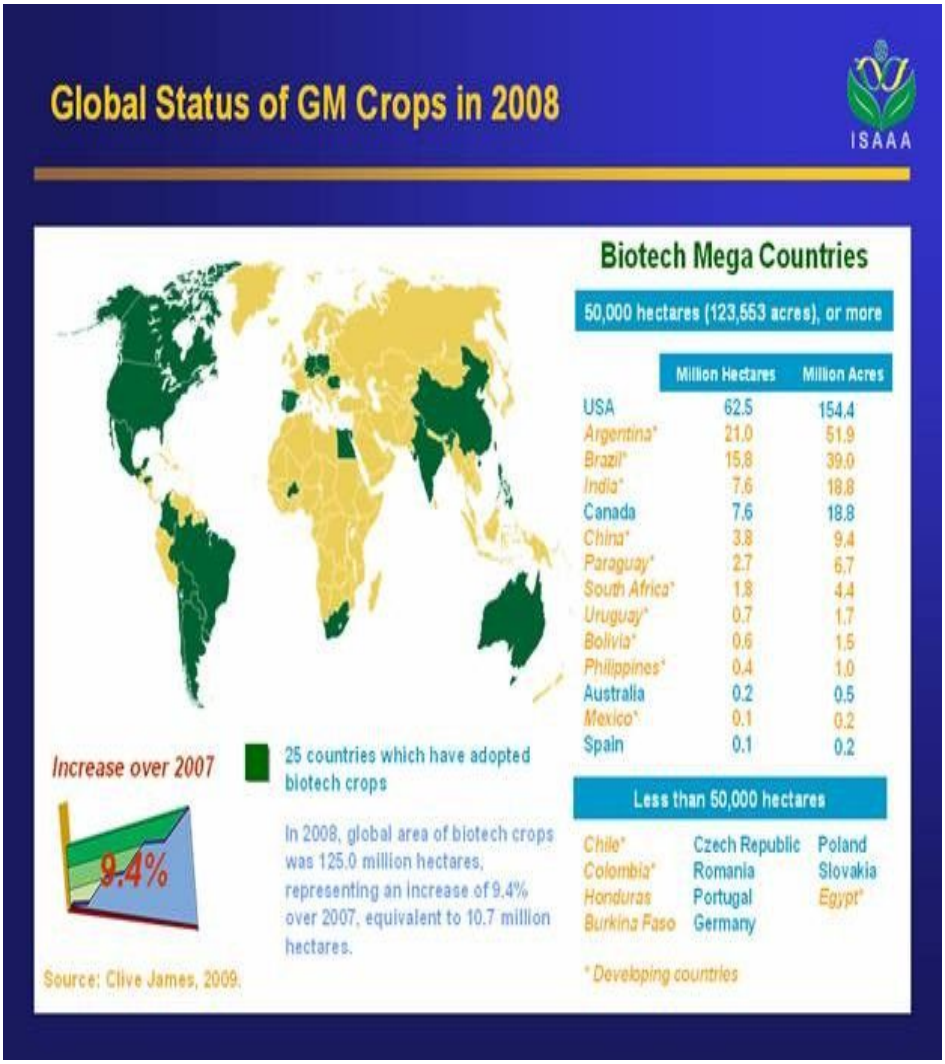
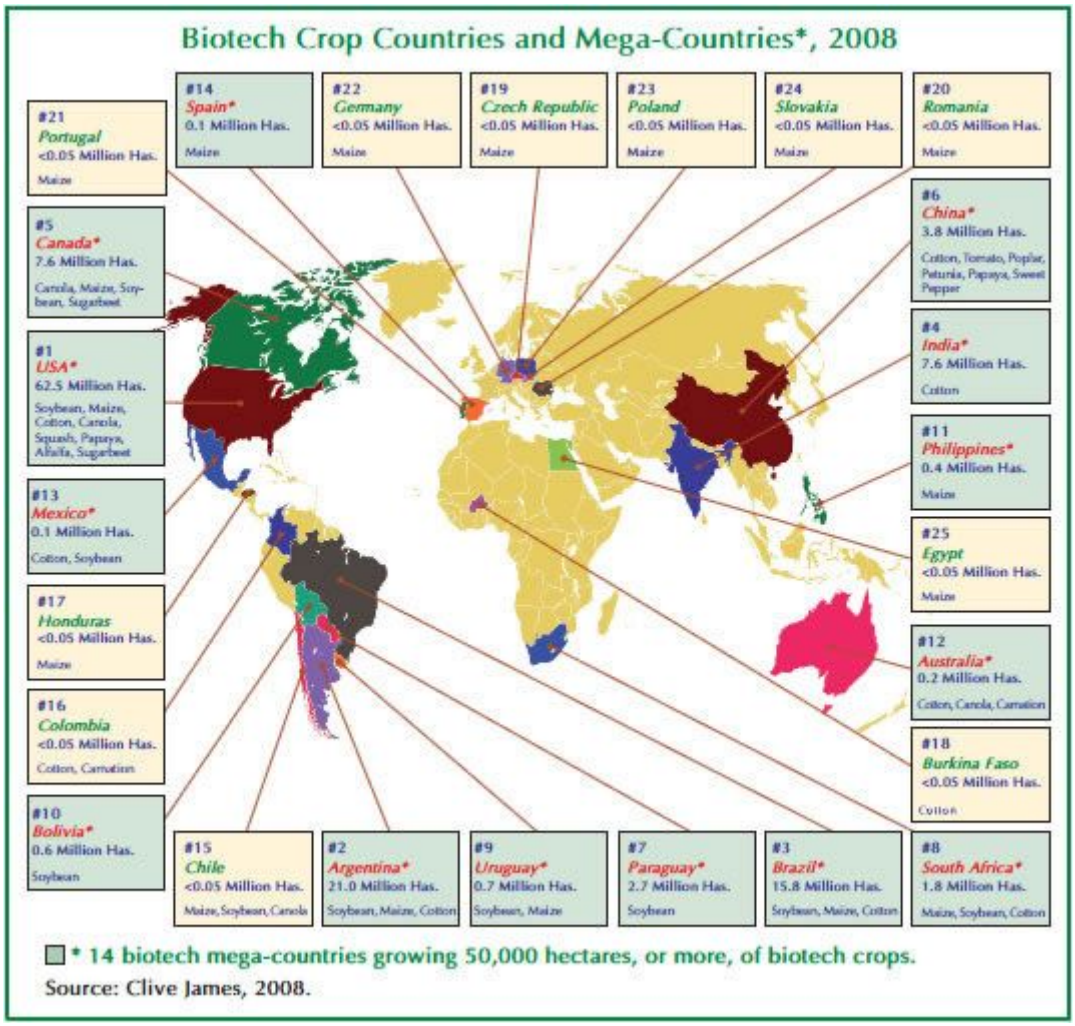


Table 1.2 Global Area of Biotech Crops in 2008: by Country (Million Hectares). 14 biotech mega-countries growing 50,000 hectares or more, of biotech crops.			
Rank	**Country**	**Area**	**Biotech Crops**
1*	**USA***	**62.5**	soybean, maize, cotton, canola, squash, papaya, alfalfa and sugar beet
2*	**Argentina***	**21.0**	Soybean, maize, cotton
3*	**Brazil***	**15.8**	Soybean, maize, cotton
4*	**India***	**7.6**	**Cotton**
5*	**Canada***	**7.6**	**Canola, maize, soybean and sugar beet**
6*	**China***	**3.8**	cotton, tomato, poplar, petunia, papaya, sweet pepper
7*	**Paraguay***	**2.7**	**Soybean**
8*	**South Africa***	**1.8**	**Maize, soybean, cotton**
9*	**Uruguay***	**0.7**	**Soybean, maize**
10*	**Bolivia***	**0.6**	**Soybean**
11*	**Philippines***	**0.4**	**Maize**
12*	**Australia***	**0.2**	**Cotton, canola, carnation**
13*	**Mexico***	**0.1**	**Cotton, soybean**
14*	**Spain***	**0.1**	**Maize**
15	**Chile**	**<0.1**	**Maize, soybean, canola**
16	**Chile**	**<0.1**	**Maize, soybean, canola**
17	**Honduras**	**<0.1**	**Maize**
18	**Burkina Faso**	**<0.1**	**Cotton**
19-25	**Czech Republik, Romania, Portugal, Germany, Poland, Slovakia and Egypt**	**<0.1**	**Maize**

Source: Clive James, 2008

Figure 1.2 Global Map of Biotech Crop Countries and Mega-Countries in 2008



VI. Important Biotechnology Institutes in Mexico

The most important institutes with experience in genetic engineering in Mexico are: firstly, the Centre for Research and Advanced Studies at Irapuato (CINVESTAV) belonging to the National Polytechnic Institute and among the pioneer research institutes in Latin America to experiment with

plant genetic modification as early as 1988.[62] CINVESTAV counts on with a team of researchers, who are exclusively dedicated to basic and applied research in agricultural biotechnology. Secondly; the International Centre for Maize and Wheat Improvement (CIMMYT) one of the centres of the Consultative Group on International Agriculture Research (CGIAR) and thirdly; the Institute for Biotechnology of the National Autonomous University (UNAM) which has also conducted field trials for research purposes or as part of the development of socially oriented products.[63] Mexico has important capacities in biotechnology, both in terms of human resources and infrastructure but without the expected financial and political support. In Mexico there are 109 institutions dedicated to biotechnology research, 21 of which are equipped with modern biotechnology laboratories.[64]Most of these institutions have training programs, which are designed to create the capacity to endorse biosafety measures and anticipate the consequences of adopting biotechnology. They are important for their contributions to national agricultural biotechnology.

VII. Multinational Biotech Corporations

To date there are only six multinationals that control the global market of transgenics seeds: Monsanto,[65] Aventis, DuPont, BASF, Bayer and Syngenta. They control the seed industry and have somehow taken control of the world's food production. Since the middle 1990s, chemical, pharmaceutical and food companies have been making unprecedented takeovers of plant breeding and genetic engineering firms. This increase of private investment in crop development has been accompanied by a worldwide adoption of neoliberal policies and reduced involvement of governments in agriculture.

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[62] Maize Biodiversity, Chapter 10 „Managing the Potential Risks and Enhancing Potential Benefits: Identification and Analysis of Management Tools and Policy Options, pp: 1-21. Online:http://www.cec.org/files/PDF/Maize-Biodiversity-Chapter10_en.pdf

[63] Alvarez Morales Ariel, "Mexico: Ensuring Environmental Safety While Benefiting from Biotechnology." pp. 90-96, 2000 In G.J. Persley and M.M. Lantin, eds., Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, D. C., 21-22 October 1999. Washington: Consultative Group on International Agricultural Research.

[64] Gálvez Mariscal Amanda, "Learning about Biosafety in Mexico: between competitiveness and conservation" in: Int. J. Biotechnology, vol. 7 nos. 1/2/3, pp. 62-75, 2005. Inderscience Enterprises Ltd.

[65] Monsanto controls 90% of the global market of transgenic seed and holds patents, which grant it rights for 20 years. For more information see Centre for Food Safety (CFS). 2007, Monsanto Vs Farmers, November 2007.

B. Protection of Biodiversity in Mexico with Special Focus on Maize

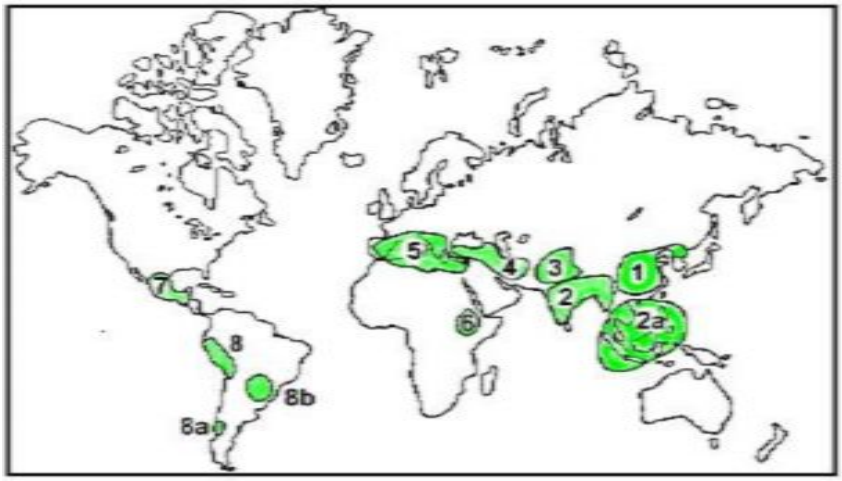
I. Current Mexican Protection of Biodiversity.

1. Defining Biological Diversity

According to the Convention on Biological Diversity, "biological diversity means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems".[66]

2. Mexico as a Vavilov Centre

Map 1.1 Mexico as Vavilov Centre



Source: Sol Ortíz García[67]

Mexico is a Vavilov centre of origin and diversity of many globally significant crops such as maize (Zea mays, Zea spp.), squash (Cucurbita spp),

[66] The definition of biological diversity means the same for the Convention of Biological Diversity (CBD) Article 2 and for the Mexican Biosafety Law Article 3 (XIII)

[67] Ortiz Garcia Sol y Adriana Otero Arnaiz, México como el centro de origen del maíz y elementos sobre la distribución de parientes silvestres y variedades o razas de maíz en el norte de México. Coordinación del Programa de Bioseguridad del Instituto Nacional de Ecología. Revista de Geografía Agrícola número 38 enero-junio 2007, pp. 141-152, Universidad Autónoma Chapingo, Dirección de Centros Regionales Universitarios, Coordinación de Revistas Institucionales, México, 2007

beans (Phaseolus spp.), cacao (Theobronnea cacao), agave (Agavacea) and chilli pepper (Capsicum annurum) that are commercially grown often in association with wild relatives. Mexico is also a COD of other crops with regional importance such as avocado (Persea americana), papaya (Carica papaya) and amaranth (Amaranthus spp). It is also a mega-diverse country with more than 10% of the global biodiversity in plant species and correspondingly high levels (40%) of endemism.[68]

3. Protection of Biodiversity and of Maize through the Mexican National Plan of Development 2007-2012

The protection of biodiversity and maize is a very important priority in the current Mexican National Plan of Development 2007-2012[69] (this plan is elaborated by each federal administration at the beginning of its six-year mandate) and is stated under Article 26 of the Political Constitution of the Mexican United States of 1917, according to the Planning Law,[70] under Articles 12 and 20 respectively. It is structured in five different branches of the public policy but this doctoral thesis will only focus on section 4: environmental sustainability, under point 4.3, biodiversity. Under this point, the Mexican government mentions that 10% of the total known species worldwide are in Mexico and some of these species are endemic. Mexico is a mega-diverse country and places fifth in variety of plants (23,441 species), fourth in amphibious species (361 species), second in mammals (491 species) and first in reptiles (804 species).[71]

Mexico is considered one of the centres of origin and diversity of maize and has a huge diversity characterized by a great quantity of improved, traditional or creole varieties and wild relatives, which are cultivated in diverse regions. Over time, the rural and indigenous communities have achieved this diversity that represents a legacy for humanity given that maize is the staple food of Mexicans and is not only a commercial commodity but constitutes a fundamental part of the Mexican culture. Therefore, the conservation and protection of its varieties is a national priority.[72]

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[68] National Biosafety Strategy, 2000, CONABIO

[69] Plan Nacional de Desarrollo 2007-2012.
Online: http://pnd.calderon.presidencia.gob.mx/index.php?page=documentos-pdf

[70] Ley de Planeación published in Mexican Official Register (D.O.F) on January 05, 1983, last amended and published in D.O.F on June 13, 2003

[71] INEGI, México hoy, edición 2007, medio ambiente pp. 27-40, published in February 2008

[72] Ibid, Plan Nacional de Desarrollo, supra note 69

4. Statement by Mexico on Transgenic Maize with Properties that Limit its Consumption as Food

In 2004, during the COP-MOP-2 in Malaysia, Mexico made a declaration against modifications to maize, which may limit its use for human consumption. The Statement can be seen below:

> *Statement by Mexico on Transgenic Maize with Properties that Limit its Consumption as Food*[73]
>
> *Being Mexico a centre of origin and diversification of maize, and:*
>
> *- paying attention to the reproductive biology of maize as an open-pollinated crop;*
>
> *- considering the dynamic character of the traditional farming systems regarding seed exchange and gene flow between local varieties and varieties originated in several geographical regions;*
>
> *- reaffirming the importance of conservation and sustainable use of that resource; and*
>
> *- understanding the strategic nature of the crop as a food for the Mexican people;*
>
> *-manifests that has decided not to allow the release to the environment of genetically modified maize that has been modified in such way as to be no longer suitable as food. That is, Mexico prohibits both experimentation and release to the environment of maize that has been modified to obtain pharmaceutical products, vaccines, industrial oils, plastics, or any modification that limits or affects its properties as food.*
>
> *-We invite all countries that are Parties, as well as all countries that are not Parties to the Cartagena Protocol to think about the use of edible crops, especially in centres of origin, as factories for products that limit its properties as food.*

As noted above, the paramount importance of this statement is crucial for Mexico as COD. In addition, the Mexican Biosafety Law provides for a "Special Regime for the Protection of Maize", which also prohibits this type of transgenic maize with properties that limit its consumption as food.

[73] "Statement by Mexico on Transgenic Maize with Properties that Limit its Consumption as Food" Online: http://bch.CBD.int/database/record.shtml?id=8601

5. Status and Trends of Biodiversity in Mexico: Overview

Mexico is situated in the zone of confluence of the Ne-arctic and Neo-tropical bio-geographic regions. It has a very varied topography and climate. Its long history of in-situ evolution and the manipulation and domestication of plant populations and species by indigenous people makes Mexico one of the five foremost biologically "mega-diverse" countries in the world. It has five of the eight principal terrestrial biomes and has one of the greatest assemblages of ecosystem diversity of the planet – a facet of biodiversity shared only with China, India, Peru and Colombia. Mexico's share of global biodiversity is estimated at 10 to 12% of all species, on a land area representing only 1.5% of the Earth's total.[74]

6. Number and Extent of Protected Areas

Mexico has 159 federal reserves covering a total of 22,275,672 hectares, with biosphere reserves comprising around 50% of the total area. 77% of this total comprises terrestrial ecosystems, while the remaining 23% protects marine environments, including coral reefs and coastal habitats. Mexico also has 67 Ramsar sites for wetland protection, with a surface of more than 5 million hectares – the second country with the highest number of wetlands of international importance in the world.[75]

7. National Biodiversity Strategy Action Plan (NBSAP)

Mexico's NBSAP 2000 has established four strategic lines that will help to accomplish CBD objectives:[76] firstly, to conserve and protect the biodiversity components; secondly, to value the different components of biodiversity; thirdly, to promote knowledge on biodiversity and fourthly, to encourage a sustainable and diversified use of biodiversity components. At a local level, the National Commission of Knowledge and Use of Biodiversity (CONABIO), has implemented the NBSAP taking into account the natural, social and cultural diversity of the country.

CONABIO is an Inter-Ministerial Commission dedicated, among other activities, to the development, maintenance and update of the National Biodiversity Information System (SNIB); to the support of projects and studies focused on the knowledge and use of biodiversity; to advise governmental institutions and other sectors; to undertake special projects and programs and share knowledge on biological diversity; and to follow up on international

[74] CBD, Mexico, Overview. Online: http://www.CBD.int/countries/?country=mx
[75] Ibid, National Biosafety Strategy, supra note 68
[76] Ibid CBD Mexico, Overview, supra note 74

agreements on topics related to biological diversity, and provide services to the public. It is a leader and innovator in biodiversity informatics and efficient processes, and maintains high quality products and services. Some of the outstanding activities and achievements of the CONABIO are: The creation of the World Information Network on Biodiversity (REMIB) and of an automated system of early warning of wildfire detection for Mexico and Central America; The Mexican priority regions program for biodiversity conservation; The development of BIOTICA curatorial information manager; and The publication of more than 350 titles and research papers. Furthermore, CONABIO acts as the scientific authority of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)[77] and as the focal point of the Clearing House Mechanism (CHM), the Scientific advisory body (SBSTTA), The Global Taxonomy Initiative (GTI), and the Global Strategy for Plant Protection (GSPC) of the Convention on Biological Diversity. At the National Level, the CONABIO also coordinates the implementation of the Biological Mesoamerican Corridor (CBM) in Mexico, and the elaboration of the Second Biodiversity Country Study, The National Biodiversity Strategy and similar processes at every State-Province in Mexico, among others.[78]

II. Defining Maize (Zea Mays Subsp. Mays)

1. General Information

Maize, or corn, is a member of the Maydeae tribe of the grass family, Poaceae. It is a robust monoecious annual plant, which requires the help of man to disperse its seeds for propagation and survival. Corn is the most efficient plant for capturing the energy of the sun and converting it into food it has a great plasticity adapting to extreme and different conditions of humidity, sunlight, altitude and temperature. It can only be crossed experimentally with the genus Tripsacum however, member species of its own genus (teosinte[79]) easily hybridise with it under natural conditions.[80]

[77] Convention on International Trade in Endangered Species of Wild Fauna and Flora, (1973), Washington 993 UNTS 243. In force 1 July 1975

[78] For more information see: http://www.conabio.gob.mx

[79] Teosinte is the name derived from the Aztec "teocentli". Serratos Hernández José Antonio, El origen y la diversidad del maíz en el continente americano, greenpeace 2009, available at: www.greenpeace.org.mx.

[80] OECD, 2006, "Safety Assessment of Transgenic Organisms", Volume 1, OECD Consensus Documents, Volume 1, Seccion 3, maize (zea mays subsp. Mays) pp. 47-71, Paris.

The following table illustrates 421 registers of teosintes: 84 registers are for Zea diploperennis, 164 are for Zea Mays mexicana, 131 are for Zea Mays parviglumis and 42 are for Zea perennis.

Table 1.3 Infra-species of Teosintes		
Number	**Taxonomie**	**Register**
1	**Zea diploperennis**	**84**
2	**Zea mays Mexicana**	**164**
3	**Zea mays parviglumis**	**131**
4	**Zea perennis**	**42**
Total		**421**

Source: CONABIO[81]

The next map illustrates the current diversity of teosintes and maize in Mexico. Thus, it is of paramount importance to protect the diversity of maize and teosintes in the country due to the fact that maize is open pollinated and may be easily contaminated without biosafety measures.

[81] CONABIO, julio de 2006. Documento base sobre centros de origen y diversidad en el caso del maíz en México. Revista de Geografía Agrícola número 38 enero-junio 2007 pp. 121-140, Universidad Autónoma Chapingo, Dirección de Centros Regionales Universitarios, Coordinación de Revistas Institucionales, México, 2007.

Map 1.2 Teosintes (red) Maize (green)

Source: Sol Ortíz García[82]

2. Reproductive Biology of Maize

a) Sexual Reproduction

Zea Mays is an allogamous plant that propagates through seed produced predominantly by cross-pollination and depends mainly on wind borne cross-fertilisation. Fertilisation occurs after the pollen grain is caught by the silk and germinates to create the pollen tube which penetrates upwards to the micropyle and enters the embryo sac. The pollen is carried mainly by wind, thus it is notable that pollination can occur even, although rarely, over long distances measured in kilometres.[83]

b) Asexual Reproduction

There is no asexually reproductive maize. Cell/tissue culture techniques can be used to propagate calli and reproduce tissues or plants asexually; however, with maize cells and tissues these techniques are difficult.[84]

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[82] Ortiz Garcia Sol. El Uso de los Organismos Genéticamente Modificados en México: retos y estrategias para su regulación. 09 de octubre del 2007, Universidad Autonoma de la Ciudad de México. CIBIOGEM

[83] Ibid, OECD, 2006, Safety Assessment of Transgenic Organisms, supra note 80

[84] Ibid, OECD, 2006, Safety Assessment of Transgenic Organisms, supra note 80

3. Crosses.

a) Intra-specific Crosses

Maize is essentially a 100% open-pollinated (cross-fertilising) crop species. Until the 20th century, corn evolved through open pollinated varieties, which are a collection of heterozygous and heterogeneous individuals developed through mass selection by the people from the different civilizations existing in the Americas.[85] There is a great sexual compatibility between maize and annual teosinte and it is known that they produce fertile hybrids.[86] In areas of Mexico and Guatemala maize and teosinte freely hybridise when in proximity of each other. The frequency reported is of one F1 hybrid (corn x teosinte) for every 500 corn plants or 3 to 5 % of the teosinte population for the Chalco region of the Valley of Mexico. Maize may introgress to teosinte[87], however, there is incompatibility between some maize population and certain types of teosinte resulting in low fitness of some hybrids that prevents a high rate of introgression.[88]

b) Inter-specific Crosses

Although it is extremely difficult, Tripsacum species (T. dactyloides, T. floridanum, T. lanceolatum, and T. pilosum) can be crossed with corn; however, hybrids have a high degree of sterility and are genetically unstable.[89] Tripsacum and Zea have different chromosome numbers and it was found that the addition of an extra Tripsacum chromosome into the maize genome would occur with low frequency and consequently the rate of crossing-over would be extremely reduced.[90]

4. Gene flow

The interaction between domesticated plants and their wild relatives can lead to hybridisation and in many cases to gene flow of new alleles from a novel crop into the wild population. While gene flow per se is not a con-

[85] Halauer, A.R. 2000. Potential for outcrossing and weediness of genetically modified insect protected corn. APHIS-USDA

[86] Wilkes, H.G. 1977. "Hybridisation of Maize and Teosinte in Mexico and Guatemala and the Improvement of Maize". Economic Bonaty 31, Pp. 254-293

[87] Kermicle, J. L. and J. O. Allen, 1990, Cross-incompatibility between maize and teosinte. Maydica 35, Pp 399-408

[88] Evans, M. M. S. and J. L. Kermicle, 2001. Teosinte crossing barrier 1, a locus governing hybridisation of teosinte with maize. Theor. Appl. Genet. 103, Pp. 259-265

[89] Mangelsdorf, P.C. 1974. Corn. Its Origin, Evolution and Improvement. Harvard Univ. Press, Cambridge, MA.

[90] Gallinat, W.C. 1988. The Origin of Corn, in: G.F. Sprague and J. W. Dudley (eds.). Corn and Corn Improvement. Agronomy Monographs No. 18. American Society of Agronomy, Madison, WI. Pp. 1-31.

cern, theoretically, it can lead to the potential for the evolution of aggressive weeds or the extinction of rare species. There has been preliminary documentation of this in some cases although not for maize.[91]

Another factor to take into account regarding gene flow is the exchange of seed and traditional maize improvement practised by peasant communities and small farmers. Rural communities are open systems where there is a constant flow of genetic material among communities over large areas therefore, as in the case of Mexico a land race variety, an improved variety, or a transgenic variety of maize, can reach any zone of the country even the most isolated ones, such as those where teosinte grows.[92] The human factor together with the changes in policy and strategies in maize production may increase several fold the chance of gene flow between improved maize, teosinte and landraces.[93]

5. Agro-ecology: Cultivation

Although Maize was domesticated and diversified mostly in the Meso-American region, at present it is cultivated mainly in warm temperate regions where the conditions are best suited for this crop.[94] The farmland of Mexico covers a wide range of ecological conditions: from sea level to 2800 meters, from very dry to wet climates, well drained to poorly drained soils, flat to severe slopes, shallow to deep soils, low to high solar radiation; drought, wind and frost damage are common. The poorest farmers are typically Indian farmers that inhabit the Sierras. Dry beans, squash, grain amaranth and several other species were also domesticated by the inhabitants of the region, as complements to their diet. They also developed the typical "milpa cropping system", a cultivated field that may involve the association of the inter-cropping of maize, beans, squash, grain, amaranth, tree species and several tolerated herbal species. The isolation of these farming communi-

[91] Ellstrand, N. C. H. C. Prentice and J. F.Hancock. 1999. Gene Flow and Introgression from Domesticated Plants into their wild Relatives. Ann. Rev. Ecol. Syst. 30, Pp. 539-563.

[92] Louette, D. 1997. Seed exchange among farmers and gene flow among maize varieties in traditional agricultural systems in: A. Serratos, M.C. Willcox and F. Castillo (eds.). Gene Flow among Maize Landraces, Improved Maize and Teosinte. Implications for Transgenic Maize. CIMMYT, Mexico, D. F. pp. 56-66.

[93] Nadal, A. 1999. El maíz en México: Algunas implicaciones ambientales del Tratado de Libre Comercio de América del Norte en: Evaluation de los efectos ambientales del Tratado de Libre Comercio del Norte. Comisión para la Cooperación Ambiental, Montréal, Quebec, Canada. Online: http://www.cec.org

[94] Norman, M. J. T., C. J. Pearson and P. G. E. Searle. 1995. The ecology of tropical food crops. Cambrigde University Press, Cambridge, Great Britain. Pp. 126-144, second edition.

ties has caused the development of a great resource of maize germplasm diversity, which is conserved using in situ and ex situ (germplasm banks) means. Inter-cropping of maize with other crops is practiced in many areas of less developed countries.[95] These systems imply changes at the level of cultivation and management of maize production which are important in terms of ecological relationships. [96] Maize has lost the ability to survive in the wild due to its long process of domestication, and needs human intervention to disseminate its seed.

6. Soil Ecology (Microbiology of Maize Rhizosphere)

Maize root systems act as a soil modifier due to their association with several microbil groups such as bacteria, fungi, actinomycetes protozoa and mites. [97] The highest microbial population usually is bacteria, followed by fungi and actinomycetes. All these microbial groups play a particular role in the soil ecology, such as nutrimental cycling and the availability of nutrients for plant growth. In addition, these microbial organisms contribute to the protection of the root system against soil pathogens.

7. Unintended Effects of Transgenic Maize

The commercial release of transgenic maize expressing delta-endoxin from Bacillus thuringiensis has been the driving force behind the interest of ecologists concerned with the evolution of pest resistance to pesticide plants.[98] The evolution of pest resistance is commonly known in any system where negative selection occurs from the use of traditional chemical pesticides, including plants bred traditionally for pest resistance. Recently, an effect of pollen from transgenic maize on the monarch butterfly larvae, a non-target insect, has preliminarily been described.[99] The possible consequences of transgenic maize in a COD like Mexico are: selection for Bt resistance in insects, super weed creation in the case that herbicide tolerance introgressed to wild relatives, effects on non-target species, community and ecosystem effects and genetic erosion.

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[95] Ibid

[96] Ibid, OECD, 2006, Safety Assessment of Transgenic Organisms, supra note 80

[97] Vega-Segovia, M. L. and R. Ferrera-Cerrato. 1996[a]. Microorganismos del rizoplano del maiz y frijol inoculados con mutantes de Rhizobium y Azospirillum en: J. Pérez-Moreno anf R. Ferera-Cerrato (eds.). Avances de Investigación, Área de Microbiología de Suelos. PROEDAF-IRENAT, Colegio de Postgraduados. Montecillo, Estado de México. Pp. 9-17.

[98] Ibid, OECD, 2006, "Safety Assessment of Transgenic Organisms, supra note 80

[99] Losey. J. E., L.S. Rayor and M. E.Carter. 1999. Transgenic pollen harms monarch larvae. Nature 339, pp. 214.

8. Maize Biotechnology

For practical purposes maize biotechnology can be divided into two fields: genetic engineering and molecular genetics.

a) Molecular Genetics

Molecular genetics refers to the identification and location (genome mapping) of genes within the genome of organisms by means of molecular techniques that make use of the chemical properties of DNA.[100]

b) Genetic Engineering

Genetic engineering methodologies can make possible the insertion of foreign DNA, from organisms of different species, into another individual organism. In maize, at the commercial level, the introduction of foreign DNA has been successfully accomplished through a technique known as biolistics. At present there are two types of commercially released transgenic maize produced by means of genetic engineering: first, insect pest resistant maize or Bt-maize; and second, herbicide resistant maize. However, more research and development in this area is underway.[101]

Transposable elements are not expected to affect transgenes any differently from their reported effects on non-modified genes of maize, unless sequences of the transposable element are contained in the inserted genetic material.[102] The potential crossing of landrace maize germplasm with transgenic improved maize, hybrids or inbreds should be considered carefully since, for example in Mexico, the high incidence of transposable elements in landraces of maize is well known.[103]

III. Mexico as Centre of Origin and Diversity of Maize

In Mexico, maize is not only the main staple food. Maize has particular cultural, social, economic and spiritual significance. To understand the origin of maize, it is important to know that for many years there have been different hypothesis about its origin but at present there are only four main

[100] Hoisington, D., G. M. L. Morris. 1998. Varietal Development, Applied Biotechnology en: M. L. Morris (ed.) Maize Seed Industries in Developing Countries, Lynne Rienner Publishers, Inc. and CIMMYT, Int. Pp. 77-102.

[101] Ibid, OECD, 2006, Safety Assessment of Transgenic Organisms, supra note 80

[102] Tsafaris, A. S. 1995. The biology of maize (Zea mays, L.). Document XI/754/95 European Commission.

[103] Gutiérrez-Nava, M. L., C. A. Warren, P. León and V. Walbot. 1998. Transcriptionally active MuDR, the regulatory element of the mutator transposable element family of Zea mays, is present in some accessions of the Mexican land race Zapalote Chico. Genetics 149, pp. 329-346

hypotheses.[104] However, the most accepted one by scientists since the end of the 1980s is about the descent from teosinte.[105] It says that maize was domesticated from teosinte by human selection. This is the oldest proposal and was advanced by Ascheron in 1895.[106] John Dobley[107] consolidated in his investi-

[104] The four main hypotheses on the origin of maize are as follow: First, the descent from teosinte hypothesis. This is the oldest proposal and was advanced by Ascheron in 1895 (Mangelsdorf and Reeves, 1939) and proposes that maize was domesticated from teosinte by human selection. This is the most widely accepted hypothesis at present (Beadle, 1986; deWet and Harlan, 1972; Doebley and Stec, 1991; Doebley, 1990; Galinat, 1977; Iltis and Doebley, 1980; Goodman, 1988; Kato, 1984; Kato and López, 1990; Timothy et al., 1979). The main problem with this hypothesis was how the distichous small female spike could have been transformed into the polistichous gigantic maize spike (ear) by human selective domestication. However, Doebley et al., (1990) have found five major genes controlling key traits distinguishing maize and teosinte, and more recently Wang et al., (1999) have discussed a gene controlling the inflorescence character in teosinte and maize. Second the tripartite hypothesis. The main assumption of this hypothesis is that there existed wild maize in the past, which is considered extinct at present. This wild maize gave origin to the annual teosintes by crossing with Tripsacum. Further crossing of teosinte with wild maize gave rise to the modern races of maize (Mangelsdorf and Reeves, 1939; and Mangelsdorf, 1974). Later on Mangelsdorf et al., (1981) based on experimental crossing between Z. diploperennis and the race Palomero Toluqueño of maize and further observations of its progenies, proposed that the annual teosintes are the products of this crossing. The fact that until now no evidence at all has been found about the existence, in the past or at present, of a wild maize, this hypothesis has lost much credence with time (although see Eubanks, 1995). Third, the common origin hypothesis, which proposes that maize, teosinte and Tripsacum originated by "ordinary divergent evolution" from a common ancestor. Consequently, it is conceived that there existed a wild maize plant that further was transformed into a cultivated plant by selection and care of man (weatherwax, 1955; Randolph, 1955; Randolph, 1959). The postulation that wild maize existed in the past makes this hypothesis not acceptable, as in the case of tripartite hypothesis. Finally, the fourth one is the catastrophic sexual transmutation hypothesis. It proposes that the maize ear evolved from the terminal male inflorescence of teosinte lateral branch by a "....sudden epigenetic sexual transmutation involving condensation of primary branches and further genetic assimilation under human selection of an abnormality, perhaps environmentally triggered" (Iltis, 1983). The finding of five mutant genes controlling key characters separating maize from teosinte (Doebley ans Stec, 1991); Doebley et al., 1990) seems to make the catastrophic sexual transmutation hypothesis untenable.

[105] Serratos Hernández José Antonio, "El origen y la diversidad del maíz en el continente americano", Greenpeace 2009.

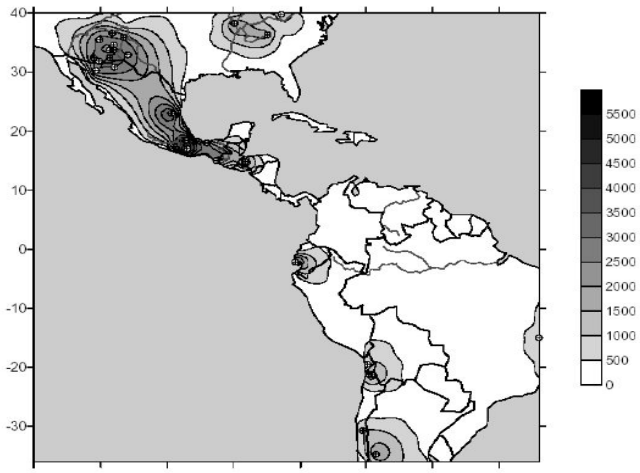
Online: www.greenpeace.org.mx.

[106] Mangelsdorf, P. C. and R. G. Reeves. 1939. The origin of indian corn and ist relatives. Texas Agric. Expt. Sta. Bull. 574.

[107] Dobley J. Goodmann J, Stuber CW. 1985. Isozyme variation in the races of maize from Mexico. American Journal of Botany 72(5): 629-639; Doebley J., Stec A, Wendel J., Edwards M. 1990. Genetic and morphological analysis of a maize-teosinte F2 population: Implications for the origin of maize. PNAS, volumen 87; paginas 9888-9892; Dobley J.,

gations this theory and at present, the scientific academy has made a consensus and they agreed that maize descended from teosinte.[108] The following map 1.1 shows the maize macrofossils in Mexico and in Latin America.

Map 1.3 Maize Macrofossils



Source: Sol Ortíz García[109]

It is worth mentioning that the centre of maize domestication is located in the Meso-American region consisting of Central and South Mexico and Central America, recognised as one of the main centres of origin and development of agriculture as well as COD of more than one hundred crops.[110] According to experts corn has several origins in both Mexico and in South America.[111] Nevertheless, experts like Doebley et al.[112] say that maize

Stec A. 1991. genetic analysis of the morphological differences between maize and teosinte. Genetics, Volumen 129; páginas 285-295; Dobley J. 1992. Mapping the genes that made maize. Treds in Genetics, Volumen 8, número 9; págnas 302-307.

[108] Ibid, Serratos Hernández José Antonio, supra note 105

[109] Ortíz Garcia Sol. El uso de los organismos genéticamente modificados en México: retos y estrategias para su regulación. Conferencia presentada el 09 de octubre del 2007, Universidad Autonoma de la Ciudad de México. CIBIOGEM

[110] Vavilov, N. I. 1951. The Origin, Variation, Immunity and Breeding of Cultivated Plants. Translated from the Russian by K. Starr Chester. The Ronald Press Co. New York. Pp. 94; Smith, B. D. 1995. The Emergence of Agriculture. Scientific American Library, new York. Pp. 231; Harlan, J. R. 1992. Crops and Man. American Society of Agronomy, Inc. Crop Science Society of America, Inc. Madison, WI. USA. Pp. 284, Second Edition.

[111] In South America there are varieties of maize: In Argentina (47), Bolivia (77), Brasil (44), Colombia (23), Cuba (11), Chile (29), Ecuador (31), Guatemala (33), El Salvador, Hondu-

originated form a single domestication in southern Mexico 9000 years ago.[113] In the American Continent at least 300 landraces have been identified.[114]

In Mexico, there are two principal seed banks: CIMMYT and the National Institute of Forestry and Agricultural Research (INIFAP).[115] The collected seeds are preserved *ex situ* in gene banks of international public institutions such as CIMMYT in collaboration with Mexican national agricultural research programs. At the same time, projects related to *in situ* conservation of maize have been established, and the dynamics of maize diversity is actually being observed, described, and analyzed.

Table 1.4 Races of Maize in Mexico	
Ancient Indigenous Group	Arrocillo amarillo, palomero toluq., nal-tel and chapalote
Pre-Columbian Exotic Group	Cacahuacintle, maíz dúlce and harinoso de 8
Pre-Historic Mestizos	Vandeño, tuxpeño, tehua, olotillo, tepecintle, jala, comitéco, zapalote grande, zapalote chico, pepitilla, cónico, reventador y tabloncillo
Modern Incipient Group	Celaya bolita, chalqueño and cónico norteño

Source: Serratos[116]

The teosinte, a close relative of maize, is still present in many corn-producing regions. It s important to mention that peasant agricultural practices have contributed to the maintenance of native corn diversity, due to selection in local environments and seed interchanges.

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ras, Costa Rica, Nicaragua and Panamá (11), Paraguay (10), Perú (66), Uruguay (8) and Venezuela (19). Serratos Hernández José Antonio, "El origen y la diversidad del maíz en el continente américano", greenpeace 2009, available at: www.greenpeace.org.mx.

[112] Doebley, J. M. M. Goodman and C. W. Stuber. 1987a. Patterns of Isozyme Variation between Maize and Mexican Annual Teosinte. Econ. Bot. 41(2):234-246.

[113] Matsuoka, Y., Y. Vigouroux, M. M. Goodman, J. Sanchez G., E. Buckler and J. Doebley. 2002. A single domestication for maize shown by multilocus microsatellite genotyping. Proc. Natl. Acad. Sci. USA 99: 6080-6084.

[114] Ibid Serratos Hernández José Antonio, supra note 104

[115] Eckard Boege y Victor Manuel Toledo: Biodiversidad, Recursos Genéticos y Areas Naturales Protegidas, pp 191-213 en: Agenda para el desarrollo, vol. 14, 2007, Editorial Porrúa.

[116] Ibid, Serratos, supra note 105

IV. Importance of Maize both Worldwide and for Mexico

1. Production of Maize for Food and Feed

Maize is the world's third leading cereal crop, following wheat and rice.[117] It is grown as a commercial crop in over 25 countries worldwide. Field maize has been grown for 8000 years in Mexico and Central America and for 500 years in Europe. Maize is naturally cross-pollinated and until about 1925 mainly open pollinated varieties were grown. Today mainly hybrids are grown. To produce hybrid seed, the tassels are removed from the plants prior to pollen shedding, so that only one sort of pollen will be received by silks. The hybrid plants grown from this seed produce a more vigorous growth and higher yields. Sweet maize, derived from field maize by crossbreeding, introducing a sugar gene, has been grown in the USA since 1930 and in Europe since 1979. Maize for popcorn is a minor crop. The cultivation and use mainly takes place in the USA.[118]

2. Nutritional Value of Maize

The importance of cereal grains to the nutrition of millions of people around the world is widely recognized.[119] Because they make up such a large part of diets in developing countries, cereal grains cannot be considered only as a source of energy since they provide significant amounts of protein as well. It is also recognized that cereal grains have a low protein concentration and that protein quality is limited by deficiencies in some essential amino acids, mainly lysine Much less appreciated, however, is the fact that some cereal grains contain an excess of certain essential amino acids that influence the efficiency of protein utilization. The classic example is maize. Other cereal grains have the same constraints but are less obvious.

3. Importance of Maize Worldwide

Maize is of paramount importance worldwide because it is grown in more countries than any other cereal[120] and it is the third most important cereal crop in the world, after wheat and rice.[121] In the member countries of

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[117] Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites, No. 6, 2002, ENV/JM/MONO(2002)25

[118] Jugenheimer RW, 1976, Corn Improvement, Seed Production, and Uses. John Wiley & Sons, Inc, New York, USA

[119] FAO, 1992, Maize in Human Nutrition. FAO: Food and Nutrition Series, No. 25. FAO, Rom

[120] Ibid OECD 2006, Safety Assessment of Transgenic Organisms, supra note 80

[121] Ibid OECD 2005, the Arable Crop Sector, p. 33 supra note 53

the Organisation for Economic Co-operation and Development (OECD), maize production ranks second, after wheat. There are six countries (the United States, China, Brazil, Mexico[122], France and Argentina), which produce 75% of the world's maize. However, the United States is the largest maize producer and exporter accounting for approximately 40% of the grain produced in the world, follow by China, Brazil and Mexico. In the majority of the cases maize production is used for animal feed or industrial input, with only approximately 20% going to human consumption.[123] Nearly 94% of maize exports from the United States are destined for Latin America in general and for Mexico in particular (11% of US exports). It is known, that the USA is the largest producer, not only of maize but of transgenic maize. The exports of these crops to Mexico are a delicate issue because of the possible contamination of wild relatives of maize and since Mexico is the COD of maize. However, this issue will be analysed and described throughout this chapter and in chapter III which explain the trade implications of GMO's, especially of maize in Mexico.

4. Importance and Significance of Maize for Mexico

Contrary to the majority of the world's use of maize, 68% of all maize grown in Mexico is used for human consumption.[124] Maize is important because all parts of the maize plant are used for different purposes.[125] In general, there are many specific uses of maize plant depending on the region. Globally, just 21% of the total grain production is consumed as food. In Mexico maize is the most important crop in terms of land area and the second one in terms of gross production volume.

There are many varieties of maize[126] (65 varieties) and its wild species (i.e. the teosintes), although their distribution has been affected by general

[122] Mexico became a member of the OECD on 18 May 1994.
http://www.oecd.org/document/58/0,3343,en_33873108_33873610_1889402_1_1_1_1,00.html

[123] Ibid OECD, the Arable Crop Sector, supra note 51

[124] Ibid OECD, the Arable Crop Sector, p. 34, supra note 53

[125] Maize is used for processed grain (dough): to make Tortillas, Tamales and Tostadas for grain: to make Pozole, Pinole and Pozol, and amongst for dry stalks: to build fences

[126] In Mexico there are at present 65 varieties of maize: Ancho, Apachito, Arrocillo Amarillo, Arrocillo, Azúl, Blandito, Blando Sonora, Bofo, Bolita, Cacahuacintle, Carmen, Celaya, Chalqueño, Chapalote, Clavillo, Comiteco, Conejo, Conico, Cónico Norteño, Coscomatepec, Cristalino Chihuahua, Complejo Serrano Jalisco, Cubano Amarillo, Dulce de Jalisco, Dulcillo Noroeste, Dzit Bcal, Elotes Cónicos, Elotes Occidentales, Elotero de Sinaloa, Fasciado, Gordo, Harinoso, Harinoso de Ocho, Jala, Lady Finger, Maíz Dulce, Maizón, Motozinteco, Mushito, Nal Tel, Nal-Tel de Altura, Olotillo, Olotón, Onaveño, Palomero

land-use practices, intensive agriculture and urbanization.[127] Much of the crop is grown by subsistence farmers on small plots under rain-fed conditions, where yields are typically low. Maize draws more heavily on soil nutrients than other grains and oilseeds, and substantial amounts of fertiliser and water are needed to maintain yields. Maize is often planted in rotation with others crops.[128] "Maize was and is the main agricultural commodity in terms of production, value and crop area in Mexico".[129] Throughout the 1990s and up to 2005, more area was allocated to maize production than to the sum of other coarse grains, wheat, beans, rice, oilseeds and sugar. Looking at food consumption for some important commodities, the importance of maize in the Mexican diet stands out.

The role of maize in the Mexican diet is not only cultural, but also of paramount importance as the main source of energy and nutrients. Maize provides up to 65% of the energy intake in lower socio-economic strata. The daily average consumption of maize + tortilla is 365 g. per capita.[130] The next table clearly shows that the consumption of maize per person in Mexico is more than six times higher than the world average.

Table 1.5 Maize Consumption per Capita (kg per person)		
	1992-1994	2001-2003
Mexico	122.6	19.1
World	126.4	18.5

Source: FAOSTAT

de Chihuahua, Palomero Toluqueño, Pepitilla, Ratón, Revenatdor, San Juan, Serrano de Jalisco, Tablilla, Tablilla de Ocho, Tabloncillo, Tabloncillo Perla, Tehua, Tepecintle, Tunicata, Tuxpeño Norteño, Tuxpeño, Vandeño, Xmejenal, Zamorano Amarillo, Zapalote Chico and Zapalote Grande. Serratos Hernández José Antonio, El origen y la diversidad del maíz en el contienente américano, greenpeace 2009, available at: www.greenpeace.org.mx.

[127] Dyer-Leal, G. and A. Yúñez-Naude (2003), "NAFTA and Conservation of Maize Diversity in Mexico", paper presented at the 2nd North America Symposium of CEC on Assessing the Environmental Effects of Trade, 14 February, Mexico City.

[128] Ibid OECD, the Arable Crop Sector, p. 34, supra note 53

[129] OECD, 2006, "Agricultural Policies and Commodity Markets", Chapter 5, p. 115 in: Agricultural and Fisheries Policies in Mexico", Recent Achievements, Continuing the Reform Agenda, OECD, Paris.

[130] Gálvez Mariscal Amanda, M. Quirasco, A. Acatzi, J. Magaña, C. Moles, C. Peña, M. Castillo and M. Signori. "Detection and Quantification of GM Maize Varieties in Mexican Imports" in: Harmonisation Needs at International and Regional level. First Conference on GMO's Analysis, June08.http://gmoglobalconference.jrc.ec.europa.eu/DetailedProgramme.htm

V. Consumption of Maize in Developed and in Developing Countries

Maize consumption differs from one country to another. In developed countries for example, maize is used as feed as well as raw material for industrial products, in contrast, in developing countries, maize is used as food, it is the basic staple food for the population and it is an important ingredient in its diet. In many Latin America countries maize is produced on small land[131] units. For instance, most of the land planted with maize (77%) in Mexico is less than 5 hectares in size, which equals 67% of total production. Only 5% of the units of land dedicated to maize production have increased in size but the technology inputs are below average: only 40% of producers used improved seed; 64% use nitrogen and phosphorous to fertilise the soil and only 42% receive technical assistance.[132]

Different researchers agree that the division of the consumption of maize around the world may be divided into two sections: In developed countries, maize is used, as mentioned above, to feed animals, directly in the form of grain and forage or sold to the feed industry and as raw material for extractive industries. And in developing countries, the use of maize differs. For example, in Africa and Latin America maize is used mainly for food. In Asia it is generally used to feed animals.[133] Under this division it is clear that for developed countries maize has little significance as human food.[134] For instance, in the European Union (EU) maize is used as feed as well as raw material for industrial products.[135] Thus, maize breeders in the USA and the EU focus on agronomic traits for its use in the animal feed industry and on a number of industrial traits such as high fructose corn syrup, fuel alcohol, starch, glucose, and dextrose.[136] It is also noteworthy to understand how the demand for corn, used for the rising consumption of sweet corn and popcorn

[131] Turrent-Fernández, A., N. Gómez-Montiel, J. L. Ramírez Díaz, H. Mejía-Andrade, A. Ortega-Corona and M. Luna-Flores. 1997. Plan de investigaciones del sistema maíz-tortilla en los Estados Unidos Mexicanos. Internal Document, INFAP-SAGAR.

[132] Ibid, OECD 2006, Safety Assessment of Transgenic Organisms", supra note 80

[133] Morris, M. L. 1998. Overview of the World Maize Economy. In: M. L. Morris (ed.). Maize Seed Industries in Developing Countries. Lynne Rienner Publishers, Inc. and CIMMYT, Int. pp. 13-34

[134] Galinat, W.C. 1988. The origin of corn. In: G.F. Sprague and J. W. Dudley (eds.) Corn and Corn Improvement. Agronomy Monographs No. 18. American Society of Agronomy, Madison, WI. Pp. 1-31; Shaw, R.H. 1988. Climate requirement. In: G.F. Sprague and J.W. Dudley (eds.) Corn and Corn Improvement. Amer. Soc. Agron. Mafison, WI. Pp. 609-633.

[135] Tsaftaris, A. S. 1995. The Biology of Maize (Zea mays, L.). Document XI/754/95 European Commission.

[136] Ibid, OECD, 2006, Safety Assessment of Transgenic Organisms, supra note 80

in developed countries, is met.[137] Transgenic maize is already being used as a crop not only with agricultural purposes in several developed countries. These countries have dominant maize production because they have advantageous factors that contribute to generate maize surplus. First, "maize production is generally concentrated in zones of abundant rainfall and fertile soils"[138], and second, the use of many inputs and technology is extensive.[139] By contrast, in developing countries the situation is highly variable. From Mexico to the Northern Andean region in South America, maize is a very important staple food in rural areas and the use of technology together with improved varieties is limited. However, Brazil, Argentina, and Chile resemble developed countries because in these countries maize is a "cash crop grown by large scale commercial producers using extensive mechanisation."[140]

C. Concerns

I. Contamination of Maize in Mexico: The Report of the Commission for Economical Cooperation (CEC)

In 1998, the Mexican Secretariat of Agriculture imposed a *de facto moratorium* on the experimental cultivation of GE maize due to fact that there is uncertainty about potential consequences on maize diversity being an open-pollination crop. However, the *de facto moratorium* did not prevent the planting of transgenic maize and the introgression was found in some localities of Oaxaca and Puebla in 2001.[141] The report on the presence of transgenes in

[137] White, P. J. and L. M. Pollak. 1995. Corn as a Food Source in the United States: Part II. Processes, Products, Composition and Nutrient Values. Cereal Foods World. Amer. Assoc. of Cereal Chemists. St. Paul. MN. Pp. 756-762; Benson. G. O. and R. B. Pearce. 1987. Corn Perspective and Culture. In: S. A. Watson and P. E. Ramstad (eds.). Corn: Chemistry and Technology. Amer. Assoc. of Cereal Chemistry. St. Paul, MN. Pp 1-29.

[138] Ibid, the Arable Crop Sector, supra note 52

[139] Pollak, L.M. and P. J. White. 1995. Corn as a Food Source in the United States: Part I. Historical and Current Perspectives. Cereal Foods World. Amer. Assoc. of Cereal Chemists. St. Paul. MN. Pp. 749-754. See Rooney L. W. and S. O. Serna-Saldivar. 1987. Food uses of whole corn and dry milled fractions. In: S. A. Watson and P. E. Ramstad (eds.). Corn: Chemistry and Technology. Amer. Assoc. of Cereal Chemistry. St. Paul, MN. Pp. 399-429. And Shaw, R.H. 1988. Climate Requirement. In: G.F. Sprague and J.W. Dudley (eds.) Corn and Corn Improvement. Amer. Soc. Agron. Mafison, WI. Pp. 609-633.

[140] Ibid, Morris M. L., supra note 133

[141] Quist D. and I. Chapela. 2001. Transgenic DNA Introgressed into Traditional Maize Landrace in Oaxaca, Mexico. Nature 414: 541-543.

peasants' maize fields of Oaxaca have been further demonstrated by the Mexican government confirming that gene movement in traditional agriculture is an open system.[142]

The introgression shows the complexity of the management of biosafety in Mexico. When the presence of transgenic sequences in the landraces was discovered, the government of Mexico commissioned an *ad hoc* group to corroborate the findings. This, in turn was difficult since the enterprises which have the molecular information required for the unmistakable identification of a transgenic variety were reluctant to reveal this information and did not cooperate fully. Also the government did not provide resources needed for the laboratory tests.[143]

Following this and given the lack of response and the absence of clear evidence on the possible repercussions of introgression in maize landraces, in 2002, members of the Mexican civil society, international organizations and in particular peasant groups from Oaxaca requested the CEC to produce an independent study about the effects of transgenic maize in Mexico. This would allow a group of experts to make pertinent recommendations to the NAFTA governments in order to achieve the appropriate monitoring in the affected regions, considering the exact peculiarities of the Mexican case. The report[144] of the CEC was issued pursuant to Article 13 of the North American Agreement on Environmental Cooperation (NAAEC). Article 13 of the NAAEC authorizes the CEC's Secretariat to investigate and prepare reports on environmental issues within its overall program. The complaint before the CEC involved possible contamination of traditional maize with transgenic sequences in 2001 and the contamination of 13% of maize varieties in 11 Mexican indigenous communities. Transgenic maize was also found in storage facilities of the Mexican government's Food Distribution Agency (DICONSA).

The report was published on November 8, 2004 and analysed: gene flow and transgenic maize; the impact of LMO's on biodiversity and on health; socio-cultural impacts of LMO's in Mexico.

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[142] Instituto Nacional de Ecología y Comisión Nacional para el Uso y Conocimiento de la Biodiversidad (INE-CONABIO) 2001. Mexican Approach: Overview and Status. LMO's and the Environment, Proceeding of an International Conference, Raleigh, North Caroline, November 2001

[143] Ibid, Gálvez Mariscal Amanda, supra note 64

[144] Maiz y Biodiversidad. "Efectos del Maíz Transgénico en México". Informe del Secretariado de la Comisión para la Cooperación Ambiental CCA del 2004.
Online: http://www.cec.org/files/PDF//Maize-and-Biodiversity_es.pdf

1. Gene Flow and Transgenic Maize

Regarding gene flow, the advisory group acknowledged that 25 to 30 percent of the transgenic maize introduced to Mexico from the United States was of transgenic origin. Furthermore, the advisory group acknowledged the importance of traditional agricultural practices, such as plant improvement through pollination. The CEC' maize report pointed out that further research was needed to fully assess the degree of maize and biodiversity: The CEC recommended that a monitoring strategy shall be implemented to guarantee the preservation of the genetic diversity of maize.

2. The Impacts of LMO's on Biodiversity and on Health

As to the impacts on biodiversity and health, the report stated that no negative effects were found and that further studies were necessary to determine the effects of transgenic maize varieties on non-target insects. Additionally, the advisory group also warned of the risks posed by the production of pharmaceuticals from plants. The report acknowledged the role indigenous farmers play in the preservation of maize and recommended that a systematic program to monitor transgenic products be implemented and that the Mexican government should strive to preserve indigenous varieties of maize.

3. Socio-cultural Impacts of LMO's in Mexico.

Regarding socio-cultural matters, the report acknowledged that Mexico was not self-sufficient in maize production, that this product was an essential component in Mexican diet and that it represented cultural and spiritual values for Mexicans. Additionally, it stated that traditional practices such as saving seeds for future seasons were essential to traditional farmers not only in the preservation of maize but also in the improvement of this grain. For these reasons, the advisory group recommended that transgenic maize imports from the USA shall be labelled as such and that farmers shall be educated over the handling of transgenic maize. The report recommended public participation in decision-making on these matters, particularly participation by parties involved in maize production

The group of experts of the CEC concluded that one explanation for the appearance of transgenic varieties of maize was that farmers may have planted maize imported into Mexico from the United States for use in tortillas, unaware that the grain was from GM crops and they recommended the protection of maize imports and its monitoring, its preservation in-situ and

ex-situ, and its conservation as Mexico is stated as centre of origin and diversity of maize.

II. The Star-Link Event

Star-Link was genetically altered to contain an insecticidal protein, known as Cry9C that enables it to resist various corn pests. Star-Link corn seed was sold in the United States between May 1998 and October 2000. In September 2000, Star-Link corn containing a Cry9C protein, a protein approved only for use in animal feed, turned up in taco shells. Without approval for human use, or exemption from approval, the Cry9C protein is considered an adulterant. The current regulatory system would still not necessarily have caught this adulterant in human food, even if there had been a mandatory notification and labelling program. The incident and subsequent problems with Star-Link corn being found in shipments that would have been used in food, however, has led the Environmental Protection Agency (EPA) to state publicly that it will probably never again allow the entry of bioengineered products that cannot be used in human food, onto the market. The incident also led the Food and Drug Administration (FDA) to develop sampling and testing guidance for the industry so that testing results could be used to verify the labelling of corn with or without the Cry9C protein.

According to EPA, any presence of Star-Link™ in grain that is destined for human consumption is unacceptable. The Aventis event has not received regulatory clearance for human consumption. Grain from Star-Link corn and any corn grown within 660 feet of Star-Link hybrids cannot enter international trade until overseas approvals are granted. Grain can be processed as conventional grain for animal feed and industrial non-food uses in the United States. Thus, the major lesson which should be learned from the Star- Link Event[145] is that regulators should not, in general, approve varieties for one use but not another unless the system is prepared to carry out the necessary segregation.

D. Conclusion

The findings of this chapter identify the development of biotechnology and show successful cases concerning mainly green and red biotechnology. The analysis of the evolution of modern biotechnology illustrates that there are three core dates to take into account. First, it can be said that its

[145] N. E. Harl, R. G. Ginder, C.R. Hurburgh und S. Moline, The Star-Link Event. Online: http://www.extension.iastate.edu/Pages/grain

origin dates from G. Mendel in 1865 known as the father of genetics. He developed the basis of the modern biotechnology. Second the knowledge on which the techniques of genetic modification are based dates from the 1950s when James Watson, Francis Maurice Wilson and Rosalind Franklin discovered the structure of DNA, which marks the beginning of the modern era of genetics. Third, in the 1970s, it became possible to isolate individual genes, refashion them and copy them in cells, leading to a huge expansion of commercial possibilities. In 2008, the global area of biotech crops was 125.0 million hectares and the number of countries planting biotech crops has increased rapidly from 6 in 1996 – the first year of commercialization- to 25 in 2008.

The findings of this chapter also show Mexico as the fifth most megadiverse country in the world and demonstrate why Mexico is recognised as a COD of different crops, especially maize. The analysis of the outcome of this research also showed the differences that exist between developed, developing countries and Mexico with regard to maize use and consumption. Whereas maize is mainly used for feed or processing in developed countries, maize is primarily used as food for human consumption in developing countries. In Mexico, maize is a crop of significant nutritional, economic, environmental, historical and social importance. Mexico's people, culture and landscape have been intrinsically linked to its development and cultivation. The release of GM maize into the environment in the country may result in a risk for its wild relatives due to the fact that maize is an open pollinated crop. Mexico still harbours a large diversity of maize folk races therefore an important key to biosafety is the risk assessment of GMO's.

The contamination of maize in the north of Oaxaca in 2001 showed the complexity of the management of biosafety in Mexico, the lack of control at the border customs when GM maize is imported from the USA without label or identification. Unfortunately, the recommendations of the CEC report have not been implemented due to the fact that they are not binding for the NAFTA trading partners. However, the importance of international trade of these transgenic crops shows the need to regulate transboundary movements of GM maize in Mexico, which has to protect its biodiversity against the deliberate release of GMO's into the environment being a centre of origin and diversity of different crops.

Chapter II

Mexican and International Biosafety Rules Regarding Genetically Modified Organisms

Introduction

There are three important stages that have played a role in the regulation of GMO's worldwide. The first stage took place in the early 1980s when regulations were developed at a national level in a number of countries (including Mexico), which addressed concerns about the new changes at the laboratory or experimental stage. The second stage started in the 1990s when biodiversity became an issue in international environmental policy as a law, and biosafety issues were also addressed internationally. These issues became

important with the adoption of the Convention on Biological Diversity (CBD)[146] in 1992 and with the adoption of the Cartagena Protocol on Biosafety (BSP)[147] in 2000. Finally, in a third stage, the new international standards were implemented at national level. Mexico's own experience is similarly related to the three stages mentioned above.

Thus, the first stage started in 1988 with experimental releases of GMO's into the environment applied for a case-by-case basis. The second stage of the regulation of GMO's began in the mid 1990's with the issue of a Mexican Official Standard i.e. the NOM-056-FITO-1995 and with the signature of international commitments such as Agenda 21 and the CBD. Together with the latter Mexico embraced the rules established by the OECD, the Food Agricultural Organisation (FAO)[148] and the World Health Organisation (WHO) and the Codex Alimentarius.

The third stage emerged with the signature of the BSP. The importance of the BSP both for Mexico and for other developing countries was that it dealt with issues that were completely new for them i.e. the implementation of the precautionary approach and the risk assessment among others. The CDB and the BSP provided developing countries with expertise and the provisions serve as a model for their national biosafety regulation. Thus, Latin American countries such as Brasil[149], Costa Rica[150], Cuba[151], Peru[152], Bolivia[153] and Venezuela[154] met at the first conference of the parties (COP) to the convention serving as the meeting of the parties (MOP) to the protocol held from 23 to 27 February 2004 in Kuala Lumpur Malaysia with biosafety Laws and regulations. However, Mexico participated in this first

[146] Convention on Biological Diversity, (CBD), 31 ILM (1992), 818. In force 29 December 1993. It was published in the Mexican Official Register (D.O.F.) on May 07, 1993.
[147] Cartagena Protocol on Biosafety, (BSP) 39 ILM (2000) 1027. In force 11 September 2003. It was published in the D.O.F. on October 28, 2003
[148] Mexico has been a FAO member since 16 October 1945.
Online:http://www.fao.org/unfao/govbodies/membernations3_en.asp
[149] Ley de Bioseguridad ó ley número 8.974 de Brasil de 1995
[150] Ley de Biodiversidad de Costa Rica de 1998
[151] Decreto Ley No. 190 sobre Seguridad Biológica de Cuba de 1999
[152] Ley No. 27104 o Ley de Prevención de Riesgos derivados del Uso de la Biotecnología de Perú de 1999
[153] Reglamento de Bioseguridad de Bolivia de 1997
[154] Ley de Diversidad Biológica de Veneuela del 2000

COP/MOP only with the NOM-056-FITO-1995 and with amended Laws and regulations regarding biosafety issues.[155]

A. Early and Sectoral Approaches

I. The United States of America (USA)

In the USA[156], the first notable attempts to address biosafety concerns occurred in 1975 when scientists proposed a set of biosafety guidelines which came to be known as the National Institutes of Health rDNA Advisory Committee (NIHRAC) guidelines. Over the years, these voluntary guidelines have evolved into a comprehensive set of precautions which are used to guide experimentation of recombinant DNA research in contained laboratories. In 1984, the Domestic Policy Council of the White House introduced the Coordinated Framework for the Regulation of Biotechnology, which was based on the premise that biotechnologically altered organism do not differ substantially from non-modified organism. Therefore, the products of biotechnology, and not the process, would be regulated. To complement the NIHRAC guidelines mentioned above, the United States Department of Agriculture (USDA) created the Office of Agricultural Biotechnology (OAB) in 1986 and subsequently the Agricultural Biotechnology Research Advisory Committee (ABRAC), involving experts from various backgrounds, including public interest groups, to give advice. These offices created guidelines to ensure the safety in the construction of laboratories and in the production of modified organisms.

Currently, the U.S. Government agencies[157] responsible for oversight of the products of agricultural modern biotechnology are the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), the EPA, and the Department of Health and Human Services' Food and Drug Administration (FDA). Depending on its characteristics, a product may be subject to review by one or more of these agencies.

The USA is the main producer of GMO's in the world. The cultivation of Bt Maize and the surveillance of environmental risks posed by trans-

[155] Nava Escudero César. Memorias del Segundo Encuentro Internacional de Derecho Ambiental, 2004, "La Seguridad de la Biotechnología: La Normatividad Internacional Vis-a-vis, la Regulación Nacional Mexicana"., pp. 439-470. SEMARNAT-INE-PNUMA.

[156] Butler, L.J. (1995), "The Regulation of Agricultural Biotechnology in the USA." Biotechnology and Development Monitor, No. 24, p. 26.

[157] United States Regulatory Agencies Unified Biotechnology.
Online: http://usbiotechreg.nbii.gov/

genic varieties are under the jurisdiction of the EPA. The commercial planting of transgenic varieties (without insecticidal characteristics) is managed through notifications submitted to APHIS of the Department of Agriculture (USDA) in the case of approved crops.[158]

Approval must be given on the basis of risk assessments evaluated by the same office. The FDA does not consider genetically modified plants for human or animal consumption to be of special concern with respect to safety. Therefore they are not subject to regulations different from those governing conventional crop improvements. USA is the COD of sunflower, cotton, pumpkin, raspberry and cranberry; crops that do not have the commercial magnitude of maize. Biodiversity conservation in the USA is therefore relatively easy to manage. This may partly explain the country's broad support for agricultural biotechnology applications. The US Government regards transgenics as a continuation of technologies applied to agriculture and therefore do not require particular measures.

Table 2.1 Overview of Agency Responsibilities

Agency	Product Regulated	Reviews for safety
FDA	**Food, feed, food additives, veterinary drugs**	**Safe to eat**
USDA	**Plant pest, plants veterinary biologic**	**Safe to grow**
EPA	**Microbial/plant pesticides, new uses of existing pesticides and novel microorganisms**	**Safe for the environment Safety of a new use of a companion herbicide**

Source: APHIS http://www.aphis.usda.gov/biotech/OECD/usreg.htm

II. Germany

In Germany, the origins of biosafety rules started with a commission ("Enquête Kommission") of the parliament (Bundestag) that issued the report called: "Chancen und Risiken der Gentechnik" in January 1987.[159] A section of this report examined the adequacy of existing Laws that pertain to biotechnology. The report recommended that existing guidelines for recombi-

[158] Gálvez Mariscal Amanda, "Learning About Biosafety in Mexico", supra note 64

[159] Enquête-Kommission " Chancen und Risiken der Gentechnik", BT-Dr.s. 10/6775, S 7; Klopfer Michael, Umweltschutzrecht, Gentechnikrecht, s. 447, 2008, C.H. Beck Verlag; Prall Ursula, Gentechnikrecht s. 483 in: Hans-Joachim Koch, Umweltrecht, 2. Auflage, München 2007, Carl Heymanns Verlag.

nant DNA research be mandatory for all research, and a five-year moratorium be imposed on the deliberate release of genetically modified microorganisms, from which exemptions would be possible on a case-by-case basis. The German parliament rejected the moratorium in October 1989.

A Genetic Engineering Law ("Gentechnik Gesetz")[160] was proposed in August 1989. This Act, in the line with the proposed EC Directives, would regulate the use of GEO's and the marketing of products containing such organisms. One of the features of the proposed Law is the establishment of mandatory review procedures for all deliberate releases. An amended version of the Genetic Engineering Law (GenTG)[161] implements into national law Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GMO's. On April 1, 2008 the Law on the changes in the Genetic Engineering Law was enacted and the purpose of the Genetic Engineering Act is to give due regard to ethical values, to protect human life and health, the environment with its interacting systems, fauna, flora and material assets against adverse effects of the techniques and products of genetic engineering, and to take precautions against the occurrence of such hazards. Furthermore, the goal is to safeguard the possibility of producing and placing on the market products, notably foods and feedstuffs, produced according to conventional standards, organic standards or using GMO's. Finally, the intention of the Law is to establish a statutory framework to research, develop, use and promote the scientific, technological and economic opportunities of GE. The regulations stipulating the use of genetic engineering in food production can be divided into four main areas: (i) licensing procedures; (ii) labelling regulations; (iii) liability and patent protection.[162]

III. The European Union

The EU has been legislating on GMO's since the early 1990s, to achieve a high degree of protection of its citizens' health and the environment. Furthermore, the EU created a unified market for biotechnology. In

[160] Gesetzt zur Regelung der Gentechnik (Gentechnikgesetz – GenTG) v. 20.6.1990. BGBI. I S. 108; Erbgut Wilfried, Schlanke Sabine, Gentechnikrecht, pp.435-366. in Umweltrecht, 2. Auflage, Nomos Verlagsgesellschaft Baden-Baden, 2008; Klopfer Michael, Gentechnikrecht s. 447-470 in: Umweltschutzrecht, C.H. Beck Verlag.

[161] Gesetzt zur Neuordnung des Gentechnikrechts vom 21.Dezember 2004, BGBI. 2004 I S. 186; Klopfer Michael, Gentechnikrecht, s. 447-470 in: Umweltschutzrecht, C.H. Beck Verlag

[162] Gesetzt zur Neuerordnung des Gentechnikrechts. It was amended on April 1, 2008, BGBl. I S. 499.

the light of scientific developments and social concerns, the EU has created a legal framework which seeks to ensure that GMO's and GM products authorized in the EU do not in any way hamper human health and the environment. For the EU, GMO's are the result from cross-breeding amongst species through biotechnological applications, producing new forms of genetic variations, for instance in crops. Article 2(2) of Directive 2001/18/EC[163] on the deliberate Release into the Environment of GMO's defines a GMO as:

> *An organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*

"A *de facto moratorium* on authorising GM crops operated throughout the Community from 1998 until 2004".[164] In the case of GM technology, there has also been a sustained media campaign on the so called "Frankenstein foods". Thus, GM-derived food products have so far been rejected by a larger retail sector sensitive to consumer market signals. Directive EC/2001/18 is now in force and affecting GMO's, or products containing GM material, that are released either into the environment or onto the market. Where the GM content is brought to market as part of the human food or animal feed chain, there is a considerable overlap between the Directive and the subsequent Regulation 1829/2003[165] on Genetically Modified Food and Feed. In such cases the latter applies, albeit using risk assessment criteria set out in the earlier measure. Briefly stated, the post-Regulation authorisation process places responsibility for risk assessment on the European Food Safety Authority (EFSA). This is the keystone of EU risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks. [166] Responsibility for the subsequent risk management exercise is placed on the

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[163] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration. OJ L 106, 17.4.2001, p. 1–39

[164] Stallwortly Mark, Understanding Environmental Law, 6.3 law risk and GMO's, p. 163, first edition, published by Thomson, Sweet & Maxwell, London, 2008

[165] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23

[166] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm

Commission, which may take into account "other legitimate factors relevant to the issue". It is required to prepare a Draft Decision (subject to expert Comitology Committee Approval, again the Member States represented are responsible for supervising matters delegated to the Commission). Only in the event of non-approval will the proposal be referred to the Council of Ministers. The main consequence of the regime is to centralise the Community decision making process in a highly controversial area. There remains a safeguard clause (Article 23 of the 2001 Directive), whereby provisional national restrictions upon use and sale of otherwise authorised GM products may be imposed, though this is subject to eventual resolution by the Commission.[167]

A further contentious feature of GM authorisation relates to incompatibilities between products containing GM and those produced by conventional and organic methods. The EU with the 2003 Regulation set a threshold that excludes from the GM definition any adventitious or technically unavoidable GM presence of up to 0.9%. This threshold also applies to labelling criteria. The Commission has bolstered the regime through Recommendation 2003/556 on Co-Existence, which offers guidance on crop management, including buffer zones and other practical measures to minimize the introgression between GM and no-GM farming. This proceeds from the assumption that, once authorisation is approved, any risk is determined as being acceptable and the only issues at stake thereafter become economic ones. It can only be assumed that current notions of conventional and especially organic forms of agricultural production are unlikely to survive increasing GM penetration in the longer term. The separate legal questions concerning potential liability for resulting loss need therefore to be considered. In addition, there exists the Regulation 1830/2003[168] on Traceability and Labelling of GMO's strengthened rules on (1) mandatory traceability and (2) mandatory labelling.

The EU Law sets up a common system for notifying and exchanging information on transboundary movements of GMO's to third countries. The ultimate goal is to ensure that movements of GMO's that may have adverse effects on the sustainable use of biological diversity and on human health

[167] Ibid, Stallwortly Mark, supra note 164

[168] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. *O*J L 268, 18.10.2003, p. 24–28

take due account of the environment and human health.[169] It is important to highlight that mandatory labelling for all GMO's and GM products (including food and feed produced from GMO's but no longer containing GM material or presence of GM material), is adventitious and below 0.9%. A 0.5% threshold for adventitious presence of unapproved GMO's assessed as risk-free.

The EU adopted the precautionary principle in the 1992 Maastricht Treaty. Article 130 (2) of the EC treaty was amended so that EC action on the environment 'shall be based on the precautionary principle. Further, the 1997 Amsterdam treaty amended the EC treaty to apply the principle to Community policy on the environment pursuant to Article 174 (2). The European Commission has published a Communication on the precautionary principle which outlines the Commission's approach to the use of the principle, establishes guidelines for applying it, and aims to develop understanding on the assessment, appraisal and management of risk in the face of scientific uncertainty.[170] The communication considers that the principle has been progressively consolidated in international environmental Law, and so it has since become a full-fledged and general principle of international Law.

To sum up, the USA was the first country in regulating biotechnology, followed by Germany and by the EU. Mexico, as a developing country, was the first country in Latin America to rule the experimental release of GMO's into the environment. As showed above, the positions of the USA and the EU with regard to GM crops are opposed. Whereas the USA has the highest rate of GM crop cultivation worldwide, the EU is rather cautious on granting approvals for crop cultivations. The latter imposed a four-year *de facto moratorium* on new GM crop cultivation licenses, which expired in 2003. The difference between the positions of the USA and the EU is rooted in divergent concepts of caution. While the USA regulates product safety independently of the technology, through product liability, the EU has created specific separate regulations for biotechnology. These are embodied in a set of directives that are to be implemented by the member countries. In these directives, the EU applies the precautionary principle, which means that a new technology must be withheld from implementation until there is sound proof that it does not cause any harm. Contrary to this approach, the USA

[169] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms. OJ L 287, 5.11.2003, p. 1–10

[170] COM 2000 (1), 2 February 2000
Online:http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf

regards the application of the precautionary principle as a barrier to technology and trade, and advocates the opinion that it prevents the development of an industry that could benefit the world's poorest.

IV. Mexico

1. Authorization of the Release of GMO's in the Early 1990s on a Case-by-Case Basis

Mexico is one of the first developing countries to start with the evaluation of genetically improved plants in the field, beginning in 1988 with trials of plants genetically improved for insect resistance (corn and cotton), virus resistance (potato), and delayed ripening (tomato).[171] In 1988 the company Calgene (now Monsanto) applied to the General Directorate on Plant Health (DGSV)[172] for permission to import and carry out the experimental release of the GM tomato of retarded maturation, *Tomato Flavr Savr* into the environment in Culiacán, Sinaloa.[173] Without any regulation on these matters the DGSV granted the approval as required by Calgene. This became Mexico's first commercial biotech crop delayed-ripening tomatoes Flavr Savr, intended to be sold as a fresh product and the corresponding tomato from Zeneca for industrial purposes. Thus, they were the first GMO's to be commercially planted in Mexico. However, the tomato Flavr Savr was intended for the U.S. market and has not been promoted in Mexico where there is no real demand for it because fresh tomatoes are available throughout the year.[174]

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[171] Persley G. J., Pp 3-21, 2000. "Agricultural Biotechnology and the Poor: Promethean Science" In G.J. Persley and M.M. Lantin, eds., Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, D. C., 21-22 October 1999. Washington: Consultative Group on International Agricultural Research; Alvarez Morales Ariel. Pp 90-96, 2000, "Mexico: Ensuring Environmental Safety While Benefiting from Biotechnology." In Persley G. J. and M.M. Lantin, eds., Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, D. C., 21-22 October 1999. Washington: Consultative Group on International Agricultural Research.

[172] The DGSV oversees the implementation of plant health policies and strategies through the management and application of phytosanitary legislation and procedures in order to prevent, to control and to eliminate pests and diseases that affect agriculture in the country.

[173] Chauvet Michelle. El Desarrollo Agrícola y Rural del Tercer Mundo en el Contexto de la mundialización: "La agricultura transgénica: esperanza ó amenaza para la sustentabilidad?", 2004, UNAM, pp 511-521.

[174] Alvarez Morales Ariel, pp 90-96, 2000, "Mexico: Ensuring Environmental Safety While Benefiting from Biotechnology." In G.J. Persley and M.M. Lantin, eds., Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, D.

The Calgene's case showed the lack of guidance and regulation in this country for the release of GMO's into the environment. Thus, the latter led the DGSV to address this gap in the Mexican legal system by creating in 1989 the National Commission for Agricultural Biosafety (CNBA). This Committee, which was substituted by the current Specialised Subcommittee on Agriculture (SEA),[175] acted as a consulting body constituted by experts from different universities and research institutes.[176] The creation of this Committee should be regarded as the first step for the regulation of biotechnology in Mexico.

2. Standards for GMO's Experiments Including Release into the Environment: The NOM-056-FITO-1995

As a result of the SEA discussion on biotechnology and biosafety, the DGSV under the current Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA)[177] issued a mandatory standard through the Phytosanitary (FITO) Agency, the NOM[178]-056-FITO-1995[179],

C., 21-22 October 1999. Washington: Consultative Group on International Agricultural Research.

[175] Cotero García Marco A. "Regulación de los Organismos Genéticamente Modificados en México en: Bioseguridad en la Aplicación de la Biotechnología y el Uso de los Organismos Genéticamente Modificados, Pp. 313-320, CIBIOGEM/PNUD/GEF, primera edición, 2008.

[176] Solleiro José Luis, Castanion Rosario y Almanza Silvia. El Desarrollo Agrícola y Rural del Tercer Mundo en el Contexto de la mundialización: "Hacia una politica y regulación de organismos genéticament modificados para la agricultura y la alimentación en México.", 2004, UNAM, Pp. 523-544.; Chauvet Michelle. El Desarrollo Agrícola y Rural del Tercer Mundo en el Contexto de la mundialización: "La agricultura transgénica: esperanza ó amenaza para la sustentabilidad?", 2004, Unam, pp 511-52; Nava Escudero César. Memorias del Segundo Encuentro Internacional de Derecho Ambiental, 2004, "La Seguridad de la Biotecnología: La Normatividad Internacional Vis-a-vis, la Regulación Nacional Mexicana"., Pp. 439-470. SEMARNAT-INE-PNUMA.

[177] SAGARPA, (formerly SAGAR) is an arm of the Federal Executive Authority tasked with providing policy support to foster and better tap the comparative advantages of the agricultural sector, to integrate rural activities into other production chains of the economy and to stimulate the collaboration of producer organizations with its own programmes and projects and with the proposed agricultural goals and objectives of the National Development Plan.

[178] To understand a NOM or a NMX, it is necessary to know that all Mexican regulations follow a fixed coding system that consists of at least the following four elements: firstly, whether the standard is mandatory (NOM) or voluntary (NMX); secondly, a three-digit sequential number; thirdly, a code for the topic or issuing agency. These include for instance Phytosanitary i.e. (FITO) and fourth, digits indicating a year, which is generally, but not always, the year it was issued as a proposal.

according to Articles 1, 2, 6, 23 (I), 29 and 43[180] of the Federal Plant Health Law[181]. The NOM-056-FITO-1995 was the first Law governing transgenic crops. It regulated the genetic engineering application in plants and was administrated by the DGSV. From 1988 to 2003 the SEA, the DGSV and now the General Directorate of Food Safety, Aquaculture and Fishery (DGIAAP)[182] approved 288 permits for the experimental release of transgenic plants in Mexico.[183]

a) Legal Basis and Nature of Mexican Official Standards (NOM's): Regulatory Process to Issue a NOM

The legal framework for the creation of NOM's is defined by the Federal Law of Metrology and Standardization.[184] According to Article 3 (XI) NOM's are defined as:

> *Obligatory technical regulations enacted by the competent Secretariat establishing rules, specifications, attributes, characteristics of a product or process, activity, service or labelling.*

This Law regulates the sector of Agriculture, Communication, Transportation, Energy, Environment, Health, Public Education, Social Development and Industrial Development. It gives the competent Mexican secretariats and agencies powers to establish regulations relating to the protection of human, animal, and plant health, and the environment. The objectives include requirements for products, processes, raw materials, services,

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[179] NOM-056-FITO-1995 por la que se establecen los requisitos fitosanitarios para la movilización nacional, importación y establecimiento de pruebas de campo de organismos manipulados mediante la aplicación de ingenieria genética published in D.O.F.on July 11, 1996. This NOM was cancelled in December 2006 and such cancelation was published in D.O.F on October 13, 2006.

[180] Article 43 of the Federal Plant Health Law defines the role of the biosafety committee.

[181] Ley Federal de Sanidad Vegetal published in D.O.F. in January 5, 1994, last amended and published in D.O.F. on November 18, 2008.

[182] DGIAAP ensures the quality and safety of foods derived from agriculture, aquaculture and fisheries through policies, a regulatory framework, plans, activities and services aimed at fostering and regulating the application and certification of systems to reduce contaminant risk in the production and primary processing of food for human consumption, and the proper use and handling of plant and animal health and production inputs, in support of the competitiveness of the country's agricultural producers and for the benefit of consumer health.

[183] Ibid, Cotero García Marco A. supra note 175

[184] Ley Federal de Metrología y Normalización, published in D.O.F. on July 01, 1992, last amended and published in D.O.F. on July 28, 2006.

testing, labelling, packaging, facilities, and safety and hygiene requirements among others.

The regulatory process is coordinated by Mexico's General Directorate of Norms (DGN) and is implemented by the Secretariat of Economy. The DGN hosts several consultative committees on different topics.[185] Although other Mexican federal agencies may promulgate regulations within their jurisdictions, they have to cooperate with the Secretariat of Economy. The secretariats and agencies involved in promulgating standards that protect biodiversity, human, animal and plant health, include SAGARPA; the Secretariat of the Environment and Natural Resources (SEMARNAT)[186] and the Secretariat of Health. All regulatory actions, regardless of the agency of origin, are published in Mexico's Federal Register (D.O.F). Each year, the Secretariat of Economy publishes its standardization plan for that year.[187]

This Law envisages two types of regulations: mandatory (NOM's) and voluntary (NMX). Within the mandatory category, there are two types: non-emergency and emergency. These NOM's are meant to verify compliance and are obligatory within the Mexican territory. The voluntary Mexican Official Standards are known as NMX. These NMX are voluntary standards and usually serve as reference guides.

To issue a NOM the competent Secretariat submits a proposal to its respective National Consultative Committee. After deliberation, these proposals come before the Secretariat of Economy for enactment. Proposals that may have economic or substantial impact on a sector of society must include an economic analysis of the projects to be authorized, alternatives to such projects and a comparative study of relevant and applicable international standards according to Article 45. As pointed out by some, the process of NOM enactment could take up to 230 days. It is important to note that issues have been raised by academics regarding the effectiveness of these standards and their constitutionality in the Mexican legal system.[188]

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[185] Ibid, Articles 43 and 44

[186] SEMARNAT was created in December 1994 (until 2000 its name was SEMARNAP).

[187] NOM's are available on the Secretariat of Economy website at http://www.economia-NOM's.gob.mx

[188] Herrera Juan Antonio, Carlos Hinojosa, Gloria Hagelsieb y René Salinas, "Mexico's Environmental Law in the GMO era", pp. 121-156 en: Mexican Law Review, new series, Volume I, number , UNAM, Instituto de Investigaciones Jurídicas, July-December 2008

3. Scope of the NOM-056-FITO-1995

The aim of this NOM was to establish control with regard to mobilization within national territory, imports, release and assessment to the environment or experimental tests performed on organisms manipulated through genetic engineering for agricultural purposes. This primary legal mechanism for plant biosafety management also set out the phytosanitary requirements for the application of field tests of transgenic crops (field trials, inspection of field trials, interstate movements, transgenics, and plant imports). It ensured compliance with biosafety regulations during field trials.

This NOM required a phytosanitary certificate for the application, use and handling of transgenic material either in experimental programs or in pest control processes.[189] The experimental release of GMO's into the environment was overseen by the SEA and by the DGSV, which are empowered by the Federal Plant Health Law to grant phytosanitary certificates for the release of GMO's into the environment.

A request for a phytosanitary certificate had to contain technical information on the genetic composition and properties of the GMO's intended to be released into the environment. When the phytosanitary certificate was granted, the decision had to be communicated to state governments where trials took place. A similar authorization was required to transport GMO's across the territory of the different Mexican states.

Imports of GMO's or transgenic material were also regulated in this NOM by means of a phytosanitary requirement mechanism. This certificate was granted by the General Directorate of Phytozoosanitary Inspection (DGIF).[190] It is important to note that to obtain this certificate required for experimentation with GMO's, it was required to also obtain an international phytosanitary certificate from the country where the GMO's originated.[191] As mentioned above, the NOM was cancelled and currently the Mexican Biosafety Law deals with these issues.

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[189] NOM-056-FITO-1995, supra note 179, Article 3

[190] The DGIF defines and evaluates programmes, policies and strategies of control and supervision of plant and animal health through international agricultural health inspection offices at ports, airports and borders, inspection points, and plant and animal health protection cordons based on existing regulations, in order to prevent the entry into the country of pests and diseases that affect agricultural production and to prevent the spread of crop and livestock pests and diseases present on the national territory, in doing so helping promote effective plant and animal health protection campaigns and reducing risks to public health.

[191] Ibid, Herrera Juan Antonio, supra note 188

4. The NOM-056-FITO-1995 in Practice

Under this NOM, 373 release permits were issued, including permits for transgenic maize, tomatoes, cotton and soybean among others. The next two tables show the requests of different cultivations for the release of GMO's into the environment from 1988 to 27 November 2006. They illustrate that cotton (234) maize (72) and soybean (63) were the transgenic crops with the major number of requests.

Table 2.2 Requests for the Release of GMO´s into the Environment from 1988 to 27 November 2006

Cultivation	Request	Total
Alfalfa	4	4
Cotton	234	234
Arabidopsis, Rice, Safflower	2	6
Bt modified genetically	3	3
Zucchini	26	26
Canola	7	7
Chilli, Carnation, Coconut, Lemon, Linen, Pineapple and Rhizobium etli	1	7
Maize/corn	72	72
Melon	8	8
Potato	11	
Papaya, Banana	7	14
Soybean	63	
Tobacco and Wheat	8	16
Tomato	30	
Total		501

Source: Villalobos Arámbula Víctor Manuel[192]

[192] Villalobos Arámbula Víctor Manuel, "Los transgénicos: Oportunidades y amenazas", page 43 primera edición 2008, Mundi-prensa, impreso en Madrid.

Table 2.3 Status of the Requests from 1988 to 27 November 2006				
Year	Request	Approved	Cancelled	In Process
1988	2	2		
1989	2	1	1	
1990	2	2		
1991	3	2	1	
1992	2	2		
1993	8	6	2	
1994	8	8		
1995	9	9		
1996	33	30	3	
1997	43	39	4	
1998	51	30	21	
1999	29	21	8	
2000	32	28	4	
2001	39	39		
2002	41	36	5	
2003	39	34	5	
2004	53	43	10	
2005	54	31	21	2
2006	51	10	5	36
Total	501	373	90	38

Source: Villalobos Arámbula Víctor Manuel [193]

a) Gaps of the NOM-056-FITO-1995

The NOM-056-FITO-1995 did not regulate the potential effects of GMO's against the environment, the biodiversity or human and animal health.[194] Also, it did not address the protection of biodiversity or the commercial release of large-scale crops.[195] However, this gap in the regulatory framework was addressed by creatively interpreting NOM-056-FITO-1995 to portray large areas (even exceeding 10,000 hectares) as experimental fields (and hence still requiring biosafety measures). This was the approach used to

[193] Ibid, page 44

[194] Gálvez Mariscal Amanda, 2000. Biotecnología Agrícola en México: aspectos de regulación, Crónica Legislativa, H. Cámara de Diputados, núm. 13, 3ª. epoca, del 1 de marzo al 30 de abril, pp 80-82.

[195] Gálvez Mariscal Amanda, In: Gene Flow, "What does it Mean for Biodiversity and Centers of Origin", Panel 6, page 26, México 2004, by Offset Reboson.

permit large-scale planting of Bt Cotton, the only transgenic crop being grown in commercial quantities in Mexico. [196]

As mentioned in chapter I, Mexico imposed a *de facto moratorium* in 1998 on the planting of transgenic maize throughout the country following a precautionary approach, and it did not accept applications for experimental, pilot program or commercial release of GM maize into the environment. However, the moratorium was lifted on 13 August 2003.[197]

Over the years that the NOM was in force the Secretariat of Health approved imports for processing and human consumption such as: herbicide-tolerant, soybean, insect-resistant cotton, insect-resistant potato, herbicide-tolerant canola, and insect- and herbicide-tolerant maize.[198]

b) Enforcement Measures

SAGARPA implemented three measures in order to comply with the Federal Plant Health Law obligations i.e. (i) on-site inspector visits, (ii) public complaint processes and (iii) administrative sanctions.[199]

SAGARPA used a public complaints procedure to enforce the provisions of the Federal Plant Health Law according to Articles 63 and 64. This procedure allowed individuals in any region nationwide to denounce acts and omissions that endanger plant health. Finally, the Federal Plant Health Law employed administrative sanctions against those who do not obtain phyto-sanitary certificates or who disregard the conditions established in such certificates. The fines established in this Law can be found under Article 66.

To sum up, the NOM-056-FITO-1995 emerged with the aim to regulate experimental release of GMO's into the environment. Over the years this NOM became important but its role in regulating GMO's had a limited scope particularly because it focused only on experimental release of GMO's excluding commercial release into the environment. Its implementation was ineffective since it depended heavily on inspector's visits to ensure compliance. Furthermore, there were few trained personnel for such inspections and their tasks were not adequately determined. However, the biosafety measures provided under this NOM had the potential to control possible threats posed by GMO's, though only on a small-scale.

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[196] Gupta Aarti and Robert Falkner, "The Influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa. In: Global Environmental Politics, November 2006, Vol. 6, No. 4 Pages 23-55.
Online: http://www.mitpresjournals.org/doi/labs/10.1162/glep.2006.6.4.23

[197] See online: http://www.cec.org/files/PDF//Maize-and-Biodiversity_es.pdf

[198] For more information see: http://www.cofepris.gob.mx

[199] Ibid, Federal Plant Health Law supra note 181, Articles 54-61

5. Mexican Laws and Regulations Addressing Biosafety and Biotechnology in the Health, Agricultural and Environmental Sector

As mentioned above, biosafety measures were first incorporated into the country's legal framework with the creation of the NOM-056-FITO-1995 for experimental release of GMO's into the environment.

As of 1995 diverse issues on biosafety and biotechnology were added into distinct laws, regulations and guidelines within the health, agricultural and environmental sector due to the need to regulate these matters in Mexico. In 2005 a comprehensive biosafety law was enacted with the aim to include all biosafety and biotechnology issues, which were dispersed in previous legislation. While most provisions were incorporated into this Law and some were derogated, few others remained in force.

a) Laws and Regulations Regarding Human Health

The protection of human health is stated in Article 4[200] of the Mexican Constitution.[201] As amended since 03 February 1983, this Article establishes the right to health protection and states:

> *Every person has a right to receive medical treatment when deemed as necessary. The Law shall not only define the guiding criteria regulating the access to health services but also establish concurrent activities to be carried out by the federation and the states in organizing public health services under Article 73, paragraph XVI of the Mexican Constitution.*

Thus, the right of all individuals to health protection is based on the Mexican Constitution as well as the conditions and modalities of access to the country's health services. It is important to highlight that the protection of health is also stated under Article 1 of the General Law on Health.[202]

In Mexico, responsibility for food control and safety resides essentially in two official agencies: The National Food Health, Safety and Quality Service (SENASICA), which reports to SAGARPA and the Federal Commission for Protection against Health Risks (COFEPRIS) which reports to the Secretariat of Health.

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[200] Paragraph 3 was added to Article 4 of the Mexican Constitution published in D.O.F. in February 03, 1983.

[201] Constitución Politica de los Estados Unidos Mexicanos published in D.O.F. on February 05, 1917, last amended and published on September 26, 2008.

[202] Ley General de Salud published in D.O.F. on February 07, 1984, last amended and published in D.O.F. on December 18, 2007.

On July 5, 2001 COFEPRIS[203] was created by Decree and was published in the D.O.F. It is a decentralized body of the Secretariat of Health with administrative, technical and operational autonomy. It is the regulatory agency in charge of control and surveillance of biotechnology products. In 1997, the Congress amended Article 98 of the General Law on Health to include the mandatory constitution of biosafety commissions whenever genetic engineering research is carried out. Hence, this Law (in chapter XII bis) provides a definition for biotechnological products related to organisms modified by genetic engineering:

> *Biotechnological products are considered those foodstuffs, ingredients, additives, raw materials, health care raw materials, pesticides, hazardous or harmful substances or their wastes, whose processing is related to living modified organisms, modified by traditional techniques or by genetic engineering.*[204]

The General Law on Health requires the Secretariat of Health[205] to be notified about all biotechnology products or their derivates, which are intended for human use or human consumption. It also states that any requirements related to the labelling of such products are to be included in NOM's.[206]

The Secretariat of Health is responsible for the health control of products, including biotechnology products, and for identifying the characteristics of such products including imports and exports.[207] It verifies, certifies and controls the quality of products subject to import. When these products do not correspond to the characteristics established by the pertinent legislation, the Secretariat of Health will apply all the correspondent safety requirements provided under Article 284 of the General Law on Health. It is important to mention that products which are new or introduced for the first time in Mexico are to be analysed in special laboratories in order to verify their compliance with NOM's issued.[208]

This Law has several regulations with regard to biotechnology. The most important of these are:

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[203] For more information of COFEPRIS see www.cofepris.gob.mx
[204] Ibid, Ley General de Salud, supra note 202, Article 282 bis
[205] Ibid, Article 282 bis-1
[206] Ibid, Article 282 bis-2
[207] Ibid, Article 283
[208] Ibid, Article 286 bis-(III)

(i) The General Law on Health Regulation in Terms of Health Research[209] states in Chapter II a definition of recombinant nucleic acids[210] and the type of biotechnological research that requires prior to authorization.[211] This regulation applies to experiments and research related human health.[212]

(ii) The Regulation on Raw Materials Health[213] pursuant to its chapter VIII, Article 81 defines bio-drugs and bio-medicines as biotechnological products.

(iii) The General Health Law Regulation in Advertising Matters[214] states in Article 70:

> *Advertising with regard to biotechnological products shall not infer properties to the products different to those technically assessed by the Secretariat; offer such products as essential for human life and use qualifiers making them appear as superior towards conventional or similar products which are not obtained through biotechnology.*

According to Article 71 the Secretariat of Health, prior agreement, will determine, if necessary, information and precaution or warning directions which might be included in products advertising.

(iv)The Products and Services Sanitary Control Regulation [215] states in Article 164:

> *The biotechnological products, which are subject to the sanitary control set forth in this regulation are foodstuff, ingredients, additives or raw materials for human use or consumption, whether directly or indirectly, derived from or which process may involve organisms or part of them and that have undergone any genetic manipulation.*

It also regulates the labelling and the marketing of these products and states that standards shall establish, accordingly, sanitary guidelines or speci-

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[209] Reglamento de la Ley General de Salud en Materia de Investigación para la Salud published in D.O.F. on January 06, 1987.
[210] Ibid, Article 85
[211] Ibid, Article 88
[212] Ibid, Article 86
[213] Reglamento de Insumos para la Salud published in D.O.F. on February 04, 1998.
[214] Reglamento de la Ley General de Salud en Materia de Publicidad published in D.O.F. on May 04, 2000, last amended and published in D.O.F. on April 06, 2006
[215] Reglamento de Control Sanitario de Productos y Servicios published in D.O.F. on August 09, 1999, last amended and published in D.O.F. on April 06, 2006

fications with regard to the activities, settlement, products and services relevant to this regulation.[216]

The Secretariat of Health plays an important role regarding biotechnology products and by-products. It is in charge among others of approvals of imports of GMO's for human use or for human consumption, labelling, identifications and marketing of those products through COFEPRIS.

b) Laws and Regulations Regarding Plant Health and Seeds

Parallel to the NOM-056-FITO-1995 there are federal Laws regarding food safety and the protection of plants health and seeds. In December 2000 the Mexican Government included food as a new element in the substantive work of SAGARPA. It took on responsibility for food safety in July 2001 as set out in its rules of procedure an in the Sustainable Rural Development Law,[217] which created SENASICA.

aa) The Federal Plant Health Law

The Federal Plant Health Law plays an important role in preserving biological diversity in Mexico by preventing, controlling and eradicating plant diseases and plagues. As mentioned in chapter I plants constitute an essential part of biodiversity in Mexico. Thus, this Law seeks to protect biological diversity, particularly from threats posed by GMO's.

The Federal Plant Health Law pursuant to Articles 5 and 43 applies to phytosanitary intakes, which includes the transgenic material i.e. artificially modified genotypes that due to its characteristics of multiplication and permanence in the environment, are capable of transferring recombinant genes to other organism with potential of having foreseeable or unexpected effects.

bb) The Federal Seeds Production, Certification and Trade Law

The Federal Seeds Production, Certification and Trade Law[218] is enforced by SAGARPA and regulates government research for the production of improved seeds and its certification. This Law also regulates experimentation with transgenic seeds and defines pursuant to Article 3(VIII) the highly hazardous transgenic materials as:

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[216] Ibid, Reglamento de Control Sanitario de Productos y Servicios, supra note 215, Articles 165-167

[217] Ley de Desarrollo Rural Sustentable published in D.O.F. on December 7, 2001, last amended and published on February 02, 2002.

[218] Ley Federal de Producción, Certificación y Comercio de Semillas published in D.O.F. in June 15, 2007. This Law repealed by Article 3 transitory the Ley sobre Producción, Certificación y Comercio de Semillas published in D.O.F. on July 15, 1991.

> *Those materials capable of transfering to another organism a re-combinable molecule or gene posing a high hazard potential as a result of unexpected effects or due to its survival, multiplication and spreading characteristics.*

This Law requires a permit for experimentation with highly hazardous transgenic material.[219] SAGARPA is empowered to establish guidelines regarding the use and handling of transgenic material. It is important to note that this Law does not provide for monitoring mechanisms. SAGARPA approves the release of GM crops into the environment as well as imports, mobilization, and transport of GMO's.

c) Additional Laws and Regulations with Regard to Environmental Concerns

The right to an adequate environment was added to the Mexican Constitution of 1917[220] in June 28, 1999 published in the D.O.F. Thus, Article 4[221] establishes the right to an adequate environment, providing as follows:

> *Every person has the right to live in an adequate environment for their development and welfare*

This provision shows concern for the preservation of the environment. However, it can be seen as a statement due to the fact that this provision is not implemented by federal legislation nor can it be directly invoked in court.[222]

aa) Mexican Environmental Legislation from 1971-2009

Mexico's environmental legislation has been evolving since the 1970s. Mexico's first environmental Law was the "Federal Law to Prevent and Control Environmental Pollution".[223] It addressed public health concerns, including provisions for the control of atmospheric emissions. Three sets of regulations were enacted to implement this Law: firstly, regulations to prevent and control atmospheric pollution caused by dust and smoke; second, regulations to control water pollution; thirdly, regulations to prevent and control pollution of the sea.

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[219] Ibid, Articles 1 and 2

[220] Ibid, Constitución Politica de los Estados Unidos Mexicanos, supra note 201

[221] Paragraph 5 was added to Article 4 of the Mexican Constitution, it was published in D.O.F. on June 28, 1999.

[222] Ojeda Mestre Ramón, "La legitimación activa para el juicio de amparo en materia ambiental" pp. 50-54 en Gaceta Ecológica INE-SEMARNAT México número 60, 2001.

[223] Ley Federal para Prevenir y Controlar la Contaminación Ambiental published in D.O.F. on March 23, 1971

In 1982, Congress enacted the "Federal Law of Environmental Protection"[224] which included provisions for the protection and preservation of ecosystems, and initiated a new legal framework to protect flora, fauna, soil and water. This Law was the first to deal with environmental principles with mechanisms for socioeconomic development.

Mexico amended its Constitution in 1987 with the aim to impose limitations on the use and ownership of real property in order to protect the ecological equilibrium. This amendment gave rise to the enactment of a new environmental Law, the General Ecological Equilibrium and Environmental Protection Law which is in force today.

bb) The General Ecological Equilibrium and Environmental Protection Law

The General Ecological Equilibrium and Environmental Protection Law (LGEEPA)[225] is Mexico's first comprehensive environmental Law. It addresses a broader range of environmental matters including protection of natural areas; exploitation of natural elements, including land and water; and protection of the environment, including atmospheric contamination, water and soil contamination, hazardous activities and waste, nuclear energy and other forms of pollution. LGEEPA also sets forth control and safety measures, penalties for non-compliance, guidelines for environmental impact statements and risk assessment. Additionally, LGEEPA addresses matters of jurisdiction, ecological zoning, and enforcement.

The LGEEPA was amended in 1996 with the aim to add the concept of sustainable development, which has not existed previously in the Law. The amendment of Article 3 replaces the rational use theory with the sustainable use theory. Sustainable development is defined as:

> *The use of natural resources for indefinite periods in a manner that respects the functional integrity and load capacity of the ecosystem of which those natural resources are a part.*

The amended of the LGEEPA in 1996 also added elements which established the right of all persons to live in an environment adequate for their development, health and well being.

Currently, the environmental regulations and NOM's in Mexico are based on the LGEEPA. It establishes the framework for all environmental regulation and grants the powers for implementing the law. It also establishes

[224] Ley Federal de Protección al Ambiente published in D.O.F. on January 11, 1982

[225] Ley General del Equilibrio Ecológico y la Protección al Ambiente published in D.O.F. on January 28, 1988, last amended and published in D.O.F. on May 16, 2008.

the basis for environmental protection. The LGEEPA allocates functions among municipalities, states and the federation and attempts to coordinate the federal agencies that are responsible for protecting the environment. It is the backbone of Mexico's environmental Law. The objectives of this Law regarding the conservation of biodiversity are stated pursuant to Article 1.

It is important to highlight that this Law follows a sustainable development approach to preserve the environment.[226] It reiterates the constitutional commitment to guarantee the right of individuals to an adequate environment and it defines Mexico's environmental policy and instruments for its implementation.[227] It also makes provisions to facilitate the formulation and execution of actions to preserve biological diversity and the use of "genetic material" countrywide.[228]

The LGEEPA considers the preservation of biodiversity and the use of genetic material as of public interest.[229] Like the CBD, the LGEEPA defines "genetic material" as:

> *Any material of plant, animal, microbial or other origin containing functional units of heredity*[230]

In addition, it also defines biological resources as:

> *Biological resources include genetic resources, organisms of parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.*[231]

The LGEEPA provides for an integrated approach to deal with Mexico's environmental problems. Three outstanding elements comprise this Law: environmental and risk assessment requirements; the establishment of protected and restoration zones; and, enforcement mechanisms to achieve its objectives.

With the creation of SEMARNAT in 1994 the Environmental Impact and Risk Assessments (EIA) was consolidated.[232] The activities that re-

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[226] Ibid, LGEEPA supra note 225, Article 1
[227] Ibid
[228] Ibid, Article 2 (III)
[229] Ibid, Article 2
[230] Ibid, Article 3 (XXI) and Article 2 of the CBD supra note 146
[231] Ibid, Article 3 XXVII and Article 2 of the CBD supra note 146
[232] National Institute of Ecology (INE), Environmental Impact Assessment: Achievements and Challenges for Sustainable Development 1995-2000; General Directorate of Law and Environmental Impact.

quire an impact and risk assessment include those involving transgenic material, such as the release of GMO's into the environment. [233]

It is important to highlight that the LGEEPA contains provisions with respect to Environmental Impact Assessment (EIA)[234]to be undertaken prior to disposal of hazardous waste, and prior to the import, export and the release of genetic material into the environment. This Law has also a regulation regarding EIA, which sets out federal guidelines and standards to evaluate and perform impact assessments of activities that could negatively disrupt the ecological equilibrium. It also develops and expands on the EIA contained in the LGEEPA and establishes a national framework for environmental protection.

The EIA procedure is initiated by an applicant's request before the SEMARNAT. The request must contain: first of all, an environmental impact statement (EIS), which contains detailed information on the project or activity that may alter or impact the environment, such as the construction of gas plants, oil plants, etc. The EIS must include information on activities that will be performed and the development plans of the project. Second, a legal analysis of the project's compliance with national legislation and regulations must be provided.[235] Third, the economic development path of the project and its potential environmental impact on the local and regional area must be set out. Fourth, identification, description and evaluation of the direct and indirect environmental impacts of the proposed activity must be provided in terms of mitigating and preventive measures.[236] Fifth, an evaluation of alternative locations, and sixth, an analysis of the methodology employed in the impact assessment must be detailed in the EIS.[237]

The LGEEPA applies to biological resources destined to biotechnological use, including wild flora and fauna, and applies, too, to the possession, management, preservation, and repopulation. It regulates the import, spreading and export of wild flora, fauna and genetic material by means of a permissions mechanism overseen by SEMARNAT. Flora and fauna species as well as other biological resources with biotechnology purposes are protected under this Law pursuant to Articles 2, 3, 82 and 87bis.

cc) LGEEPA´s Regulation in Terms of Environmental Assessment

[233] Ibid, LGEEPA, supra note 225, Article 28
[234] Ibid, Articles 28-35 BIS-3
[235] Ibid, Article 31
[236] Ibid
[237] Ibid

LGEEPA's Regulation in Terms of Environmental Impact Assessment[238] is of paramount importance because it applies to forest plantation, including reforestation or installation of breeding grounds with transgenic varieties and to sowing of transgenic species in aquatic ecosystem, installed units of production in water bodies, or aquatic infrastructure located in ground.

It seeks to protect the biodiversity pursuant to Article 5 ñ) II and u) requiring prior authorization granted by SEMARNAT (i) if there is an intention to carry out reforestation or installation of tree nurseries containing exotic species, hybrids or transgenic varieties and (ii) if the intention is also to carry out aquaculture activities that may endanger preservation of one or more species or may cause damage to the ecosystems.

Regarding the EIA applicants must include a risk assessment of the proposed activity where potential harm to the environment is envisaged, such as those projects or activities involving genetic material and GMO's. The risk assessment must be based on the technical information on the environment and on the activity contained in the impact statement. The risk assessment report must contain: first, a detailed analysis of the environmental risks of the project; second, possible scenarios and preventive measures regarding the risks of the proposed project; third, a delimitation of buffer protection zones in the surrounding areas; and, fourth, safety measures to protect from environmental harm.[239]

dd) Enforcement Measures

The Federal Attorney for Environmental Protection (PROFEPA) is the enforcement agency of SEMARNAT. It enforces the LGEEPA provisions in three ways: first, by means of audits and monitoring inspections; second, by imposing administrative sanctions;[240] and third, by means of public participation in the EIA procedure and the public complaint procedure overseen by the Attorney General for Environmental Protection.[241]

Monitoring and compliance is ensured by means of inspector visits and audits conducted by SEMARNAT.[242] Inspectors verify compliance with the commitments or conditions included in authorized impact assessments.

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[238] Reglamento de la Ley General del Equilibrio Ecológico y la Protección al Ambiente en Materia de Evaluación del Impacto Ambiental, published in D.O.F. on May 30, 2000.

[239] Ibid, Reglamento de la Ley General del Equilibrio Ecológico y la Protección al Ambiente en Materia de Evaluación del Impacto Ambiental, supra note 238, Article 18

[240] Ibid, LGEEPA, supra note 225, Articles 160-166

[241] Ibid, Article 189

[242] Ibid, Articles 160-171

By means of audits, compliance with emissions established in official standards is assessed. Pecuniary sanctions are imposed on those responsible for altering ecological equilibrium or causing environmental deterioration.[243]

The EIA procedure prescribed by LGEEPA and its regulation has the potential to help preserve biological diversity from harmful individual projects. Environmental NOM's, although available in the implementation of the LGEEPA, are only concerned with activities in the oil, electric and communications industries and their impact on the environment but not for biotechnology. NOM's are necessary to establish guidelines for evaluating EIA. In addition, the potential effectiveness of audits and inspection visits to enforce environmental Laws remains low unless financial resources are made available to carry them out. It is important to highlight that the citizen complaint process established in the LGEEPA is an innovative mechanism to aid SEMARNAT in enforcing environmental legislation. It has the potential to contribute to the preservation of biodiversity in cases where pollution and harm to the environment are easily identified by the general population. In the case of GMO's, the complaint procedure may not be very helpful since complicated technical analysis and scientific expertise is required to differentiate these organisms from their organic counterparts. Such specialized knowledge and skills are generally beyond the reach of the common citizen.

ee) The General Sustainable Forestry Development Law

The General Sustainable Forestry Development Law[244] protects biological and genetic forestry resources. Its goal is the conservation of biodiversity pursuant to Articles 7, 33, 58, 101, and 103. It requires authorization from SEMARNAT for applications contemplating germoplasm, genetic modification or manipulation for GMO's to be used for commercial purposes.

The requirement of an environmental impact assessment regarding reforestation, sowing or installation of tree nurseries containing transgenic varieties is the most important regulation concerning GMO's in the environmental sector. The aim is to avoid activities that may endanger preservation of one or more species or may cause damage to the environment.

[243] Ibid, Article 171 (I-III)

[244] Ley General de Desarrollo Forestal Sustentable published in D.O.F. on February 25, 2003, last amended and published in D.O.F. on December 26, 2005.

6. Federal Criminal Code

Another important change in the domestic regulation was the addition of Article 420Ter in the Mexican Criminal Code in 2001.[245] According to the above, a GMO is defined as:

> *Any organism having a new genetic material combination which had been obtained through the application of biotechnology procedures, including those resulting from genetic engineering techniques.*

The Criminal Code enforces penalties ranging from one to nine years in prison and imposes sanctions ranging from three hundred to three thousand salary days to whoever brings into or out the country, trades, transports, stores or releases into the environment, any genetically modified organism that negatively affects or may affect ecosystems.

7. Legal Framework for Biotechnology

On the one hand, Mexican experts[246] consider biotechnology as the key to avoid the loss of biodiversity, they also consider biotechnology as a tool to control plagues and to protect the environment and the human health by reducing the use of pesticides and fertilizers. However, in order to achieve this challenge Mexico needs to invest and promote the development of biotechnology.

The regulation of biotechnology has its legal foundation according to Article 3(V) of the Mexican Constitution.[247] This Article states:

> *The State shall promote and assist all sorts of educational models – including initial education and college education alike – which are deemed as necessary to develop the nation. The State shall also support scientific and technological research and motivate the strengthening and promotion of our culture.*

Likewise, the Science and Technology Law[248] in Articles 1, 9 and 9-bis[249] envisages the obligation of the Mexican Government to promote and

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[245] Código Penal Federal, Article 420Ter de los delitos en materia de bioseguridad published in D.O.F on August 14, 1931, last amended and published on November 27, 2007

[246] Bolivar Zapata Francisco G., "Biotechnologia Moderna para el Desarrollo de México" en: Alimentos Transgénicos "Ciencia, ambiente y mercado: un debate abierto, pp 261-268, siglo xxi S.A. de C.V. en coedición con el Centro de Investigaciones Interdisciplinarias en Ciencias y Humanidades, UNAM, primera edición 2004.

[247] Ibid, Constitución Politica de los Estados Unidos Mexicanos supra note 201

[248] Ley de Ciencia y Tecnología published in D.O.F. in Juny 5, 2002, last amended and published in D.O.F. on August 21, 2006.

develop the investment in science and technology and points out that this investment shall not be less than 1% gross domestic product (GDP). [250]However, Mexico has not attained this target and the investment has declined since 2000 from 0.42% to 0.33% in 2009. This can be seen in table 2.4.

Table 2.4 GDP: Investment in Science and Technology	
Year	**Percent**
2000	0.42
2001	0.41
2002	0.39
2003	0.43
2004	0.36
2005	0.37
2006	0.36
2007	0.35
2008	0.34
2009	0.33

Source: INEGI,[251] la Jornada[252] and Academia Mexicana de Ciencias.[253]

This table clearly shows the decline of the investment of the GDP in science and technology from 2000 to 2009. The attempt of the Mexican government to set aside at least 1% of GDP has failed as shown in table 2.1. This seems to suggest that science and technology are not a priority for the Mexican government. However, in other countries the allocation of GDP in sci-

[249] The addition of Article 9-bis to the Science and Technology Law was published in D.O.F. on September 01, 2004.

[250] Kubli-García Fausto, Capitulo V, Bioseguridad de Organismos Genéticamente Modificados en México, Pp 191-241 en: Régimen jurídico de la bioseguridad de los organismos genéticamnete modificados, Instituto de Investigaciones Jurídicas, UNAM, primera edición 2009.
Online:http://www.bibliojuridica.org/libros/libro.htm?l=2637

[251] Instituto Nacional de Estadistica, Geografia e Informática, (INEGI), Gasto Federal en Ciencia y Tecnología como porcentaje del Producto Interno Bruto (PIB) del 2000 al 2005, en México hoy, edición 2007, ciencia y tecnología pp. 95-111, publicado en febrero del 2008

[252] Gala José, "Alarmante el deficit de México en Tecnología: De la fuente en la Jornada, sección sociedad y justicia, México 17 de enero del 2007, página 39. The GDP assigned to science and technology in 2006 was 0.36% and in 2007 was 0.35%.

[253] Academia Mexicana de Ciencias, Boletín AMC/134/08, México, D. F., 5 de diciembre de 2008. The GDP set aside in science and technology in 2008 was 0.34% and in 2009 it reaches 0.33%.

ence and technology is 1% or higher as is the case of USA (2.7%), Japan (3%), the countries of the EU (1.9% average) and Brazil (1%).[254]

The lack of investment in science and technology especially in the development of biotechnology in the country not only endangers Mexico's global competitiveness in this area, but also its capacity to protect its natural resources and the corresponding reaction to possible risks resulting from the import of biotechnology products.

B. Conceptualization of the Issue with Relevance to Biodiversity and Biotechnology by the Lead of the CBD and the BSP

International Environmental Law (IEL) is formally a branch of public international Law – a body of Law created by nation states for nation states, to govern problems that arise between nation states.[255] The Statute of the International Court of Justice states in Article 38 that treaties, customary law, general principles of law and judicial decisions are a source of law.[256]

Usually, environmental commitments under international law are considered both in the form of "soft law" and "hard law". The latter creates binding obligations between states, while soft law does not have binding effects and lacks both specificity and enforceability. [257]

Notwithstanding, there have been important soft law milestones in the progressing of an international environmental agenda. Thus, the 1972 UN Stockholm Conference on Human Environment was a ground breaker in the sense of its key contribution to emergence of "sustainable develop-

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[254] Poy Solano Laura, "México, entre las naciones que menos recursos destinan a ciencia y tecnología", en la Jornada, sección sociedad y Justicia, México, 18 de enero del 2007, pág 45.

[255] Guruswamy Laksman D., International Environmental Law in a Nutshell, chapter one, "Sources and Forms of International Environmental Law" p. 1, second edition, 2003 by West, a Thomson Business.

[256] Article 38 (1) of the Statute of the International Court of Justice (Statute of the ICJ), confirms that "the Court ... shall apply: a. international conventions...; b. international custom, as evidence of a general practice accepted as law; c. the general principles of law recognized by civilized nations; d. ... judicial decisions and the teaching of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law".

[257] Stallworthy Mark. "Understanding Environmental Law", 1. Introduction: the Task of Understanding Environmental Law, 1.3 Human Environment and Legal Jurisdiction, p. 8, first edition 2008, by Sweet & Maxwell

ment". Principle 1 of the ensuing Declaration expressed the notion in terms of rights and responsibilities:

> *Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being, and he bears a solemn responsibility to protect and improve the environment for present and future generations.*

This was supplemented by principle 2, with respect to the earth's natural resources, described as "including the air, water, land, flora and fauna, and especially representative samples of ecosystems." It stated that these "must be safeguarded for the benefit of present and future generations through careful planning and management, as appropriate." Increasing concern at the global nature of environment problems, and their close relationship with economic development, led to the 1992 UN Rio Conference on Environment and Development. This followed in the wake of the 1987 Brundtland Report (World Commission on Environment and Development, Our Common Future), which produce the most widely accepted definition of sustainable development:

> *The development that ensures the needs of the present generations without compromising the ability of future generations to meet their own needs*

Following Rio, as already indicated, environmental and development concerns were to become integrated so as to bring about "the further development of international Law in the field of sustainable development".

In 2002, at the Johannesburg Summit held in South Africa, i.e. ten years after the "Rio Earth Summit", countries met to review progress towards sustainable development. They recognised that poverty eradication, changing consumption and production patterns, and protecting and managing the natural resource base for economic and social development are overarching objectives and essential requirements for sustainable development. States recognized also that sustainable development requires a long-term perspective and a broad-base participation in policy formulation, decision making and implementation at all levels.

As mentioned above, environmental principles have often been incubated in IEL. This is the case of the precautionary principle. Thus, the Rio Declaration (also known as the Rio Earth Summit) states in principle 15 the precautionary principle as follows:

> *In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

Thus, the Rio process produced an agreement for the first time seeking international protection of biodiversity: the 1992 CBD. For the first time biodiversity became an issue. The emphasis on national sovereignty was however retained, and many aspects regarding conservation are premised upon what amounts to encouragement of appropriate protection measures.

A key focus is upon innovations in biotechnology, and it is perhaps not surprising that other features, such as equitable sharing of benefits arising from the use of genetic resources, attract a high level of political attention. Biotechnology is emerging as a major source of dispute given the relationship between environmental protection and trade, and subsequent attempts to develop appropriate standards include the sophisticated regime, involving the application of the precautionary principle in the control mechanisms for cross frontier trade in LMO's, contained in the 2000 BSP.

I. Agenda 21

In 1992, at the UN Conference on Environment and Development held in Rio de Janeiro, the states agreed that the protection of the environment and social and economic development are fundamental to sustainable development, based on the Rio principles. The Rio summit produced a major plan for sustainable development called Agenda 21. It proposes that poverty can be reduced by giving people access to the resources they need to support themselves. Thus, developed nations agreed to assist others to develop in a way that will minimise the environmental impact of their economic growth. Agenda 21 calls on countries to reduce pollution, emissions and the use of precious natural resources. It states that Governments need to lead this change but emphasises that everyone can play their part in tackling non-sustainable practices. In this way, local actions can lead to the solution of global problems.

Regarding biotechnology Agenda 21[258] states that it promises to make a significant contribution to enabling the development of, for instance better

[258] Agenda 21, 1992, in the preamble and in chapter 16
Online:under:http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=52&ArticleID=64&l=en

health care, enhanced food security through sustainable agricultural practices, improve supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation and detoxification of hazardous wastes. Agenda 21 recognizes that biotechnology offers new opportunities for global partnerships, especially between the countries rich in biological resources (which include genetic resources) but lacking the expertise and investments needed to apply such resources through biotechnology and the countries that have developed the technological expertise to transform biological resources so that they serve the needs of sustainable development. However, it is necessary to foster internationally agreed principles to be applied to ensure the environmentally sound management of biotechnology, to engender public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms, especially within developing countries through the activities mentioned above.

II. Convention on Biological Diversity

The CBD has significantly enhanced the scope and potential effectiveness of the international legal regime for conserving the earth's biological diversity and ensuring the sustainable use of its components. It goes well beyond conservation of biological diversity per se and comprehends such diverse issues as sustainable use of biological resources, access to genetic material, and access to technology, including biotechnology.[259] The CBD entered into force on 29 December 1993, had 191 parties by mid-2008, and has thus become one of the most widely ratified of all environmental conventions.[260]

The conservation of biological diversity and biological resources is the prime objective of this CBD. It gives countries the responsibility for conserving their biological diversity and for using their biological resources in a sustainable manner.[261] It also states that the conservation of biological diversity is a common concern to humankind.[262] The most significant obligations

[259] Birnie Patricia, Boyle Alan and Redgwell Catherine, International Law and the Environment, chapter 11 "Conservation of Nature, Ecosystems and Biodiversity" page 612, third edition, Oxford University Press, 2009.
[260] Ibid
[261] Ibid, CBD, supra note 146 at the fifth preamble recital
[262] Ibid at the third preamble recital

placed on Parties concern in-situ,[263] and to a lesser extent, ex-situ[264] conservation which are dealt with under Articles 8 and 9.

Regarding LMO's the CBD contains three provisions: First, Article 8(g) deals with domestic measures in general and requires parties to regulate, to manage or to control risks associated with the use and release of LMO's resulting from biotechnology, which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity and taking into account the risks to human health. Article 8 (g) is closely related to Article 19 concerning the handling of biotechnology and its benefits. However, the responsibility for taking measures falls on the parties. Second, Article 19 (3) calls on parties

> *to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, Advanced Informed Agreement (AIA), in the field of the safe transfer, handling, and use of any living modified organism resulting from biotechnology that may have adverse effect on conservation and sustainable use of biological diversity.*[265]

This Article also provides the mandate for the negotiation of the BSP and indicates that the main focus of the negotiations was to be on the transboundary movements of LMO's primarily in the course of trade. Some of the concerns about the potential risks associated with LMO's were raised during the negotiations of the CBD, which focuses on the conservation of biodiversity and the sustainable use of its components.[266]In fact, the introduction of GMO into the environment may have an impact on the receiving ecosystem such as a possible transfer of genes and a subsequent modification of native species.[267]

Third, Article 19(4) considers transfers of LMO's from one party to another. It requires each party to provide information on domestic regulations concerning use and safety to any other party to which a LMO is pro-

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[263] In situ conservation means according to Article 2 the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and in the case of domesticated or cultivated species in the surroundings where they have developed their distinctive properties.

[264] Ex situ conservation means according to Article 2 conservations of components of biological diversity outside their natural habitats.

[265] Ibid, BSP, supra note 147 Article 1

[266] Ibid, Stoll Peter Tobias, supra note 22

[267] Ibid

vided, as well as any available information on the adverse effects which the introduction may have for this party.

The CBD mandates parties to cooperate in the formulation and adoption of protocols[268] and sets out basic rules as to their consideration and adoption.[269]

However, the CBD leaves the parties to decide in the course of its implementation, whether and on which subject a protocol would be a useful additional tool in the achievement of the CBD objectives.[270]

It is important to highlight that the CBD provides for precautionary measures in its ninth preamble recital, which states:

> *Where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.*

III. Cartagena Protocol on Biosafety

As noted above, the CBD expressly recognized the need to develop further international regulation of the transfer and use of LMO's which may have an adverse effect on the conservation and sustainable use of biodiversity.[271] Thus, an outcome of the CBD was the BSP,[272] which requires safe transfer, handling, and use of all LMO's.[273] It recognises the specificity of trade in biotechnology and the need to treat GMO's in a cautionary way i.e. applying the precautionary principle stated in the Article 15 of the Rio Declaration. The BSP is considered the most important key instrument between transboundary risk management and international trade.[274] Presently, 147 countries are party to the BSP.

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[268] Protocol is a binding international instrument, separate from, but related to another treaty.
[269] Ibid, CBD, supra note 146, Article 28
[270] Ibid
[271] Ibid, Birnie Patricia, page 640, supra note 259
[272] During the course of the meetings in Cartagena, five distinct negotiating groups of countries had emerged with different views on the outstanding core issues. They were: The Miami Group: Argentina, Australia, Canada, Chile, Uruguay and USA. The like-minded Group: the G77 countries (less the three members of the Miami Group. The European Union, the Central and Eastern Europe Group, the Compromise Group: Japan, Korea, Mexico, Norway and Switzerland, later joined by Singapore and New Zealand.
[273] Ibid, BSP supra note 147, Article 1
[274] Ibid, Peter Tobias Stoll, supra note 22

1. The Precautionary Principle

The precautionary principle has its origin in the German "Vorsorgeprinzip".[275] It was developed in the early 1970s into a fundamental principle of German environmental Law and has been invoked to justify the implementation of vigorous policies to tackle acid rain, global warming and North Sea pollution.[276]

In 1982 an early version of the precautionary principle was adopted in a non binding instrument (soft law) by the UN in its General Assembly Resolution on the World Charter for Nature. This was the first time that the idea of the need for precaution was internationally announced.[277] The resolution did not specifically incorporate the precautionary principle by name but principle 11 stated:

> *that activities which might have an impact on nature shall be controlled and the best available technologies that minimize significant risks to nature or other adverse effects shall be used in particular; (a) activities which are likely to cause irreversible damage to nature shall be avoided and (b) activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination.*

Thus, the key of this principle is the "irreversible damage to nature" and the "exhaustive examination," nowadays well known as the risk assessment. The precautionary principle[278] was first employed internationally in the North Sea Conference in 1984 and later affirmed by EC governments in the 1990 Bergen Ministerial Declaration on Sustainable Development. Based on these precedents, a text proposed by the European Union secured global endorsement in the 1992 Rio Declaration on Environment and Development in the following terms:

> *Principle 15: In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not*

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[275] Von Moltke, K. 1988. "The Vorsorgeprinzip in West German Environmental Policy": In Royal Commission on Environmental Pollution, Twelfth Report. Best Practical Environmental Option. Cmnd 310. London: HMSO.

[276] Weale A., 1992, "The New Politics of Pollution". Manchester University Press: London.

[277] Nava Escudero César, "El principio de precaución en el derecho internacional ambiental" pages 57-66 en: Estudios Ambientales, Instituto de Investigaciones Jurídicas, UNAM, primera edición 2009. Online:http://www.bibliojuridica.org/libros/6/2641/pl2641.htm

[278] Ibid, Birnie Patricia, page 154, supra note 259

be used for postponing cost-effective measures to prevent environmental degradation.

The Rio Declaration was adopted by states at that time and is the most important non-binding international instrument after the Stockholm Declaration of 1972. The precautionary principle aims to provide guidance in the development and application of IEL where there is scientific uncertainty.[279]

European Treaties and EC law refers to the precautionary principle,[280] whereas global agreements refer to the precautionary approach or precautionary measures.[281] In this matter, few commentators regard the difference between precautionary principle and precautionary approach as significant, although one view is that the precautionary principle applies in situations of high uncertainty with a risk of irreversible harm entailing high costs, whereas the precautionary approach is more appropriate, it is argued, where the level of uncertainty and potential costs are merely significant and the harm is less likely to be irreversible.[282] The question if it must now be applied by all states as a matter of international law is an open question. An important achievement of the BSP is that it places the precautionary approach in prominent positions: in its preamble and objectives of Article 1 and in the provisions of the risk assessment. Regarding biosafety, the application of the precautionary approach is crucial because biotechnology has only recently developed and its impact on ecosystems is difficult to ascertain and may be difficult to reverse. However, the application of the precautionary approach differs from country to country.

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[279] Sands Phillip, Principles of International Environmental Law, 6 General Principles and Rules page 267, second edition, 2003, Cambridge University Press

[280] See: 1992, Paris Convention for the Protection of the Marine Environment of the Northeast Atlantic, Article 2; 1992 UNECE Convention for the Protection of Transboundary Watercourses and Lakes, Article 2 (5); 1992 Maastricht Treaty on European Union, Article 174; 1994 Danube Convention, Article 2(4); 1999 Rhine Convention, Article 4

[281] See: Convention on Climate Change, Article 3; 1992 Convention on Biological Diversity, Preambel and 2000 Protocol on Biosafety; 1994 Sulphur Protocol, 1998 Heavy Metals Protocol, and 1998 Persistent Organic Pollutants Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution; 1996 Protocol to the London Dumping Convention, Article 3; 2001 Stockholm Convention on Persistent Organic Pollutants, (POPs) Convention, Article 1.

[282] See Garcia, in FAO, Precautionary Approach to Fisheries, Technical Paper 350/2 (Rome, 1996) 53-5 for the most detailed elaboration of the distinction.

2. The Risk Assessment and the Advance Informed Agreement

Regarding the import of LMO's according to Article 10.1, 11.6 (a) and 15.1, 15.2 and annex III section 3 of the BSP, the Parties must undertake a risk assessment prior to taking decisions on imports i.e. importing countries obtain all information about the LMO's to be imported, so that they may accept or reject the imports of LMO's on a precautionary basis without scientific certainty. The risk assessment should be carried out on a case-by-case basis and in a scientifically sound manner.[283]

According to Article 7 the Advance Informed Agreement (AIA) is designed to ensure that Contracting Parties are provide with the information necessary to make informed decisions before agreeing to the import of LMO's for intentional introduction into the environment into their territory. This approach reflects the underlying risk philosophy, which holds that the effects given LMO's may produce largely depend on the kind of ecosystem or environment into which it is introduced. The risk assessment must be based at least on information obtained under Article 8 of the BSP which requires the prior notification of movements accompanied by basic information and on other available scientific evidence.

It is important to mention that the risk assessment places a considerable burden on potential importing states, which must take decisions of imports of LMO's. Options for compensation for the burden and cost of risk assessment are provided as technical cooperation, assistance, and capacity building. Further, an importing party under Article 15.2 and 15.3 may require the exporter to carry out the risk assessment or may require the notifier to bear the cost. Nevertheless, as their wording reveals, both provisions are only applicable in the case of AIA and, thus, they do not cover an import state's risk assessment in the case of LMO FFPs.[284]

3. The Biosafety Clearing House

The BSP establishes mechanisms for parties to the protocol to inform each other about what they are doing in relation to modern biotechnology. This is known as the Biosafety Clearing House (BCH). It provides the sys-

[283] UNEP International Technical Guidelines for Safety in Biotechnology, pp. 21-22

[284] Article 15.2 refers to Article 10 only. Article 15.3 stipulates that the cost shall be borne by the notifier if the Party of import so requires. Article 11, however, dealing with the procedures for LMO's FFPs does not envisages a notification. Also Annex I. which lays down specific notification obligations for the importer - including a risk assessment- is entitled Information Requiring Notification under Articles 8, 10, and 13 but does not mention Article 11. For more information see Stoll, supra note 24

tems needed to ensure acceptability of the products of technology when living modified organisms that meet the definition in the protocol are transferred between member states.[285]

The types of information to be exchanged are broadly described as scientific, technical, environmental and legal information. The special role of the BCH in relation to LMO-FFPs is addressed in Article 11 of the BSP. The existing international biosafety information exchange mechanisms are the OECD[286], United Nations Industrial Development Organization, Biosafety Information Network and Advisory Service (UNIDO- BINAS)[287], International Centre for Genetic Engineering and Biotechnology Biosafety Bibliografic database (ICGEB)[288], UNEP[289], Microbial Strain Data Network (MSDN) and Information Resource for the Release of Organisms (IRRO).[290]

4. Transboundary Movements between Parties and Non Parties

Under the Vienna Convention on the Law of Treaties[291] a protocol cannot create rights and obligations for non-parties without their consent. The BSP regulates the conduct of parties in relation to transboundary movements of LMO's involving non-parties.[292] It envisages the transboundary movements of LMO's between parties and non-parties, and states that such movements must be consistent with the objective of the BSP and must be in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration and contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMO's that may have adverse effects on biological diversity, taking into account risk to hu-

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[285] Kinderlerer Julian. "Regulation of Biotechnology: needs and burdens for developing countries".
Online:http://www.unep.org/biosafety/Documents/BtregulationJK.pdf

[286] Organization for Economic Cooperation and Development – Biotrack.
Online: http://www.oecd.org/biotrack

[287] United Nations Industrial Development Organization, Biosafety Information Network and Advisory Service.
Online:http://binas.unido.org/binas/

[288] International Centre for Genetic Engineering and Biotechnology Biosafety Bibliografic database.
Online:http://www.icgeb.org/~bsafesvr/bsfdata1.htlm

[289] United Nations Environment Programme

[290] Information Resource for the Release of Organisms
Online: http://panizzi.shef.ac.uk/msdn/

[291] La Convention de Viena sobre el Derecho de los Tratados was published in D.O.F. on February 14, 1975.

[292] Ibid, BSP, supra note 147, Article 24

man health. The arrangement should also provide for mechanisms to ensure safe transfer, handling and use of a LMO and for a method to provide the importing country with an opportunity and a basis for deciding whether or not to consent to the import of LMO's.

Another Article that it is important to mention is Article 14 of the BSP since it addresses the situation where Parties to the BSP have concluded a separate agreement on intentional transboundary movements of GMO's. Such agreements or arrangements must also be consistent with the objective of the BSP as well and must not result in a lower level of protection for biodiversity and for human health than that provided for by the BSP.

In the case of Mexico these two Articles should be analysed for two reasons: Firstly, Mexico belongs to a regional economic block, NAFTA, with two countries that are not parties to the BSP; secondly, Mexico is a Party to the BSP. The BSP recognizes that trade and environmental agreements should be mutually supportive with a view to achieving sustainable development.[293] The challenge for Mexico is to find a key where trade and environment are mutually supportive. With this background, at the end of October 2003,[294] Mexico signed a trilateral arrangement concerning Article 18.2(a) of the BSP. The analysis of this agreement will be explained in chapter III.

5. Capacity Building Project for Implementation of the BSP

The BSP requires parties to cooperate in building capacity for the implementation of the BSP in developing countries.[295] This Article is closely linked to Articles 16 and 18 of the CBD. The Article 16 of the CBD requires parties to the CBD to provide and facilitate access to and transfer of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment. Article 18 of the CBD requires parties to cooperate technically and scientifically especially with respect to the development and strengthening of national capabilities in human resources development and institution building.

Mexico lacks adequate human, technical and financial resources to implement the BSP fully. Hence Mexico can not undertake an adequate risk

[293] Ibid, BSP, supra note 147, supra note 1, at the ninth preamble recital.

[294] CIBIOGEM, 2003 Agreement: "Documentation Requirements for Living Modified Organisms (LMO's) for Food, Feed and Processing. Internal Document of the Government of Mexico, Canada and the U.S. Restricted Document.

[295] Ibid, BSP, supra note 147, Article 22

assessment, or risk management of LMO's. Mexico can not even monitor LMO's once released into the environment. Mexico enforced the project "Capacity Building for Implementation of the BSP"[296] with the support of the Global Environmental Facility (GEF) from June 2002 to July 2005.

The project's main goal was to support the Mexican Government's implementation of the objective of the BSP, including the assessment, management and monitoring of the potential risks posed by transboundary movement of LMO's to the conservation and sustainable use of biodiversity, including human health risks. The project provided strategic, sustained and long-term support for the consolidation of Mexico's technical capacity to meet the challenges associated with the transboundary movement of LMO's under the BSP.

The national approach to capacity building included risk assessment and management, monitoring and evaluation, legal and regulatory reform/strengthening, broad social participation and a dissemination strategy in the context of the Advanced Informed Agreement procedure.

The lack of capacity for generating experimental data in the field limits the capacity of the country to accept and process requests under the AIA procedure. GEF support covered strategic elements of this approach over the medium-term horizon (3 years), which did permit the longer-term consolidation of the strategy. The GEF financed a part of the project that included regional activities of training and risk management to ensure sustainability and information exchange over the long-term. The GEF support had a catalytic and consolidating effect on the national effort spearheaded by the Inter-Secretarial Commission on Biosafety and Genetically Modified Organisms (CIBIOGEM).

In addition, the project also promoted wider dialogue and consensus between the different agencies that integrate the technical committee of CIBIOGEM and helped to centre the federal government's priorities in relation to GMO's. This improved coordination and dialogue was a key aspect of the proposed capacity building activity with the GEF. It is important to highlight that the project developed a methodology for environmental risk assessment. SEMARNAT uses a specific database[297] for the support of decision-makers to review the possible effects caused by GM crops on the non-GM

[296] Proyecto PNUD-CIBIOGEM. Online at http://www.cibiogem.gob.mx/

[297] The database contains key information, including the genetic information, reproductive biology of transgenic plants, including their wild relatives. It was developed with the aim to know in advance the hybridization rate of the improved LMO variety, and that of its wild relatives, in different environments.

crops growing alongside them.[298] The project also financed the equipment of two LMO detection laboratories, one in SAGARPA and the other in SEMARNAT.[299]

With this positive experience the Mexican Government considered it was necessary to carry out a second stage of the "Capacity Building for Implementation of the BSP" project. This second stage was financed with the resources of the Mexican Government through CIBIOGEM from May 2006 to November 2008. The core elements of this new stage are to first achieve institutional capacity building,[300] technical, scientific and telecommunications infrastructures, second, human resource development and training, third, awareness, participation and education at all levels, and fourth, information exchange and data management, including full participation in the BCH.[301]

This second stage also seeks to achieve the mechanisms for follow-up: monitoring and assessment of environmental and agricultural risk as well as the risk to human health against GMO's. It also seeks to build sufficient capacity to assess and manage risks associated with biosafety through the strengthening of the legal and regulatory frameworks, to enhance institutional capacity and administrative frameworks, to promote effective public awareness and communication strategies and to share and transfer knowledge and methodologies on biosafety through the establishment of regional training programs based in Mexico.

VI. Other International Developments

1. Organization for Economic Cooperation Development

a) The Blue Book

The OECD has been developing harmonised approaches to the risk/safety assessment of products of biotechnology since the mid-1980s. It has published reports on safety considerations, concepts and principles for risk/safety assessment and also information on field releases of transgenic crops, and a consideration of traditional breeding practices. It has established working groups, which are comprised of delegates from the 30 member countries of the OECD and the European Commission. The working group

[298] López Herrera Agustín, Best Practices and Lessons Learned from the UNDP-GEF Capacity Building Project fort he Implementation of the National Biosafety Framework of Mexico, pp. 5-6 in: Biosafety Protocol News, Volume 3/Issues 5, December 2008
Online http://www.cbd.int/doc/newsletters/bpn/bpn-03-05-en.pdf

[299] Ibid

[300] Ibid, BSP, supra note 147, Article 22

[301] Ibid, Article 20

also includes a number of observer delegations and invited experts who participate in its work. They include: Argentina, Russia, Slovenia, the United Nations Environment Programme (UNEP); the Secretariat of the CBD; the United Nations Industrial Development Organisation (UNIDO); and the Business and Industry Advisory Committee to OECD (BIAC).

The "Blue Book"[302] of the OECD was one of the first international scientific frameworks for the safe use of organisms derived from DNA techniques in industry, agriculture and the environment. The reason for focusing specifically on DNA organisms in the Blue Book was that techniques were being used to produce organisms with novel genetic combinations and there was limited, or no, experience with such organisms. It included the issues relevant to human health, the environment and agriculture that might be considered in a risk/safety assessment. It also included general scientific considerations. Regarding agricultural and environmental applications, it suggested that risk/safety assessors:

> *(i) Use the considerable data on environmental and human health effects of living organisms to guide risk assessment.*
>
> *(ii) Ensure that recombinant DNA organisms are evaluated for potential risk, prior to application in agriculture and the environment by means of an independent review of potential risks on a case-by-case basis.*
>
> *(iii) Conduct development of recombinant DNA organisms for agricultural and environmental applications in a stepwise fashion, moving, where appropriate, from the laboratory to the growth chamber and greenhouse, to limited testing and finally to large scale field testing.*
>
> *(iv) Encourage further research to improve prediction, evaluation, and monitoring of the outcome of applications of recombinant DNA organisms.*

b) Scale-up of Crop-plants: Risk/safety Analysis

In 1992, OECD published its Good Developmental Principles for the design of small-scale field research involving GM plants and GM micro-

[302] OECD, 1986: Recombinant DNA Considerations. Safety Considerations for Industrial, Agricultural and Environmental Applications of Organism Derived by DNA Techniques (The Blue Book), Paris, OECD

organisms. It described the use of confinement in field tests.[303]However, the focus of attention to the scale-up of crop plants changed by 1993, as plant breeders began to move to larger-scale production and commercialisation of GM plants. Thus, OECD published general principles for scale up, which re-affirmed that:

> *Safety in biotechnology is achieved by the appropriate application of risk/safety analysis and risk management. Risk/safety analysis comprises hazard identification, and if a hazard has been identified, risk assessment. Risk/assessment is based on the characteristics of the organism, the introduced trait, the environment into which the organism is introduced, the interaction between these, and the intended application. Risk/safety analysis is conducted prior to an intended action and is typically a routine component of research, development and testing of new organisms, whether performed in a laboratory or a field setting. Risk/assessment analysis is a scientific procedure which does not imply or exclude regulatory oversight or imply that every case will necessarily be reviewed by a national or other authority.*[304]

The issue of scale-up led to an important concept, "familiarity",[305] which is one key approach that has been used to address the environmental safety of transgenic plants. From the beginning, one of the goals of OECD was to promote international regulatory harmonisation in biotechnology among member countries.

c) Defining Substantial Equivalence as a Standard for Approving Novel Food

The OECD developed the concept of substantial equivalence in 1993.[306] It states that an assessment of a novel food, in particular one that is genetically modified, should demonstrate that the food is as safe as its traditional counterpart.[307] The safety assessment of GM foods is carried out through a comparison of the properties of the GM food with those of an

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[303] Confinement includes measures to avoid the dissemination or establishment or organisms from a field trial, for example the use of physical, temporal, or biological isolation (such as the use of sterility).

[304] OECD, 1993, Safety Considerations for Biotechnology: Scale-up of Crop Plants, 1993(a).

[305] The concept of familiarity is based on the fact that most GEO are developed from organisms such as crop plants whose biology is well understood.

[306] OECD, 1993: Safety Evaluations of Foods Derived by Modern Biotechnology: Concepts and Principles. Paris, OECD

[307] Conventional counterpart means a related organisms/variety, its components and/or products for which there is experience of establishing safety based on common use as food. CAC, Guideline 44-2003

existing food from which the GM food has been derived with a long history of safe use. It is a comparative analysis and embraces the idea that the existing traditionally produced food supply can be considered as safe due to its long history of safe use. The comparative analysis does not characterise the hazard and or the risk, which means that substantial equivalence is not an endpoint but provides a starting point for regulatory questions.[308] Its application assists in identifying the similarities and differences between an existing, conventionally produced food and the new GM-product, which are then subject for further toxicological investigations, as required.

Substantial equivalence has been formulated as a guiding tool for the assessment of GM food as part of a general safety evaluation framework, which means that the characteristics of the modified crop are compared to an existing traditionally bred crop. It also states that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety. Thus, no additional safety concerns would be expected. However, where substantial equivalence is more difficult to establish because the food or food component is either less well known or totally new, then the identified differences or the new characteristics should be the focus of further safety considerations. Thus, the goal of substantial equivalence is to ensure that the food and any substances that have been introduced into the food as a result of genetic modification are as safe as its counterpart.

To sum up, the aim of the risk assessment of food and feeds produced by GM technologies is to demonstrate that the novel crop, food or feed is a safe as its traditional counterpart and as such does not introduce any additional new risks to the health of man and animal. This approach involves the concept of substantial equivalence.[309] It is used in the USA and in Mexico to approve GMO's for human use and human consumption. The OECD de-

[308] Kuiper, H. 2003. The Use of Profiling Methods for Identification and Assessment of Unintended Effects in Genetically Modified Foods. National Academy of Sciences Workshop on identifying unintended health effects of genetically engineered foods, February 6-8, 2003. Washington, D. C.

[309] OECD, 1993, Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles. OECD, Paris; OECD, 2001, Consensus Documents, OECD Inter-Agency Network for Safety in Biotechnology; OECD, Paris; WHO, 1995, Application of the Principles of Substantial Equivalence to the Safety Evaluation of Foods or Food Components from Plants Derived by the Modern Biotechnology. Report of the WHO workshop. World Health Organization, Geneva; WHO/FAO, 2000 Safety Aspects of Genetically Modified Foods of Plant Origin. Report of a joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, 29 May- 2 June, 2000

veloped from 1993 to 1998 different consultations with regard to biotechnology.[310]

d) Unique Identification System for Transgenic Plants

The unique identification system for transgenic plants[311] has been used without any major problems as a "key" to access information of each transgenic product.[312] In addition, it has been recognised as an appropriate identification system of products included both in the BCH of the BSP and in the Mexican National Register of Biosafety on GMO's.

The objective of this database is to allow OECD member countries to share basic information on products derived from the use of modern biotechnology. This database is updated using information provided on a voluntary basis by authorities in OECD member countries and certain institutions that developed these products. Unique identifiers and relevant information on LMO's are then transferred to the database of the BCH based on a memorandum of corporation between the Secretariat of OECD and the Secretariat of Convention on Biological Diversity.

2. Activities Related to Food Safety: Codex Alimentarius/FAO/WHO

The Codex Alimentarius Commission (CAC) was established in 1962 to implement the Joint FAO/WHO Food Standards Programme. The objectives of the CAC include the protection of the health of consumers and the assurance of fair practices in the food trade. It is a non-binding code developed by the Codex Alimentarius Commission, a body of FAO/WHO which elaborates standards, general principles, guidelines and recommended codes of practice in relation to food safety and related issues. It plays an important

[310] OECD, 1992: Safety Considerations for Biotechnology; OECD, 1993 Safety Considerations for Biotechnology: Scale-up of Crop Plants. OECD, 1993: Traditional Crop Breeding Practices: An historical Review to Serve as a Baseline for Assessing the Role of Modern Biotechnology; OECD, 1995: Safety Considerations for Biotechnology: Scale-up of Micro-organisms as Biofertilizers.

[311] Unique Identifier is a code of a fixed length of 9 alphanumeric digits for a transformation event derived from recombinant DNA techniques. It is composed of three elements separated by dashes: 2 or 3 alphanumerical digits to designate the applicant; 5 or 6 alphanumerical digits to designate the "transformation event" and one numerical digit as verification.

[312] OECD 2002, "Guidance for the Designation of a Unique Identifier for Transgenic Plants" ENV/MONO (2002)7. Product Database.
Online: http://www.oecd.org/biotrack/productdatabase

role in relation to the safety of food derived from biotechnology.[313] It addresses issues of potential allergenicity, possible gene transfer from LMO's, pathogenicity deriving from the organism used; nutritional considerations; risk assessment, authorization procedures, and an appropriate labelling.

In 1991, the Code of Conduct on Biotechnology as it relates to Genetic Resources for Food and Agriculture (CGRFA) requested the preparation of a draft Code of Conduct on Biotechnology, with the aim of maximizing the positive effects, and minimizing the possible negative effects, of biotechnology. The draft Code of Conduct on Biotechnology was drawn up following a survey of over 400 international experts from the scientific community and members of the civil society. It contained five modules: first, biosafety and other environmental concerns; second, intellectual property and farmers rights; third, appropriate biotechnology for developing countries; fourth, minimizing the possible negative effects of biotechnology; and fifth, monitoring.[314]

In 1990 and 1996 FAO and WHO organized joint expert consultations to consider the safety and nutritional aspects of genetically modified foods. The 1990 consultation regarded biotechnology as a continuum, embracing traditional breeding techniques and modern techniques based on recombinant DNA technologies and concluded that foods from modern biotechnology were inherently not less safe than those from traditional biotechnology.[315]

In June 2000, a Joint FAO/WHO consultation on foods derived from biotechnology was held in Geneva.[316] It addressed the overall safety aspects of foods derived from genetically modified plants and focused on the applicability of substantial equivalence as a general guidance for scientific risk assessment. This consultation identified specific areas on which further expert consultation was needed and recommended that FAO/WHO should convene an expert consultation on the assessment of allergenicity of geneti-

[313] CAC addresses issues of potential allergenicity; possible gene transfer from LMO's, pathogenicity deriving from the organism used; nutritional considerations; risk assessment and authorization procedures, and an appropriate labelling.

[314] For more information see online: http://www.fao.org/ag/cgrfa/biocode.htm

[315] WHO 1991: Strategies for Assessing the Safety of Foods Produced by Biotechnology, Report of a joint FAO/WHO Consultation, WHO, Geneva.

[316] FAO/WHO (2000): Safety aspects of genetically modified foods of plant origin, FAO/WHO consultation 29 May – 2 June 2000. WHO, Geneva, Switzerland

cally modified foods and the novel proteins contained therein as a matter of priority.[317]

The 2000 consultation adapted a decision-tree (Annex 3) for the evaluation of allergenicity of novel proteins introduced into genetically modified foods. It agreed that the reliability of the risk assessment procedures for allergenicity of genetically modified foods using the decision-tree approach should be further enhanced, including the consideration of additional criteria.

The joint FAO/WHO expert consultation on foods derived from biotechnology in 2000 concluded that the safety assessment of genetically modified foods requires an integrated and stepwise, case-by-case approach, which can be aided by a structured series of questions.

Consultations convened by FAO/WHO and OECD recommended substantial equivalence as an important component in the safety assessment of foods and food ingredients derived from genetically modified plants intended for human consumption.[318] The concept of substantial equivalence embodies a science-based approach in which a genetically modified food is compared to its existing, appropriate counterpart. The approach is not intended to establish absolute safety, which is an unattainable goal for any food. The goal of this approach is rather to ensure that the GM food is as safe as its traditional counterpart. The concept of substantial equivalence was developed as a practical approach to the safety assessment of genetically modified foods.

FAO and WHO convened a consultation to evaluate experience gained since the 1996 Joint FAO/WHO Consultation[319] and to assess whether any new scientific information would suggest a need for modifying current approaches for assessing the safety of foods and food ingredients derived from genetically modified plants. This consultation also provided an opportunity, in the light of recent scientific reports, to review the scientific basis, application, and limitations of the concept of substantial equivalence.

Hazard and risk were other issues discussed in the Joint FAO/WHO expert consultation on the application of risk analysis to food safety stan-

[317] Safety Assessment of Foods Derived from Genetically Modified Microorganisms, a joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, Geneva, Switzerland, 24 to 28 September 2001; Allergenicity of Genetically Modified Foods, a joint FAO/WHO Consultation on Foods Derived from Biotechnology, Rome, Italy, 22-25 January 2001

[318] FAO, 1997: Biotechnology and Food Safety, Food and Nutrition Paper 61, FAO, Rom.

[319] FAO/WHO 1996: Biotechnology and food safety, Report of a joint FAO/WHO consultation. FAO, Food and Nutrition, Paper 61, FAO, Rome.

dards in 1995.[320] Hazard was defined as a biological, chemical or physical agent in, or condition of, food with the potential to cause harm. In contrast, risk is an estimate of the probability and severity of the adverse health effects in exposed populations, consequential to hazards in food. Understanding the association between a reduction in hazards that may be associated with food and the reduction of risks of adverse health effects to consumers is of particular importance in the development of appropriate food safety controls.

Risk analysis is widely recognised as the fundamental methodology underlying the development of food safety standards. Risk analysis is composed of three separate but integrated elements: firstly, risk assessment[321]; secondly, risk management[322] and thirdly, risk communication[323]. Their definitions are provided in the principles for the risk analysis of foods derived from modern biotechnology CAC/GL 44-2003.

It is worth mentioning that there are three important stages regarding in the development of guidelines related to biotechnology. The first stage took place from 1993-1998. During this time the CAC approved a task force for five years with the aim to elaborate strategies for assessing the safety of foods produced by biotechnology. The second stage took place from 1999-2003.

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[320] Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Safety Standards, held in Geneva, Switzerland, 13-17 March 1995.

[321] Risk assessment includes a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity. The safety assessment should include a comparison between the food derived from biotechnology and its conventional counterpart focusing on determination of similarities and differences. If a new or altered hazard, nutritional, or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health.

[322] Risk management includes, as appropriate, food labelling, conditions for marketing approvals and post-market monitoring. Post market monitoring may be undertaken for the purpose of verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects, and monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact. To facilitate the implementation and enforcement or risk management measures they may include appropriate analytical methods; reference materials; and the tracing of products for the purpose of facilitating withdrawal from the market when risk to human health has been identified.

[323] Risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers. It should include transparent safety assessment and risk management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny, whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information.

Thus, in 1999, the CAC at its 23rd session decided to establish an ad hoc intergovernmental task force on foods derived from biotechnology. In 2003, three documents of relevance to LMO's were issued: first, the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL/ 44-2003); second, the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) and third, the Guideline for the Conduct of Food Safety Assessment of Foods produced using Recombinant-DNA Microorganisms (CAC/GL 46-2003).

The third stage took place at the fifth meeting in September 2005. It concluded with three other important documents: first, the "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals", presided by Japan; second, "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and Regarding Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits", presided by Canada, and third; "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-level Presence of Recombinant-DNA Plant Material" presided by the USA and Germany.

C. The Mexican Biosafety Law as an Implementation of International Commitments in the Sense of a Homogenous Approach

I. Hierarchy of International Agreements in Mexico

There are international agreements, which address the risks posed to the environment and human health in case GMO's are intended to be released into the environment, either for research and for contained use but especially for commercial purposes. In the biosafety area there are on the one hand binding instruments (hard law) for Mexico like the CBD and the BSP. On the other hand, there are other international instruments addressing biotechnology like the OECD, the FAO of the United Nations,[324] the WHO and the CAC, which are not binding instruments but due to the fact that Mexico is a member of such international organizations, it should take into

[324] Mexico has been a UN member since 7 November 1945.
Online: http://www.un.org/members/list.shtml#m

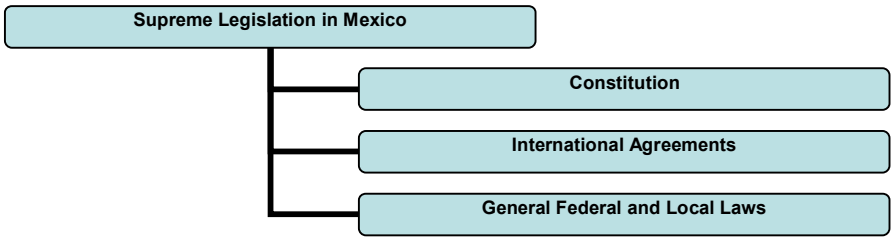
account their recommendations related to the development of measures and procedures regarding the protection of human health and of the environment against GMO's.

The CBD and the BSP are binding instruments for Mexico because the Mexican Constitution granted them a hierarchy of Supreme Law according to Article 133, which states:

> *This constitution, and the Laws enacted by the Congress which shall be made in pursuance thereof; and all Treaties made, or which shall be made, by the President of Mexico with the Senate's consent shall be the supreme Law of the Union. The judges in every State shall be bound thereby, anything in the constitution or Laws of any state to the contrary notwithstanding.*

Furthermore, the Supreme Court of Justice of the Nation (SCJN)[325] issued a jurisprudence[326] regarding the hierarchy of international agreements. [327] The SCJN states that based on an interpretation of Article 133 of the Mexican Constitution, it is possible to identify a supreme legal order. This is comprised of the Constitution, international agreements and general laws enacted by Congress. Thus, the SCJN held that international agreements are part of the supreme legislation of the country and are hierarchically above the general federal and local Laws but below the Mexican constitution. [328]

Figure 2.1 Supreme Legislation in Mexico



[325] The SCJN is the highest federal court in Mexico

[326] In Mexico, in order for a ruling to become jurisprudence, which for Mexican purposes means that the SCJN should resolve subsequent cases using the same criteria, it must rule five times consecutively in the same manner the same issue.

[327] Jurisprudence: Novena Epoca; Instancia: Pleno; Fuente; Semanario Judicial de la Federación y su Gaceta; Tomo: X, Noviembre de 1999; Tesis P.LXXVII/99; Página: 46; Jurisprudence: Novena Epoca; Instancia: Pleno; XXV Abril de 2007; Tesis P.IX; tesis aislada, registro no. 172650

[328] Ibid, Nava Escudero César, supra note 155

Thus, international agreements like the CBD and the BSP are binding instruments for Mexico and belong to the supreme legislation.

II. Historical Development of the Mexican Biosafety Law

As mentioned at the beginning of this chapter the commercialisation of GMO's in the world has been rapidly increasing since the 1990s. The first stage of the regulation of biotechnology and biosafety in Mexico dates from 1996 with the issue of the first Law governing GMO's the NOM-056-FITO-1995, which was in force until its cancelation in December 2006 due to the fact that the Mexican Biosafety Law was promulgated.

Before 2005, Mexico had a fragmented and disperse legal framework for the regulation of biotechnology and biosafety. The existing laws and regulations sought to regulate mainly the agricultural, the environmental and the health area regarding biotechnology and its implicated risks.

Prior to the enactment of the Mexican Biosafety Law the Mexican Congress created in 2002 Committees for Science and Technology and Environment, Natural Resources and Fisheries to conduct comprehensive studies on how to balance Mexico's wealth of biological resources against its international obligations to promote free trade. These committees acknowledged that there was a close relationship between biotechnology and biosafety and that biotechnology offers innumerable benefits to agriculture and human health, plant and animal health, and the improvement of contaminated soil through bioremediation. They also noted that biotechnology could provide a venue for Mexico to develop economically. [329]

In addition, Congress considered the six legislative initiatives by Mexico's political parties, namely, the Green Ecological Party of Mexico (PVEM), the National Action Party (PAN), the Institutional Revolutionary Party (PRI) and the Democratic Revolution Party (PRD).[330] With the support of some members of the Mexican Science Academy (AMC)[331] the Mexican Government developed a bill, which covers all stockholders regarding the regulation of biotechnology and the biosafety policies in the country. It involves all sectors and applies to all functions such as: the contained use,

[329] Ibid, Juan Herrera, supra note 188

[330] Ibid, Nava Escudero César, supra note 155

[331] Academia Mexicana de Ciencias: Comite de biotecnologia, cronologia de proceso legislativo de la Ley de Bioseguridad de Organismos Genéticamente Modificados.

Online: http://www.amc.unam.mx

handling, transport, packaging and identification, Intentional release of GMO's into the environment; GMO's for use as food or feed or for processing, pharmaceuticals, public awareness and participation; transboundary movements (import/export) and transit.

Thus, the Mexican Biosafety Law[332] was published in the D.O.F. in March 18, 2005 and it is considered the most important regulatory development in biosafety and biotechnology policies in Mexico. It was designed to comply with the provisions of the BSP. Furthermore, it establishes the foundation on biosafety regulations in Mexico and the institutional structure needed for this purpose.

The Mexican Biosafety Law has a regulation[333] which provides the guidelines for the release of GMO's into the environment in its three stages: experimental, pilot and commercial. It also provides the guidelines for the use of GMO's as FFPs.

III. Coordination of Biotechnology Policies

CIBIOGEM was created by Decree and was published in the D.O.F. on November 5, 1999 to comply with a difficult mandate in a mega diverse country and centre of origin and diversity of maize and different crops. It has the core institutional responsibility for policy-making and scientific advice regarding biosafety. It is a committee of the executive branch of the government, which was established to develop GMO-related policies. [334] Its goal is to protect the Mexican health and to protect and preserve its biological resources through biosafety measures. It is composed of: Mexico's National Council of Science and Technology (CONACYT),[335] plus representatives from the Secretariat of Health, SAGARPA, SEMARNAT, the Sectretariat of Finance and Public Credit (SHCP), the Secretariat of Education (SEP)[336] and the Secretariat of Economy.

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[332] Ley de Bioseguridad de Organismos Genéticamente Modificados (LBOGM) published in D.O.F. on March 18, 2005

[333] El Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados was published in D.O.F. on March 19, 2008, last amended and published on March 06, 2009.

[334] See online: http://www.cibiogem.gob.mx/que_es_CIBIOGEM/que_es_CIBIOGEM.html

[335] CONACYT is responsible for implementing biosafety research useful for risk analysis. The results of this research, as well as information on biotechnology information in general will be fully accessible in the CIBIOGEM website and in the biosafety clearinghouse mechanism.

[336] Secretariat of Public Education is responsible for designing and implementing dissemination strategies on LMO's for primary and secondary level textbooks, as well as for teachers and professors in the mandatory public education system.

The Mexican Law on Biosafety states that the Commission aims to promote and coordinate the actions of Government agencies. CIBIOGEM receives support from the Executive Secretary[337], the Technical Committee[338], the Scientific Advisory Board[339] and the Joint Advisory Council[340]. In addition to these three technical and advisory groups, CIBIOGEM establishes mechanisms for participation of all sectors (academic, scientific, technological, indigenous communities, social and productive), with experience in issues directly related to biosafety. All of them are allowed to participate through opinions, studies and consultations in order to generate knowledge and expertise to support public policies and promote research on biotechnology and biosafety. CIBIOGEM is run by an executive secretary, which according to the Mexican Biosafety Law is appointed by CONACYT after consultations with the member secretariats and with the approval of the President. CIBIOGEM has a consultative council on biosafety. It is comprised by researchers from diverse higher education institutes as well as representatives from the biotechnology industry. In addition, there is a technical committee and it works as an operative and administrative body. It is integrated by directors of the above mentioned Secretariats.

The role of CIBIOGEM is the establishment of mechanisms and procedures allowing an adequate and reasonable assessment of potential risks when handling GMO's. CIBIOGEM has also the obligation to establish

[337] The Executive Secretariat, headed by the Executive Minister, follows up implements CIBIOGEM agreements. In addition, its role is to support the Commission for the implementation of the Mexican Biosafety Law and its regulations.

[338] Technical Committee: formed by coordinators, general directors or their equivalent with experience in biotechnology and GMO's biosafety from the six secretariats and CONACYT. This committee supports the Commission's actions and may propose the creation of special subcommittees in different specific subjects.

[339] Scientific Advisory Board: a technical and scientific council which must be consulted on aspects of modern biotechnology and GMO's biosafety. The resulting technical recommendations are considered by CIBIOGEM in decisions that it takes. This group is composed of 13 experts of different disciplines from centres, research institutions, scientific societies and universities of recognized standing. They work in a personal capacity, regardless of the institution to which they belong. Among the functions of the Advisory Council is the development of research procedures, analysis and methodologies and technical expert advice.

[340] Joint Advisory Council: an auxiliary group for consultation and opinion polls of CIBIOGEM, composed of 15 association representatives, chambers or private, social and productive sectors. Its main objective is to know and comment on social, economic, and other aspects relating to regulatory policies and promotion. Furthermore, their discussion is also focused on the priorities of standardization of administrative procedures, improvement of paperwork and procedures related to biosafety of GMO's.

mechanisms to monitor potential risks of GMO's against biological diversity, human, animal and plant health at short, medium and long-term intervals. It develops and promotes the foundation of applied research in biotechnology and biosafety. Its objective is to coordinate the policies of the Mexican Federal Public Administration related to biosafety and to the production, import, export, movement, propagation, release, consumption, and, in general, the uses and benefits of GMO's, their products and by-products.

Under the umbrella of CIBIOGEM there are four main secretariats[341] that enforce biotechnology and biosafety policy within the Mexican Government: the Secretariat of Health, SAGARPA, SEMARNAT, and the Secretariat of Finance and Public Credit. These Secretariats are responsible for the import, export and release of GMO's into the environment. They are also responsible for the risk evaluation and risk management of GMO's. The carrying out of coordinated activities from the different secretariats under the guidance and mandate of CIBIOGEM ensures an equilibrated development of national capacities in biosafety in the areas of health, agriculture and environment.

It is important to mention that CONABIO is not part of CIBIOGEM although as a member of its consultative body it provides information on Mexico's biodiversity, risk evaluation methodologies and database support.[342] Unfortunately, the reports provided by CONABIO are only for informative purposes. The information of the reports is used principally by SAGARPA and SEMARNAT with the aim to avoid the release of GMO's into the environment in zones with potential concentrations of wild relatives. CONABIO is also charged with developing a biosafety information module based on its national biodiversity information system through the CIBIOGEM constitutional decree. CIBIOGEM is the national focal point for the secretariat of the BSP.[343] It is the competent authority and it is responsible for the implementation of the provisions of the BSP therefore, it coordinates the specialised subcommittees and in general all government activities related to biosafety, risk evaluation and management of GMO's. As aforementioned, it has the responsibility to control the release of GMO's

[341] Ibid, Mexican Biosafety Law, supra note 332, Article 10

[342] Acevedo Gasman Francisca, Huerta Ocampo Elleli, Barrios Pérez Alejandra y Oliveros Galindo Oswaldo. El análisis de riesgo a la biodiversidad: la experiencia de Conabio en: Bioseguridad en la aplicación de la biotecnología y el uso de los organismos genéticamente Modificados, pp. 145-159, CIBIOGEM/PNUD/GEF, primera edición 2008.

[343] Ibid, BSP, supra note 147, Article 19

into the environment and to establish and coordinate biosafety measures in Mexico.

IV. Adoption of the Precautionary Principle

Mexico has signed binding and non-binding instruments related to the protection of biodiversity and of the environment. Mexico, as a mega diverse country and as COD of maize and other important crops such chilli pepper, beans, squash, papaya, cotton, tomato, guayaba, cacao, agave, and amaranth among others, thus has the obligation to protect, conserve and preserve its biological diversity in a sustainable way with the aim to comply with its international and national commitments. The current Mexican Biosafety Law adopted the precautionary principle as defined in Principle 15 of the Rio Declaration and in the Sanitary and Phyto-sanitary Agreement of the World Trade Organization (WTO) in its paragraphs 6 and 7 of Article 5.[344] The precautionary principle has played an important role in the last three decades. It has been included in current national and international regulations and agreements concerning the protection, conservation and preservation of biodiversity and in the regulation of the safe use and transfer of LMO's resulting from biotechnology. Hence, Mexico adopted the precautionary principle in chapter II, Article 9 (IV). It states that:

> *In order to protect the environment and biological diversity the Mexican Government has the obligation to apply the precautionary approach according to its capabilities, taking into account commitments established in international treaties and agreements of which Mexico is a party. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. Such*

[344] Paragraph 6:.....when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary and phytosanitary protection, taking into account technical and economic feasibility

Paragraph 7:...."In cases where relevant scientific evidence is insufficient, a member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary and phytosanitary measures applied by other members". In such circumstances, members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

measures shall be applied according to the provisions and administrative procedures established in this Law.

Article 9 (IV) seeks to harmonize both the environmental and the commercial commitments of Mexico. On the one hand, the adoption of the whole definition of the precautionary principle of the 1992 Rio Declaration reflects the paramount importance of the precautionary approach in the Mexican Biosafety Law. On the other hand, the Article subjects the application of the precautionary approach to the provisions provided in this Law. In this sense, decision-makers have the obligation to apply the precautionary approach which depends on the law. As a result of the above, the application of the precautionary approach results difficult since the law does not provide guidelines to apply it. In this sense, decision-makers have the obligation to apply the precautionary approach but due to the fact that it depends on the provisions and administrative procedures established in the Mexican Biosafety Law it makes the application of the precautionary approach difficult because the Law does not provide guidelines to apply it. The precautionary approach is also mentioned at the risk assessment stage. Article 63 states:

where there is uncertainty regarding the level of the possible risk of GMO's against biological diversity the competent secretariat shall request additional information from the applicant based on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the GMO's in the receiving environment.

In case of serious or irreversible damage, uncertainty regarding the level of risk GMO's may cause, against biological diversity or human health, shall not be used as a reason for the Secretariat in charge to postpone effective measures that prevent negative effects on biological diversity or human health.

In adopting such measures, the Secretariat in charge shall take into account existing scientific evidence to be employed as criteria to establish such measures; administrative procedures provided in this law; international trade agreements and guidelines developed by relevant international organizations, of which Mexico is a party.

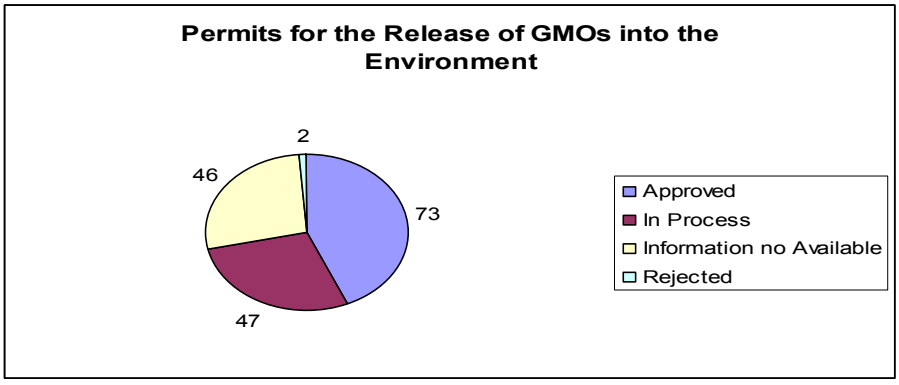
It envisages the precautionary approach as well but once again, the Law does not define how this precautionary approach should be applied rather, it provides that the precautionary approach should be applied taking

into account precautionary measures and Mexico's obligations contained in international trade agreements. Nevertheless the Law does not provide guidelines for the implementation of those measures.

V. National Register of Biosafety on GMO's

The National Register of Biosafety on GMO's[345] is in charge of the executive secretary of CIBIOGEM. It recognises the unique identification system for transgenic plants developed by the OECD in 2002[346] as a key to access information of each transgenic product. It is also adopted in the BCH [347] of the BSP. The National Register of Biosafety on GMO's and the BCH of the BSP were designed to facilitate the exchange of information concerning GMO's. Thus, it provides information about the authorized permits of GMO's to be released into the environment and about the GMO's approved for human consumption. Currently, the National Register of Biosafety on GMO's[348] contains 168 requests for permits for the release of GMO's into the environment of alfalfa, canola, cotton, maize and soybean: 73 are approved, 47 are in process, 2 are rejected and 46 do not have available information. See figure 2.2 and table 2.3 below.

Figure 2.2



Source: CIBIOGEM

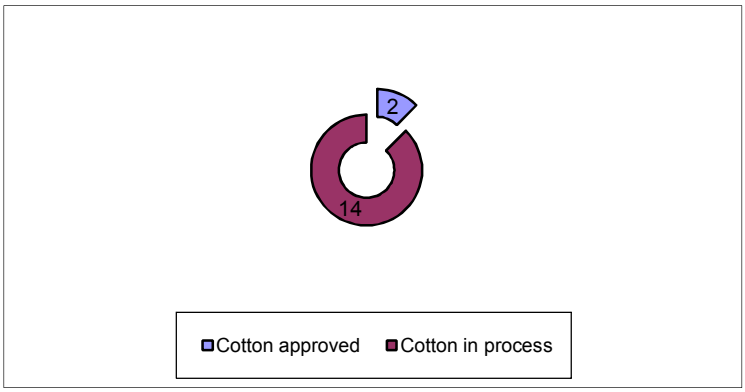
[345] Ibid, Mexican Biosafety Law, supra note 332, Article 109
[346] Ibid, OECD, 2002, "Guidance for the Designation of a Unique Identifier for Transgenic Plants", supra note 312
[347] The BCH is established as part of the CHM created under the CBD Article 18 paragraph 3.
[348] Registro Nacional de Bioseguridad de los Organismos Genéticamente Modificados. Online: http://www.cibiogem.gob.mx/RegistroOGMs.html

Table 2.5 Request of Permits for the Release of GMO's into the Environment				
Cultivation	Approved	In Process	Rejected	No Available information
Alfalfa	1	7		
Canola			1	
Cotton	55	32	1	21
Maize				25
Soybean	17	8		
Total	73	47	2	46

Source: CIBIOGEM

It is important to highlight that there are currently two authorizations of permits for a pilot program of cotton and fourteen permits are in process of being authorized. This is the second stage of the release of GMO's into the environment following a step-by-step basis. This seems to suggest that the last stage i.e. the commercial release of cotton will take place in Mexico soon.

Figure 2.3 Permits in Pilot Program

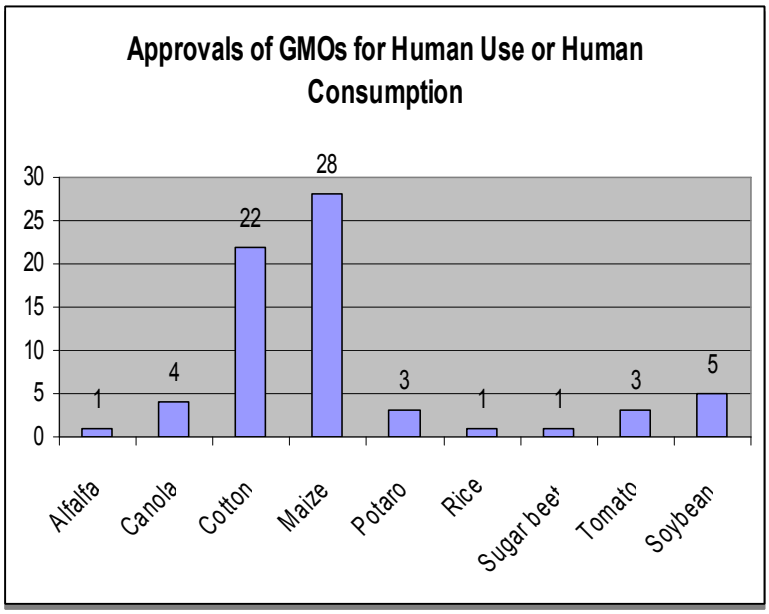


Source: CIBIOGEM

With regard to GMO's approved for human use or human consumption, the National Register of Biosafety on GMO's contains 68 authorized biotechnology-derived products for human use or human consumption in

Mexico.[349] These include: alfalfa 1, canola 4, cotton 22, maize 28, potato 3, rice 1, sugar beet 1, tomato 3 and soybean 5.

Figure 2.4



Source: Author Survey[350]

The authorizations have been granted to 11 Multinationals: AgrEvo (2), Aventis Crop Science (1), Bayer (6), Calgene (2), DNA Plant Technology Co. (1), Dow AgroScience (9), Hibridos Pioneer/Dow AgroSciences (4), Hibridos Pioneer (4), Monsanto (31), Syngenta (7), Zeneca Plant Science (1).

While the authorizations of GMO's for human consumption focus mainly on maize, in contrast, the permits of GMO's to be released into the environment are commonly for cotton.

[349] Ibid, Registro Nacional de Organismos Genéticamente Modificados, supra note 348
[350] For more information see: COFEPRIS, online: www.cofepris.gob.mx

VI. The Information System of Living Modified Organisms (SIOVM)

From 1998 the SIOVM has been operating under CONABIO's supervision which has developed a risk assessment methodology with the purpose of analyzing the risk that LMO proximity could present on wild populations of related species. The main purpose of the analysis is to detect the possibility of gene flow taking place between the LMO and the wild relative populations in existence. The methodology is divided into three sections: firstly, identifying the wild relatives of the LMO that pretend to be released into the environment; secondly, determine the wild relative and LMO characteristics needed for the hybridization to take place; thirdly detect if the release of the LMO falls inside the potential dissemination of the wild relatives. Once the analysis is done, an opinion is issued. This technical opinion helps SAGARPA and SEMARNAT to make a decision regarding the approvals of permits for the release of GMO's into the environment. With regard to maize (Zea mays L.), the SIOVM has information about 39 varieties.[351]

VII. Objectives and Scope of the Mexican Biosafety Law

This Law seeks to prevent, avoid or reduce the possible risks to human, plant, animal and aquaculture health as well as risks against the environment and biological diversity that the experimental, the pilot program and the commercial release of GMO's into the environment may cause.[352] It also regulates imports, exports, marketing and the contained use of GMO's.[353]

The objectives set out in this Law are quite ambitious because it covers the control and regulation of all activities in the country that deal with various aspects of biosafety and biotechnology. It sets out broader objectives than those employed by the BSP since it addresses issues of labelling, pharmaceuticals and consumption of transgenic commodities.[354]

VIII. The Risk Assessment Applying the Precautionary Principle on a Case-by-case Basis

The word "risk" plays a special and important role not only in the Mexican Biosafety Law where it constantly appears but it is a legal concept adopted both in Mexican and in international legislation.[355] Risk assess-

[351] Ibid, Acevedo Gasman Francisca, supra note 342
[352] Ibid, Mexican Biosafety Law, supra note 332, Article 1
[353] Ibid
[354] Ibid, Juan Herrera, supra note 188
[355] Betancour Rodríguez, Andres, 2001, Instituciones de Derecho Ambiental, Madrid, la Ley.

ment[356] is the key to guarantee biosafety when releasing GMO's. It ensures biosafety in activities involving the release of GMO's into the environment. The objective of a risk assessment is to identify and evaluate the possible risks or effects GMO's may produce in the likely or potential receiving environment, in biological diversity, and in the human, animal, plant and aquaculture health.[357]

It is worth mentioning that neither the BSP defines "possible adverse effects" on the release of LMO's into the environment nor does the Mexican Biosafety Law define the "possible risks" on the release of GMO's into the environment. However, in this matter, the EU legislation made a categorization of direct, indirect, immediate and delayed effects of GMO's on release of GMO's into the environment.[358]

The risk assessment of GMO's is carried out and followed up on a case-by-case basis, i.e. each organism is individually analysed based (i) on the scientific principles, (ii) on the available techniques, and (iii) on scientific evidence. The case-by-case basis requires the application of the precautionary approach to take into account expert advice.[359] It is worth mentioning that the risk assessment takes into consideration a trinomial method: (i) the recipient organism[360], (ii) the genetic modification[361] (iii) the receiving envi-

[356] Ibid, Mexican Biosafety Law, supra note 332, Risk Assessment Articles 60-65

[357] Ibid, Article 60

[358] Annex II, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms. OJ L 106/1 (17 April 2001). Categorization of the EU: (i) Direct effects refer to primary effects on human health or the environment which are caused as result of the GMO itself and which do not occur through a causal chain of events; (ii) Indirect effects refer to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management. Observations of indirect effects are likely to be delayed; (iii) Immediate effects refer to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect; (iv) Delayed effects refer to effects on human health or the environment which may not be observed during the period of the release of the GMO but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

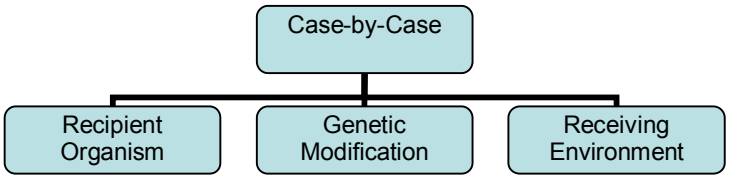
[359] Ibid, Article 61 (I) Mexican Biosafety Law, supra note 332

[360] It should take into account the biological characteristics of the recipient organism, including information on taxonomic status, common name, origin, centres of origin, centres of genetic diversity, if know, and a description of the habitat where the organism may persist or proliferate.

[361] It should take into account the genetic characteristics of the inserted nucleic acid and the function it specifies, and/or the characteristics of the modification introduced

ronment.[362] However, if one of the elements of the trinomial changes a new risk assessment should be made. [363]

Figure 2.5 Case-by-Case Basis



The risk assessment entails, as appropriate, the following steps[364]: (i) an identification of any novel characteristics associated with the GMO that may have possible risks to biological diversity[365]; (ii) An evaluation of the likelihood of these risks being realized, taking into account the level and kind of exposure of the GMO[366]; (iii) An evaluation of the consequences should these possible risks be realized[367]; An estimation of the overall risk posed by the GMO based on the evaluation of the likelihood and consequences of the identified possible risks being materialized;[368]A recommendation as to whether or not the possible risks are acceptable or manageable, including where necessary, identification of strategies to manage these possible risks.[369] Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.[370] With the aim of avoiding possible risks of the release of GMO's into the environment SAGARPA and SEMARNAT request technical opinions from CONABIO and from the National Institute of

[362] It should take into account the information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.
[363] Ibid, Article 61, Mexican Biosafety Law, supra note 332, for more information see; Ortíz García Sol, Herramientas de la bioseguridad, páginas 115-130, en: Bioseguridad en la aplicacion de la biotecnologia y el uso de los organismos genéticamente modificados, CIBIOGAM/PNUD/GEF, primera edicion, México, 2008.
[364] Ibid, Mexican Biosafety Law, supra note 332, Article 62
[365] Ibid, Article 62 (I)
[366] Ibid, Article 62 (II)
[367] Ibid, Article 62 (III)
[368] Ibid, Article 62 (IV)
[369] Ibid, Article 62 (V)
[370] Ibid, Article 61 (III)

Ecology (INE). The technical opinions produced by these two institutions are non-binding but provide the secretariats with the required information before they make decision about the approval of the permit for the release of GMO into the environment.

With regard to risk assessment Article 63 sets out that where there is uncertainty regarding the level of the possible risk of GMO's to biological diversity the secretariats shall request additional information from the applicant based on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the GMO's in the receiving environment.

The Law establishes that the characteristics and requirements of the assessment of the potential risks shall be established in NOM's. However, over the last four years these NOM's have not been established. Another gap in the Law is that it does not provide for an EIA as provided in the LGEEPA.[371] Some experts pointed out that it was not relevant to include the EIA in the Mexican Biosafety Law since the release of GMO's into the environment would be on agricultural land but this does not encompass a forest land-use change. Nevertheless, over the years, researchers have identified agricultural expansion as a major factor in almost all studies on deforestation. In the 1990s, according to UNEP, 70% of total deforested areas were converted to permanent agriculture systems. For example in Latin America conversion to agriculture has been large scale and permanent whereas in Africa small-scale agricultural enterprises have predominated. In Asia, the changes have been more equally distributed between permanent agriculture and areas under shifting cultivation. Historically, increases in food production have been at the expense of millions of hectares of forest.

To sum up, as mentioned before, SAGARPA and SEMARNAT should apply the precautionary approach where there is uncertainty on the level of risk GMO's may cause against biological diversity or human health. However, since the Law does not provide guidelines for its application, the decision-maker shall decide how to apply it.

IX. Procedure for Approval of Permits for the Release of GMO's into the Environment.

1. Procedure

The Law envisages three permits for the release of GMO's into the environment: (i) experimental, (ii) pilot program and (iii) commercial release. All permits must comply with both the requirements provided in the Law

[371] Ibid, LGEEPA, supra note 225, chapter IV, Articles 28-37 bis

and in its Regulation.[372]The procedure with regard to approval of permits is quite similar. The procedure of authorization[373] starts with a request to SAGARPA or SEMARNAT who grant the permits within the scope of their corresponding jurisdiction, including their import. When all requirements are completed, the information is send to the National Register of Biosafety on GMO's[374] for its notation and publication.

The requests[375] must include the characteristics of the GMO to be released into the environment; the information concerning the area where such release will take place; the requirements contained in NOM's; a risk assessment study must be enclosed which must address the possible risks the GMO may cause to biological diversity and to plant, animal and aquaculture health. Furthermore, the requests must also include biosafety measures, monitoring mechanisms and contingency measures with the aim to preserve biodiversity from the unintended release of GMO's into the environment.

It is worth mentioning that GMO's that are not allowed in their country of origin shall not be allowed in Mexico either.[376] A very important consideration for the authorization of permits, for the release of GMO's into the environment, is public opinion.[377] This is a procedure where public participation is asked for. The public can give their opinion within 20 working days following the submission of the request for authorization. However, the public opinion should be technically and scientifically based.[378]

In the event of the release of GMO's into the environment, SAGARPA or SEMARNAT will be in charge. Whereas SAGARPA[379] analyses and evaluates all possible risks that activities carried out with GMO's may cause to animal, plant, and aquaculture health SEMARNAT[380] analyses and assesses the possible risks that activities carried out with GMO's may cause to the environment and biological diversity. SAGARPA monitors the effects that accidental or permitted releases of GMO's may cause to animal, plant, aquaculture health, and biological diversity.

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[372] Ibid, Mexican Biosafety Law, supra note 332, Articles 32, 42,43,50,51,55,56 and Articles 5, 6, 7,16,17 and 19 of its Regulation, supra note 333
[373] Ibid, Article 33
[374] Ibid, Article 109
[375] Ibid, Articles 42, 50 and 55
[376] Ibid, Articles 40, 43, 51 and 56
[377] Ibid, Article 33
[378] Ibid
[379] Ibid, Article 12
[380] Ibid, Article 11

Regarding monitoring[381] SAGARPA must monitor the effects that accidental or permitted releases of GMO's may cause to animal, plant, aquaculture health, and biological diversity, and SEMARNAT monitors[382] the effects on the environment or biological diversity that may be caused by the accidental release of GMO's.

Regarding authorizations of the release of GMO's into the environment it is important worth mentioning that SAGARPA may authorize the release of GMO'S into the environment once it has obtained SEMARNAT's favourable opinion. Likewise, SEMARNAT requires SAGARPA's authorization in order to approve the release of GMO's in forests. Both are empowered by the Biosafety Law to suspend[383] or revoke permits for the release of GMO's into the environment, in forests and for bioremediation. They monitor[384] GMO's within areas of their competence and apply measures to restore biological diversity. A decision taken by the SAGARPA or SEMARNAT is based on an analysis of the scientific studies conducted by the applicant and additional scientific considerations of the possible risks that the GMO's intended to be released into the environment may cause to biological diversity, animal, plant, and aquaculture health.

Permits for the release of GMO's into the environment may be denied:[385] (i) if the request is not complete and/or does not fulfil the requirements of the NOM's, (ii) if the information is false, incomplete or insufficient or (iii) if SAGARPA or SEMARNAT conclude that risks posed by such organisms being released are to great, arguing that the organisms that are proposed to be released could have a negative impact on human, plant, animal and aquaculture health as well as on biological diversity, causing severe or irreversible damages.

The presentation of false information when requiring permits and the use or release of GMO's or any other organism with the purpose of making biological weapons[386] shall also be sanctioned. Furthermore, it is impor-

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[381] Ibid, Articles involving monitoring are as follow: 2 (VI), 3 (V), 9 (V and XV), 11 (IV), 13 (IV) 25 (I), 28, 34 (I), 37 first paragraph and (III), 38, 39, 42 (IV), 45 (II b), 50 (IV), 58, 63 and 71 (IV)

[382] SEMARNAT has been involved in the monitoring and detection of GM material in maize landrace biodiversity regions: Oaxaca (2001-2007), Jalisco (2002), Michoacán (2003), Puebla (2006-2007), DF (2007), Guerrero (2002) and Sinaloa (2007).

[383] Ibid, Mexican Biosafety Law, supra note 332, Article 11 (VI), and Article 13 (VI)

[384] Ibid, Article 38

[385] Ibid, Article 34

[386] Ibid, Article 41

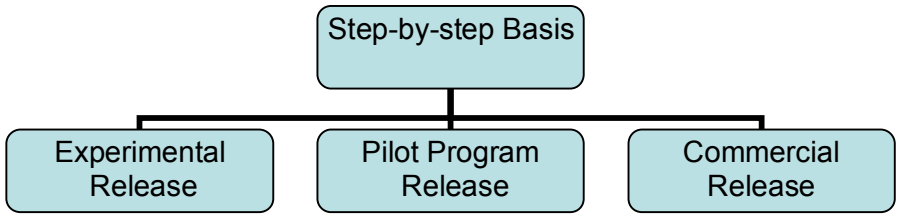
tant to note that GMO's that are not allowed to be released in their country of origin shall not be allowed in Mexico.[387]

The permit term for the experimental and pilot program release of GMO into the environment is proposed by the applicant.[388] However, the secretariats may limit the permit term taking into account the requests provided.[389]The permit term for the commercial release of GMO's into the environment is undefined.[390] The Mexican Biosafety Law relies on NOM's to establish specific biosafety regulations for the release of GMO's into the environment, however, NOM's have not been developed for fourth years.

2. The Step-by-step Basis

The step-by-step basis refers to the moving, where appropriate, from the laboratory to the growth chamber and greenhouse, to limited field testing and finally to large-scale field testing. Mexico implemented this methodology provided by the OECD and by FAO/WHO/CAC focusing on three stages: (i) the experimental, (ii) the pilot program; and (iii) the commercial release of GMO's into the environment. Hence, before an organism can be commercially released into the environment it is necessary that such organism has completed all stages mentioned above.

Figure 2.6 Step-by-Step Basis



a) First Stage: The Experimental Release

The experimental release of GMO's into the environment[391] refers to the intended and permitted release of GMO's or the combination thereof having adopted contention measures such as physical barriers or a combina-

[387] Ibid, Articles 40, 43, 51,56
[388] Ibid, Articles 16 (VIII), 17 (IX) and 22 of the Regulation of the Mexican Biosafety Law, supra note 333
[389] Ibid, Regulation of the Mexican Biosafety Law, supra note 333, Article 22
[390] Ibid
[391] Ibid, Mexican Biosafety Law, supra note 332, Article 3 paragraph (XVII), 42-49, 62, 70, 71 (Confidential Information) and Article 16 of its Regulation, supra note 333

tion of chemical or biological barriers. This is with the aim of limiting contact with either the population or the environment. The resolution of the authorization for this permit[392] should be granted by SAGARPA or SEMARNAT within sixth months after the request is submitted.

b) Second Stage: The Pilot Program Release

A permit for a pilot program release of GMO's into the environment[393] is the second step of the step-by-step-basis. This is the stage prior to the commercial release of GMO's into the environment. The resolution of the authorization for this permit[394] should be granted by SAGARPA or SEMARNAT within three months after the request is submitted.

According to Articles 46 and 53 of the Mexican Biosafety Law and 18 of its Regulation the holder of a permit for the experimental and pilot program release of GMO's into the environment should inform SAGARPA or SEMARNAT about the results report concerning the release, when the report is required.

c) Third Stage: The Commercial Release

A permit for the commercial release of GMO's into the environment[395] is the last stage of the step-by-step. The resolution for the authorization for this permit[396] should be granted by SAGARPA or by SEMARNAT within four months after the request is submitted. However, it is important to note that the experimental and pilot program release permissions, with regard to the specific GMO, are an obligatory requirement for the commercial release into the environment.[397] This is due to the fact that the methodology for authorizations of permits follows a step-by-step basis.

X. Procedure for Authorization of GMO's Intended for Direct Use as FFP's, Including Imports

1. Authorization of GMO's Intended for Direct Use as FFP's.

The Secretariat of Health authorizes[398] GMO's: (i) intended for human use or consumption, including grains; (ii) those intended for foodstuff

[392] Ibid, Mexican Biosafety Law, supra note 332, Article 44

[393] Ibid, Articles, 3 para (XVIII), 50-54, 70, 71 (Confidential Information) and Article 17of its Regulation, supra note 333

[394] Ibid, Mexican Biosafety Law, supra note 332, Article 52

[395] Ibid, Article, 3 paragraph (XVI), 55-59, 70, 71 (Confidential Information) and Article 19 of its Regulation, supra note 332

[396] Ibid, Mexican Bioasfety Law, supra note 332, Article 57

[397] Ibid, Article 55

[398] Ibid, Article 16 and 91, 92, 93 and Articles 23 and 31 of its Regulation, supra note 333

processing for human consumption;[399] (iii) those intended for public health purposes; (iv)those intended for bioremediation.[400]

The request for authorization[401] must include an assessment of possible risks that the GMO may cause to human health. Scientific and technical information about the safety of the GMO must be included as well as requirements contained in NOM's. If all requirements are met, the Secretariat of Health sends the information to the National Register of Biosafety on GMO's for its notation and publication.[402] The Secretariat of Health may deny the request:[403] (i) if the request is not complete and it does not fulfil the requirements of the NOM's, (ii) if the information is false, incomplete or insufficient or (iii) if the Secretariat of Health concludes that risks posed by such organisms are such that their release may have a negative impact on human health, causing severe or irreversible damages. Authorizations have to be issued within six months after the request was submitted when the requirements are complete.[404]

The authorisation procedure for the approval of LMO's-FFPs is intended to ensure that the safety of these products is scientifically established before they are allowed on the market. Hence, GMO's are evaluated for their safety in a comparative manner applying the substantial equivalence developed by the OECD in 1993 and endorsed in by the FAO/WHO in 1996. The safety assessment of GM foods is carried out through a comparison of the properties of the GM food with those of an existing food from which the GM food has been derived with a long history of safe use. Its application assists to identify the similarities and differences between an existing, conventionally produced, food and the new GM-product, which are then subject for further toxicological investigations, if required. [405]

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[399] It is important to mention that in Mexico the GMO's considered for human use or consumption are also those for animal consumption which might be directly consumed by human beings.

[400] Ibid, Mexican Biosafety Law, supra note 332, Article 3(IV) defines bioremediation as the process in which genetically engineered micro-organisms are used for contaminant degrading or disintegration affecting natural resources and/or elements with the purpose to turn them into simpler and less harmful or even harmless components to the environment.

[401] Ibid, Article 92

[402] Ibid, Article 94

[403] Ibid, Article 96

[404] Ibid, Article 95

[405] Ibid, Francisca Acevedo, supra note 342

2. Labelling and Identification of GMO's

a) Labelling

Regarding labelling[406] rules are in place for all GMO's that have been authorized by the Secretariat of Health in Mexico. The Law requires GM products to be labelled in an effort to ensure consumers are informed about the nutritional characteristics, the composition and the advantages of GM crops. It also sets out general criteria that the information on the label must be truthful, objective, clear, understandable and useful for the consumer. However, GMO's or products containing GMO's require labelling only if they differ significantly in safety, composition, or nutritional content when compared to their non-GM counterpart. Hence, it is common that GMO's in Mexico intended for direct use as FFPs do not have a GM label since they do not differ significantly to their non-GM.

Notwithstanding the labelling of seeds, including corns, vegetative material intended for planting, cultivation and agricultural production is subject of the NOM's that SAGARPA issues jointly with the Secretariat of Economy.[407] The labelling of these GM seeds is obligatory and the label must include (i) the fact that it is a GMO; (ii) the characteristics of the acquired genetic combination; (iii) the implications with regard to special conditions and growing requirements as well as the changes in reproductive and productive characteristics.

b) Identification

The information required for import[408] of GMO's shall be established in NOM's, which shall be issued by the Secretariat of Health, by SAGARPA, and by the Secretariat of Economy. However, when the import of the GMO is intended for the release into the environment the NOM's shall also be issued by SEMARNAT. It can be seen that NOM's play a very important role in the Law not withstanding that NOM's are not yet in place.

XI. Imports and Exports of GMO's

The Secretariat of Finance and Public Credit[409] controls the country's ports[410] through the Mexican Custom Agencies and is responsible for im-

[406] Ibid, Mexican Biosafety Law, supra note 332, Article 101
[407] Ibid
[408] Ibid, Article 102
[409] Ibid, Article 18
[410] Ports: Matamoros, Altamira, Coatzacoalcos, Cd. Juárez, Veracruz 430, Piedras Negras, Veracruz Centro y Nuevo Laredo

ports[411] and exports[412] of GMO's and products containing GMO's. The secretariat must ensure that the appropriate permits or approvals are in place at borders and that any identity requirements required under (i) the Mexican Biosafety Law, (ii) its Regulation and (iii) in NOM's are met.[413]

The Secretariat may restrain[414] the entry into the country of GMO's (i) if the GMO's do not have permission and/or approval, (ii) if the GMO's are forbidden in their countries of origin, (iii) if the imports contain unauthorized varieties of GMO's or (iv) if they do not have a label or identification of the imports. Regarding exports, the holder of the permit or approval must notify the country where the release of the GMO into the environment will take place.[415]

The Secretariat of Finance and Public Credit through the Mexican Customs Agency controls the country's ports of entry and carries out mandatory registration of GMO's imports. This information is of paramount importance both for CIBIOGEM and for other secretariats such SAGARPA and SEMARNAT that monitor the release of GMO's in the country. NOM's shall be jointly issued by SAGARPA, by the Secretariat of Health and by the Secretariat of Economy. However, when the imports of GMO's are intended to be released into the environment the NOM's shall be issued by the aforementioned Secretariats and by SEMARNAT as well.

XII. Restriction of Release of GMO's into the Environment

1. Centres of Origin and Centres of Genetic Diversity

Given that Mexico is a mega diverse country and a centre of origin and genetic diversity[416] of different crops the release of GMO's into the environment is forbidden in centres of origin[417] and in centres of genetic diversity.[418]SEMARNAT and SAGARPA are in charge to determine jointly the

[411] Ibid, Mexican Biosafety Law, supra note 332, Articles 32, 42, 43, 50, 51, 55, 56, 93, 102, and Articles 41 and 42 of its Regulation, supra note 333

[412] Ibid, Article 72

[413] Ibid, Article 18 (I)

[414] Ibid, Article 18 (V)

[415] Ibid, Article 72

[416] Ibid, Article 86 and Article 49 and 50 III(a) of its regulation, supra note 333

[417] Centre of origin is the area where a particular organism was first domesticated and brought into use by humans. Centres of origin may still retain a very high diversity of the genetic resources base and wild relatives from which the organism concerned was domesticated.

[418] A centre of genetic diversity is an area where there is a high diversity present amongst a particular group of related species – either within a family, genus, or sub-species, varieties, cultivars, strains, or other sub-categories within a species

centres of origin and genetic diversity in Mexico[419] with information provided by national institutions,[420] by international treaties and agreements about the species originated in Mexico. They shall take into account two criteria. The first is that in these centres of origin and diversity, there are still GMO's' wild relative populations, including different breeds or varieties of the same species so that they constitute a genetic reserve.[421] The second criteria is that in case of cultivations, the geographical region should be known as the region where the organism was domesticated for the first time and that it still exists in the location.[422]

Presently, there are two crucial documents related to the establishment of centres of origin and genetic diversity. [423] The first document was developed by CONABIO:[424] "Elements to Determine Centres of Origin and Centres of Genetic Diversity in General and Specific in the Experimental Release of Transgenic Maize into the Environment". The document contains information about maize and teosinte, maps and tables which show the maize diversity through the country. CONABIO is opposed to the commercial releases of GM maize in Mexico because of the risk it may cause to maize diversity and argues that the application of the precautionary approach is crucial. The second document was developed by INE[425]: "Mexico as Centre of Origin of Maize, Elements about the Distribution of Wild Relatives and Varieties or Races of Maize in the North of Mexico". This document explains the process of maize domestication and analyses the presence of wild relatives in Tamaulipas, Sonora and Sinaloa. It points out that the gene flow of GM maize is unavoidable.

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[419] Ibid, Mexican Biosafety Law, supra note 332, Articles 86 and 87

[420] INEGI, INIFAP, INE, CONABIO and CONAFOR

[421] Ibid, Mexican Biosafety Law, supra note 332, Article 87 (I)

[422] Ibid

[423] De Pina García Juan Pablo, "La diversidad del maíz y los riesgos de la experimentación transgénica" en: Revista de Geografía Agrícola número 38 enero-junio 2007 pp 117-120, Universidad Autónoma Chapingo, Dirección de Centros Regionales Universitarios, Coordinación de Revistas Institucionales, México, 2007

[424] CONABIO, "Elementos para la determinación de centros de origen y centros de diversidad genética en general y el caso específico de la liberación experimental del maíz transgéncio al medio ambiente en Mexico". Julio del 2006.

Online:http://www.conabio.gob.mx/conocimiento/bioseguridad/doctos/Doc_CdeOCdeDG.pdf

[425] INE, "México como el centro de origen del maíz y elementos sobre la distribución de parientes silvestres y variedades o razas de maiz en el norte de México", noviembre del 2006

The information of these two documents serves SAGARPA and SENMARNAT as guideline for the establishment of the centres of origin and genetic diversity. Nevertheless, currently SAGARPA and SEMARNAT have not established the centres of origin and diversity.

2. Restricted Areas

The release of GMO's in restricted areas is permitted[426] when the GMO intended to be released is different from the native animal and plants species of the region and the release does not cause a negative impact on human health or biological diversity.

The release of GMO's into the environment is restricted in national protected areas. Though they are allowed as part of bioremediation efforts to cleanse and restore polluted areas or to fight pests and disease, they are banned from the core zones or designated areas within a protected area where an ecosystem is preserved.

The release of GMO's is also restricted in GMO-free zones because of organic certification purposes.[427]These zones are established to preserve agricultural organic production in communities across the country. They will be established in regions where according to scientific studies, GMO's and their organic counterparts cannot coexist in the same area. These GMO-free zones will be established by SAGARPA which may request technical opinion from CIBIOGEM and from CONABIO.

SAGARPA must also take into account provisions established in NOM's on the production of organic products.[428] To establish a GMO-free zone, a community request, approved by the municipality and the state government must be made. After such a request, SAGARPA will conduct the scientific and technical tests required by the Biosafety Law on GMO's to determine if it can establish a GMO-free zone.[429]

The restrictions on the release of GMO's into the environment in the areas mentioned before have the aim to preserve biological diversity and native species. Nevertheless, neither centres of origin nor centres of genetic diversity have been yet established by SAGARPA and SEMARNAT.[430] National Protected areas may provide only limited protection to biological di-

[426] Ibid, Mexican Biosafety Law, supra note 332, Article 88
[427] Ibid, Article 90
[428] Ibid
[429] Ibid, Juan Herrera, supra note 188
[430] Ibid, de Pina García Juan Pablo, supra note 423

versity since the release of GMO's into the environment is only banned in the core zones established within these areas.

XIII. Regime for Special Protection of Maize

The legal framework for the Regime for Special Protection of Maize has its foundation both in the 2005 Mexican Biosafety law pursuant to Article 2(XI) and in the 2008 Regulation of the Mexican Biosafety Law according to Article 65 and under its transitory disposal of Article 8.[431]

The objective of this Regime for Special Protection of Maize is to protect maize before GM maize can be cultivated in the country. The first attempt of this regime was first published in DOF[432] on November 29, 2006 under the title, "Regime for Special Protection of Maize for Experimental Release of GM Maize." Unfortunately, this first attempt failed because of lack of resources. The second attempt to develop the Regime was in 2007 when SAGARPA and SEMARNAT called for a group of experts and in November 2007, two papers were developed. These two papers provided for the issue of legal provisions regarding biosafety of the experimental release of GMO's into the environment: (i) The extents of maize protection should be included in the Regimen for the Special Protection of Maize (ii) Considerations regarding public policy. In April 2008 SAGARPA and SEMARNAT finished a draft of the Regimen for the Special Protection of Maize.[433] Thus, SAGARPA send it to the Federal Commission for the Regulatory Improvement (COFEMER)[434] of the Secretariat of Economy.

On April 4, 2008 the preliminary draft of the Regimen for the Special Protection of Maize was submitted for review under the Regulatory Impact Assessment (MIRs) of COFEMER. On May 2008 COFEMER issued an opinion and required SAGARPA to clarify the preliminary draft of the Regimen for the Special Protection of Maize regarding among others: cost-benefit analysis of the implementation; biosafety measures; loss of biodiversity; prohibition of experimental release of maize that impedes its use for

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[431] Article 8 states that SAGARPA and SEMARNAT have sixty days for the formulation and issue of the Regime for Special Protection of Maize.

[432] D.O.F., Tomo DCXXXVIII No. 20, México, D.F., miercoles 29 de Noviembre de 2006, primera sección p.71.

[433] Acuerdo por el que se establecen las disposiciones jurídicas relativas a la bioseguridad que forman parte del Régimen de Protección Especial del Maíz, necesarias para resolver las solicitudes de permiso de liberación al ambiente de maíz genéticamente modificado.

[434] COFEMER is a technically and administratively autonomous body of the Secretariat of Economy

Online: http://www.cofemermir.gob.mx/crAnteproyectos.asp?dep=7

human consumption; monitoring etc. On December 10, 2008 SAGARPA answered the requirements of COFEMER and send a new preliminary draft of the Regimen for the Special Protection of Maize and established that the Regimen for the Special Protection of Maize shall be established in the Regulation of the Mexican Biosafety Law, in doing so, the regulation shall be amended and eight Articles shall be added. On December 11, 2008 COFEMER issued a final opinion.

The government published by Decree on March 6, 2009 in D.O.F. "Reforms and Additions to the Regulation of the Mexican Biosafety Law".[435] Following this, Article 65 was amended, Articles 66, 67, 68, 69, 70, 71, 72 and 73 were added, and Article 8 transitory was derogated. Thus, the "Regimen for Special Protection of Maize" is included in the Regulation of the Mexican Biosafety Law.

Thus, Article 67 prohibits both experimentation and release into the environment of GM maize that impedes or limits its use for human or animal consumption as food. [436] Article 68 states that before the permission for the experimental release is granted SAGARPA must verify that there is no conventional alternative to the GM organisms in question.

According to Article 70 SAGARPA and SEMARNAT must promote in situ conservation of native breeds and varieties of maize and its wild relatives. Article 72 provides that in cases where SAGARPA or SEMARNAT realized the non-authorized presence of GM material in breeds, varieties and wild relatives of maize, measures must be taken with the aim to eliminate, control or mitigate such presence. Article 73 states that activities related to the protection of maize shall have a special section in the National Biodiversity Information System.

At this point is worth mentioning that in the second semester of 2005 when the Mexican Biosafety Law was in force, the multinationals: Monsanto, Dow and Pioneer requested authorization of permits for the experimental released of their main varieties of GE maize into the environment in the fields of INIFAP situated in Sinaloa, Sonora and Tamaulipas. They submitted the so called: "the Maize Master Plan" designed to demonstrate the agronomic benefits of GE maize in Mexico through the proposed field trials. Following this, from 2005 to 2006 SAGARPA and SEMARNAT approved

[435] Decreto por el que se reforman, adicionan y derogan disposiciones del Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados, published in D.O.F. on March 6, 2009

[436] Ibid, Statement by Mexico on Transgenic Maize with Properties that limit its Consumption as Food, supra note 73

the requests of the multinationals but since the centres of origin and diversity as provided in the Mexican Biosafety Law have not been established SAGARPA and SEMARNAT must deny the approved requests.[437]

In the newspaper "Excelsior"[438] in an interview with the director of Monsanto for Latin America Eduardo Pérez Rico said, that Monsanto will request the authorization of permits for experimental release of GM maize[439] into the environment commencing; (i) in autumn 2009 in the north of Mexico: first in Sonora and Sinaloa and then in Tamaulipas and Chihuahua; (ii) in spring 2010 in the Comarca Lagunera (Coahuila and Durango); and (iii) in 2010 in Jalisco, Nayarit and Campeche.[440]

Eduardo Pérez Rico also said that Monsanto will request additional authorization of permits for experimental release of GM maize tolerance to drought and GM maize with eight different genes coding for several pest resistant and herbicide tolerant traits named Smartstax™ which is expected to be released in Mexico between 2010 and 2011.[441]

It seems that the "Maize Master Plan" emerged for a second time because of both (i) the regions where the experimental release of GM maize into the environment will take place are the same as in the 2006 "Maize Master Plan" and because the GM maize varieties intended to be released are also the same.[442]

D. Conclusion

The creation of CIBIOGEM in Mexico was crucial to coordinate biosafety and biotechnology policies throughout the country. Also, the promulgation of the Mexican Biosafety law was another achievement since it incorporates into a single homogenous law much dispersed existent legislation. Nevertheless, the implementation of the law is difficult as it relies on NOM's, which have not yet been developed. Besides, which, Mexico lacks adequate human, technical and financial resources, which in turn, is a hurdle to undertake a risk assessment and an appropriate risk management of GMO's.

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[437] Ibid, De Pina García Juan Pablo, supra note 423

[438] CAMPO, Excélsior, suplemento mensual, martes 24 de marzo de 2009 Pp.1, 6 and 7

[439] The varieties of GE maize are: Roundup Ready maize (NK603), Bt maize (MON810, MON88017, Herculex), and combinations of these (MON 810 x NK603 and Herculex x NK603).

[440] Ibid, CAMPO, supra note 438

[441] Ibid

[442] Ibid, De Pina García Juan Pablo, supra note 423

The application of the precautionary approach will also be difficult since the Law does not provide guidelines to do so. Thus, the statement provided by the biosafety principles in Article 9 (IV) requires the Mexican government to apply the precautionary approach according to its capabilities taking into account commitments established in international treaties and agreements of which Mexico is Party. This means, in determining whether and how to apply the precautionary approach Mexico has to take into account its own capacity and the provisions of the BSP and of the SPS Agreement. Article 9 (IV) also states: "where there are threats of serious and or irreversible damage, lack of full scientific uncertainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" and subject such measures to provisions and administrative procedures established in the Law. That is to say, Mexico has to take into account its economic priorities, the cost effective of proposed measures and the nature and the degree of environmental risk when deciding what preventing measures to adopt. With regard to the measures which have to been taken in case of serious or irreversible damage Article 63 states that in adopting such measures, the Secretariat in charge i.e. SAGARPA or SEMARNAT should take into account administrative procedures provided in this Law, and international trade agreements and guidelines developed by international organizations of which Mexico is Party. Thus, the law subjects the application of the precautionary principle to the provisions and administrative procedures established in the law but the Law does not provide for guidelines to do so. To sum up, Mexico will face a potential conflict since it is party to the BSP and Member to the WTO. On the one hand, the BSP allows the application of the precautionary approach even in the face of "lack of scientific uncertainty due to insufficient scientific information". On the other hand, the SPS Agreement allows for the application of the precautionary approach "where there is insufficient scientific evidence" but only on a provisional basis.

As has been seen it may be difficult for Mexico to decide how to apply the precautionary approach. Notwithstanding, the application of the precautionary approach in Mexico is crucial when importing GMO's, especially maize, and when granting authorizations of permits for experimental release of GM maize into the environment because the impact on ecosystems is difficult to ascertain and may be difficult to reverse, especially in a COD of maize.

To date, no authorizations of permits for experimental release of GM maize into the environment have been granted. However, with the amendment of the Regulation of the Biosafety Law in March 2009, the multina-

tionals e.g. Monsanto have requested authorization of permits for the experimental release of GM maize into the environment. Hence, SAGARPA and SEMARNAT will have approved or denied authorizations of permits for experimental release of GM maize into the environment in the following months. By deciding if the authorizations can be granted they should have taken into account the reports (even though they are only for informative purposes) from CONABIO, which is responsible for the database of GMO's and has the methodology for environmental risk assessment.

In the next chapter, the trade conflict between Mexico and its NAFTA trading partners regarding imports of unlabelled GM maize, will be analysed and discussed.

Chapter III

The Mexican Biosafety Law and the NAFTA/WTO Regimes Regarding Imports of GM Maize

Introduction

This chapter deals with the Mexican Biosafety Law and the NAFTA/WTO regimes regarding imports of GM maize. It is divided into two main sections. The first section provides an overview of the main developments in agricultural policies from 1990 to 2008 in Mexico and of the imports of GM maize within NAFTA. This section also concerns the 2003 trilateral inter-institutional agreement and its addendum regarding labelling and identification of imports of GM maize within NAFTA, and explains the incompatibility of the Mexican Biosafety Law with the inter-institutional agreement signed by the NAFTA trading partners regarding imports of GM maize. It also partly explains why Mexico gives priority to trade instead of environmental protection.

The second section gives an overview of the general trade rules that members of NAFTA/WTO regimes have to comply with, and deals with the exceptions that members may invoke to protect domestic environment, human, plant and animal health and life. This section also explains the possibilities for a Mexico ban on imports of GM maize from the USA and illustrates the different approaches of the TBT-Agreement and of the SPS-Agreement.

A. Process of Economic Liberalisation in Mexico

The process of economic liberalisation has its foundation in the economic theory of free trade developed by David Ricardo, "which implies that all participating States profit from open trade, even if their economies differ in terms of competitiveness and development, and even if states unilaterally open their market".[443] Designers of neoliberal policies assume that an increase in international trade produces greater economic development and that the opening of trade creates profits for all actors in the areas in which they have comparative advantage.[444]

During the 1980's[445]Mexico started a process of transformation of the economy from being trade-protected and inward-looking, to market openness. Restrictions on foreign investment were reduced and trade policy was liberalised. A process of market liberalisation of products also began in the 1980s with the lifting of price controls, including in agriculture, and the deregulation efforts in transport and communication. Thus, trade barriers were reduced on a multilateral basis. In 1986 Mexico joined the General Agreement on Tariffs and Trade (GATT) and from 1986 to 1990 the Mexican policy was oriented to diminish the inflation rate. However, the key step in the liberalisation in the early 1990s was the North American Free Trade Agreement (NAFTA).[446]

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[443] Stoll Peter Tobias and Schorkopf Frank, Concepts and Legal Structure p.33, WTO, World Economic Order, World Trade Order, December 2005, Max Planck Commentaries on World Trade Law

[444] Alejandro Díaz Bautista, "El TLCAN y el crecimiento económico de la frontera norte de México", NAFTA and the Economic Growth of the Northern Border of Mexico in: Revista Comercio Exterior, Vol. 53, No. 12, Mexico, December 2003, p. 1090.

[445] OECD, 2006, Agricultural Policies and Commodity Markets, Chapter 5, p.71: in: Agricultural and Fisheries Policies in Mexico", Recent Achievements, Continuing the Reform Agenda, Paris; Rubio Blanca, "la politica agropecuaria neoliberal y la crisis alimentaria", en José Calva, El campo mexicano: ajuste neoliberal y alternativas, México, Juan Pablos-CIETAAM, UACH, 1997; Hubert Carton de Grammont, "Politica Neoliberal, estructura productiva y organización socialde los productores: una visión en conjunto", en: Antonio Yunez-Naude, los pequeños productores rurales en México: Las reformas y las opciones, México, El Colegio de México, 2000; y J. L. Calva, "El modelo de desarrollo agropecuario impulsado mediante la Ley Agraria y el TLC", en: J. L. Calva, Aternativas para el campo mexicano, México, PUAL-UNAM-Friedrich Ebert Stiftung-Fontanamara, 1993.

[446] North American Free Trade Agreement, NAFTA is a regional economic block celebrated between Canada, Mexico and the United States of America in 1992, which came into force from the beginning 1994. It was published in the D.O.F. on 20 December, 1993. Washington, 8, 17 December 1992; Ottawa, 11 and 17 December 1992, Mexico City, 14 and 17 December 1992, in force 1 January 1994, 32 ILM 289 (1993) and 32 ILM 605 (193). http://www.nafta-sec-alena.org/DefaultSite/index_e.aspx?DetailID=78

I. Agricultural Policies Objectives from 1990 to 2008

The Mexican agricultural sector is divided into two basic forms of land ownership as a result of the agrarian reform of the 20th century: (i) private property, where owners make productive decisions on an individual basis and (ii) social property (ejidos y comunidades agrarias), that accounts for over half of the Mexican territory, or 105 million hectares out of a total of 197 million hectares.[447] Article 27 of the Mexican Constitution was amended in 1992 with the aim of strengthening property rights, generating a functional land market and an efficient allocation of land resources. This was called as *"the Agrarian Reform process"* (1917-1992), which redistributed more than 100 million hectares –half of the country's present land – to 3.8 million producers organised in the *ejido* ó communities of the social property system[448] bringing to an end the uncertainty on land tenure associated with discretionary powers to expropriate land. The restrictions on *Ejido* property rights and land rental and sales within *Ejido* were removed, however, sales to outsiders require permission of the *Ejido* assembly, and inherited land cannot be parcelled out to multiple beneficiaries. The full privatisation of the *Ejido* was also provided, although this conversion requires a two-thirds majority vote of its members. The Program of Certification of Rights to Ejidos Land, called (PROCEDE) was established with the aim of implementing the constitutional reforms referring to land property rights. However, contrary to the expectations, the *Ejido* reform led neither to a significant rise in agricultural productivity through a more efficient allocation of land resources and complementary inputs, nor to massive outflows of the newly landless into the cities. It is important to note that "less than 1% of *Ejidos* had chosen to self-privatise, and these few cases have mostly involved *peri-urban* intended for housing development".[449]

As of 1990s, Mexico has undertaken an important shift towards market-oriented policies. In particular, four major changes were made to agricultural policies: (i) steps towards commodity market liberalisation; (ii) introduction of a new payment tied to historical entitlement to support income;

[447] INEGI, Censo Ejidal 2001

[448] According to the 2001 Ejido Census, there were 2.9 million Ejido communities and 1 million comuneros

[449] Téllez Kuenzler Luis, La modernización del sector agropecuario y forestall, México, FCE, 1994; y SARH, el sector agropecuario en las negociaciones del TLC, México 1992;OECD, 2006, Agricultural Policies and Commodity Markets, Chapter 6, Pp.139-160 in: Agricultural and Fisheries Policies in Mexico", Recent Achievements, Continuing the Reform Agenda, Paris

(iii) steps toward deregulation of input markets, with greater support for the introduction and use of technical improvements; and (iv) reforms to land tenure system.

In the National Programme of Countryside Modernisation 1990-1994,[450] the emphasis was on increasing the well-being of the rural population and improving the efficiency of the use of resource, as well as improving the agricultural trade balance, particularly through greater market orientation, less regulation and improved targeting policy. From 1995 to 2000, the National Farming and Rural Development Program defined the objectives of farming policy as: (i) to increase producer's incomes; (ii) to increase agricultural production faster than population growth; (iii) to balance agricultural trade; (iv) to obtain self-sufficiency in basic foods; (v) to reduce regional differences in productivity, employment and income; (vi) to contribute to the reduction of rural poverty; and (vii) the conservation of natural resources and better use of the land.

From 2001 to 2006, Mexico's agricultural policy, overseen by SAGARPA, pursued the objectives of the Sectoral Programme of Agriculture, Livestock, Rural Development, Fishing and Food,[451] namely, to produce food that is healthy for the consumers and profitable for the producers; to produce quality non-food goods for end markets; to step up the development of the rural communities; to preserve and improve the environment and to promote public policies that create a level playing field for competition with other NAFTA members. [452]

In December 2001, the Law of Sustainable Rural Development[453] was promulgated and published in the D.O.F. It seeks to create a unifying and harmonising framework within which policies, oriented towards productive development, improving social welfare, and preserving the environment are brought together. Its objectives are: to ensure that rural areas are able to fulfil their role of providing sufficient and safe food; to ensure that rural areas offer a certain quality of life to all their inhabitants while also acknowledging the need for welfare programs to meet the needs of the most vulnerable groups. It also establishes the importance of supporting all kinds of produc-

[450] Programa Nacional de Modernización para el Campo 1990-1994

[451] Programa Sectorial de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación 2001-2006

[452] SAGARPA, Report on Federal Public Administration (Informe de Rendición de Cuentas de la Administración Pública Federal) 2000-2006, part I. See also Sectoral Programme for Agriculture, Livestock, Rural Development, Fishing and Food (Programa Sectorial de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimenatción) 2001-2006

[453] Ibid, Ley de Desarrollo Rural Sustentable, supra note 217

tive activities that generate employment and income in rural areas; to ensure the long-term preservation of natural resources by promoting their rational use in primary production activities. Currently, the National Development Plan for 2007 to 2012[454] establishes similar objectives, including improving the income of agricultural producers through increased exports, value-added processes and the production of bio-energy crops.

II. Liberalization of the Corn Market: Domestic Intervention

The principal form of agricultural support implemented in Mexico from the mid 1960s to the beginning of the 1990s was an expensive combination of price support and general consumption subsidies based on trade barriers and direct intervention in the market. The institution involved in implementing this policy was the National Company of Popular Subsistence (CONASUPO), supporting producers through a guaranteed minimum price system for basic crops, especially maize and beans, while subsidising urban consumers, especially of tortillas. Federal transfer of funds to CONASUPO absorbed close to half a percentage point of GDP annually, on average, over a quarter of a century.

CONASUPO embraced the small and medium farmer. Until 1990, CONASUPO would purchase at government determined prices all major grains and oilseeds production for which no buyer could be found. In 1991, CONASUPO ceased its activities of direct intervention in the marketing of agricultural products and between 1990 and 1998, made only maize and beans purchases and discontinued purchases of all other crops. [455] During the 1990s the state dismantled the institutional framework that supported agriculture i.e. the rural credit bank and the state fertilizer and seed industry. After this, the role of CONASUPO in the market was gradually reduced and it was dismantled in 1999. As a way to help producers and traders adjust this transition, the government introduced the Agricultural Marketing Support Services (ASERCA) in 1991 with the purpose of giving assistance to wheat, sorghum, rice, soybean, and other oilseeds producers through a "marketing payment" that covered the difference between the announced policy price an the price equivalent to the import price of the commodity (called the differ-

[454] Ibid, Plan Nacional de Desarrollo 2007-2012, Supra note 69

[455] Rivera Herrejón María Gladys, "El sector maicero y la política agrícola en México durante los noventa", Pp. 287-316 en: El Desarrollo Agrícola y Rural del Tercer Mundo en el Contexto de la mundialización, 2004, UNAM; OECD, 2006, Agricultural Policies and Commodity Markets, Chapter 3, Pp.69-86: in: Agricultural Fisheries Policies in Mexico", Recent Achievements, Continuing the Reform Agenda, Paris

ence price as a buyer would be equally willing to buy domestic or imported goods at that price). The marketing support given through ASERCA, from its creation until 2000, was not national in coverage; its scope was limited to states with an historical surplus (this refers to those states where regional supply exceeds regional demand historically) of one of the products mentioned above. Following the dismantling of CONASUPO, maize was incorporated into the ASERCA marketing support scheme, and once again, support was given only to those states with an historical surplus of production. The Program of Direct Payments to the Country side (PROCAMPO) operated by ASERCA, started in 1993, before the inception of NAFTA, to help farmers cope with lower trade protection and with the removal of direct price support programs. Initially PROCAMPO covered land owners who grew any of nine selected crops (maize, wheat, beans, rice, sorghum, soybean, cotton, safflower and barley) during the three agricultural seasons previous to August of 1993.[456] The program was established for a 15-year period, and was phased out in 2008. By linking the payment to historical use of land, rather than current production, it was intended to help farmers switch to more profitable crops in the context of a more competitive economy. Moreover, by paying all land owners who grew one of these crops, rather than only those who sold their output, the program's scope extended to subsistence farmers. The programs benefits to poor land-owners were increased by a modification that introduced a minimum payment size equivalent to the payment for one hectare that applied even to those owning less land. In 1995 PROCAMPO was further modified to expand the number of eligible crops. Nevertheless, there remain some restrictions: recipients must allocate the land to producing crops on this list, or other crops, fruits or vegetables, pasture for livestock in an approved environmental program. Another program, Alianza productive development (Alianza para el Campo) began in 1996 and was revised in 2003 (Alianza Contigo) to serve as an umbrella for around 1000 programs, including many that focus on increasing agricultural productivity and helping farmers to increase the capital investment of their operations. The basic objectives of Alianza elements, focused on agricultural productivity, are to increase productive infrastructure, combat animal diseases, transfer relevant technology and promote integrated development of rural communities.[457]

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[456] Ibid, OECD, 2006, Agricultural Policies and Commodity Markets, Chapter 3, Pp.69-86: in: Agricultural Fisheries Policies in Mexico", Recent Achievements, Continuing the Reform Agenda, Paris

[457] Ibid

III. Asymetries in Terms of Economics, Technology, Production Factors, and Agricultural Policies and Support between Mexico vis-á-vis USA Regarding Maize

As mentioned in chapter I, the role of maize in the Mexican diet is not only cultural, but also of paramount importance as the main source of energy and nutrients for the most vulnerable segments of the population. In the USA, the main use of maize is for feed and for the production of starch and oil.[458] While USA farmers buy seeds for cultivation, Mexican farmers keep seed from their harvest in order to use it for the subsequent planting period.[459]

Table 3.1 Asymestries between Mexico vis-á-vis USA		
	Mexico	**USA**
Population dedicated to agricultural work	**25%**	**3%**
Hectares for cultivation	**27.3 million hectares**	**179 million hectares**
Hectares per farmer	**3.1 hectares**	**59.1 hectares**
Production per hectare	**2.4 tons**	**8.4 tons**
Governmental Subsidies per year, per hectare	**45 dollars**	**125 dollars**
Irrigated land in million hectares	**4.6**	**17.9**
Production of 1 ton of maize	**17 days**	**1.2 hours**

Source: Author Survey using Information of Gálvez Mariscal Amanda,[460] Acosta Córdova Carlos,[461] and Dávila Patricia[462]

[458] Maize and Biodiversity: the effects on transgenic maize in Mexico, Chapter 7, Assessment of human health effects for the Article 13 initiative on Maize and Biodiversity. Online: http://www.cec.org/files/pdf/Maize-Biodiversity-Chapter7-en

[459] This practice has produced a larger number of landraces in the country

[460] INEGI (2000) 'XXII Censo General de Población y Vivienda', INEGI, Mexico City; Michelle Chauvet and Amanda Gálvez, "Learning About Bio-safety in Mexico: between competitiveness and conservation", Int. J Biotechnology, Vol. 7, Nos. 1, 2 and 3: 62-71, 2005, Inderscience Enterprice Ltd; INEGI (2000) 'Encuesta Nacional de Empleo, INEGI,

As can be seen the asymmetries between Mexico vis-à-vis the USA are relevant. Mexico does not have a good infrastructure or technological base and the farmers do not have the support of the Mexican government plus the investment in the field is insufficient. In the last 10 years the production costs have increased by 300%.[463] Resources assigned for research and development are very limited in Mexico in comparison with its NAFTA trading partners.[464]

Mexico is not self-sufficient in basic foodstuffs. From 2001 to 2006 Mexico imported from the USA 46.8 million tons of maize.[465] The production of maize in Mexico from 1994 to 2007 has increased less than 30% in 14 years. In 1994 the production of maize was 18 million tons (2.2 tons per hectare) and 23.3 million tons in 2007 (2.9 tons per hectare).Hence, Mexico will continue to import about 10 million tons of GM yellow maize from the USA with the aim to cope with its domestic demand.[466]

Mexico has about 10 million hectares which are dedicated to maize cultivation. However, it is not possible to increase the growing area without recurring to negative ecological practices such: deforestation, erosion, and loss of biodiversity. Hence Mexico must invest in science and technology with the aim of improving maize production. Almost two and a half million farmers are dedicated to the cultivation of maize and more than 12 million Mexicans depend directly on maize production.[467]

Last year Mexico produced 20 million tons of white maize for human consumption and imported about 7 million tons of maize (70% GM maize) from the USA.[468] Some experts argued that Mexico could loss its food

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Mexico City showed that 18% of the total employed population is economically active in the agricultural sector.

[461] Carlos Acosta Córdova, Proceso, Semanario de Información y Análisis Número 1626, 30 diciembre 2007, Economía, pp. 8-12, Mexico.

[462] Dávila Patricia, Proceso, Semanario de Información y Análisis Número 1626, 30 diciembre 2007, Economía, pp.13-16, Mexico.

[463] Ibid

[464] Gálvez Mariscal Amanda, "Experiences and Lessons Learned: Mexico" in: Biosafety Protocol News, Vol. 2/issue 3, December 2007, page 5-6
Online at: http://www.CBD.int/doc/newsletter/bpn/bpn-02-03-en.pdf

[465] Ibid, Dávila Patricia, supra note 462

[466] Ibid, Carlos Acosta Córdova, supra note 461

[467] Cassio Luiselli Fernández. "Estrategias para abatir la bimodalidad agraria en México" Pp 76-99 en: Desarrollo Agropecuario, Forestal y Pesquero, Agenda para el Desarrollo, volumén 9, editorial Porrúa, México 2007.

[468] Gálvez Mariscal Amanda, "Boletín UNAM-DGCS-216, 06 de abril del 2008.
Online:http://www.dgcs.unam.mx/boletin/bdboletin/2008_216.html

security since imports of basic crops have rapidly increased. With regards to maize it is important to mention that the GM maize imports are mainly for feed and processing and not for human consumption. As mentioned before Mexico produces enough maize for human consumption. Thus, embracing the concept of "food security" agreed upon by the FAO 1996 World Food Summit which states that:

> *Food security exists when all people at all times, have access to sufficient safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life.*

It can be seen that Mexico is not losing its food security but has to support the production of maize to cover its domestic demand regarding maize intended for direct use as feed and processing.

IV. Elimination of Trade Barriers and the Protection for Import-Sensitive Products such as Maize within the NAFTA Regime

NAFTA negotiations began in 1990 and concluded 1992, with the treaty coming into force from the beginning of 1994. Article 101 establishes a free trade area consistent with Article XXIV of GATT. The objectives of NAFTA[469] are set out in Article 102, which includes national treatment, most favoured nation treatment (MFN) and transparency. With the inception of NAFTA in 1994, all the import barriers insulating the agricultural sector from trade with Canada and the U.S. became tariffs or tariffs-rate quotas (TRQ's) and were scheduled to be eliminated gradually for all commodities.[470] Many tariffs were eliminated immediately and others were phased out over transition periods of 5, 10 or 15 years.[471] The tariff elimination is divided into five categories (A, B, C, C+ and D) with different schedules.[472]

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[469] Article 102, the objectives of NAFTA are to eliminate barriers to trade in, and facilitate the cross border movement of, goods and services between the territories of the parties, promote conditions of fair competition in the free trade area, substantially increase investment opportunities in the territories of the parties, provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory, create effective procedures for the implementation and application of the agreement, for its joint administration and resolutions of disputes and to establish a framework for further trilateral, regional and multilateral cooperation to expand and enhance the benefits of the Agreement.

[470] Ibid, OECD, 2006, supra note 456

[471] See annex 302.2 of NAFTA

[472] NAFTA, Annex 302.2, Category A: duties on goods provided for in the items in staging category A in a Party's Schedule shall be eliminated entirely and such goods shall be duty-

The measures adopted or maintained by a party relating to agricultural trade are set out under Article 701 and the statement of the market access is described in Article 703. NAFTA helped to eliminate a number of non-tariff measures affecting agricultural trade between Mexico and the USA. Prior to January 1st 1994, the single largest barrier to U.S agricultural sales was Mexico's import licensing system. However, this system was replaced by TRQ's or ordinary tariffs. Both Mexico and the USA protected their import-sensitive sectors with longer transition periods such as TRQ's and stated special safeguard provisions for certain products. This means, each party may, in accordance with its schedule to annex 302.2 of NAFTA, adopt or maintain a special safeguard in the form of a TRQ's on agricultural good listed in its section of annex 703.3.

As aforementioned, the process of agricultural trade liberalisation at the beginning of the 1990s, advanced more rapidly. The quantitative restrictions on imports of 12 traditional crops were eliminated by 1991, except for maize and beans. As of 2006, most of the NAFTA tariffs on agricultural product imports either have been phased out, or were close to zero (see table 3.1). Export licenses were phased out and completely eliminated by 1994. Although these tariff eliminations applied only to bilateral trade with Canada and the USA, they marked a significant step towards trade liberalization given the importance of these trading partners: in 2005, 78% of total agro-food imports came from NAFTA countries and 86% of Mexico's agricultural and food exports were destined for those same countries.

free, effective January 1, 1994; Category B: duties on goods provided for in the items in staging category B in a Party's Schedule shall be removed in five equal annual stages beginning on January 1, 1994, and such goods shall be duty-free, effective January 1, 1998; Category C: duties on goods provided for in the items in staging category C in a Party's Schedule shall be removed in 10 equal annual stages beginning on January 1, 1994, and such goods shall be duty-free, effective January 1, 2003; Category C+: duties on goods provided for in the items in staging category C+ in a Party's Schedule shall be removed in 15 equal annual stages beginning on January 1, 1994, and such goods shall be duty-free, effective January 1, 2008; and Category D: goods provided for in the items in staging category D in a Party's Schedule shall continue to receive duty-free treatment.

Table 3.2 Tariffs on Imports of Selected Agricultural Products				
Cultivation	MFN bound in 2006	Applied MFN 2006	NAFTA 2006 (from US)	NAFTA tariff zero in
Wheat	67%	67%	0%	2003
Maize	*194%	*194%	*18%	2008
Barley	115%	115%	0%	2003
Sorghum	45%	**0% - 15%	0%	1994
Rice	45%	20%	0%	2003
Soybean	45%	**0% - 15%	0%	2003
Sugar	0.36 USD/kg	0.36 USD/kg	0.078 USD/kg	2008
Dairy Products (except milk powder)	38% - 45%	10% - 15%	0%	2003
Milk powder	*125%	*125%	*24%	2008
Beef	45%	20% - 25%	0%	1994
Pork	45%	20%	0%	2003
Poultry	***234%	***234%	0%	2003
Eggs	45%	45%	0%	2003
Dry Edible beans	***125%	***125%	12%	2008
Tomatoes	36%	10%	0%	2003
Potatoes	***245%	***245%	0%	2003
Apples, pears and other fruit	45%	20%	0%	2003

* Intra-quota tariff zero. ** The tariff rates depend on the dates in the year. *** Intra-quota tariff is 50%. Sources: Secretariat of Economy, New Import Tariffs 2006; WTO and EU Commission, Applied Tariffs database.

As can been seen, a central pillar of NAFTA was the immediate replacement of the corn tariff system with a TRQ system. The TRQ aimed to bring domestic prices in line with international corn prices by gradually phasing out tariffs on imports over a fifteen-year period starting in 1994. Experts say that a long transition period is considered to be very important because the pace of liberalization is accompanied by heavy investments in

irrigation and without this gradual pace of reform and adequate adjustment measures, their model concludes that all benefits accrue to the richer groups in both rural and urban areas.[473] Thus, an immediate tariff free quota of 2.5 million metric tons of maize was granted by Mexico. The tariff-free quota is to expand at a compound rate of 3 percent *per annum* beginning in 1995. The tariff for over quota imports was set at 206.9% starting 1 January 1994. In NAFTA's first six years the over quota tariff will be reduced by 29.6% of the base tariff. After this period, the remaining tariff will be phase out linearly over the subsequent nine years. (See table 3.2).[474] Thus, by year 14 of NAFTA i.e. 2008 the tariff-free quota for maize imports will amount to 3.6 million metric tons, and after fifteen year all imports will have a zero tariff.[475]

It is worth mentioning that Mexican maize imports have exceeded levels in the tariff-free quota established by NAFTA since 1994. Total imports of more than 5 million metric tons in 1996 exceeded even the tariff-free quota for the 14 year of the transition period by 64%, even though during 1996 a record harvest of more than 18 million metric tons was recorded in Mexico. The imports were directed principally at livestock producers, milling industries and starch manufacturers. An important share of those imports was for the cattle feed industry. Animal consumption has risen steadily since 1990 and in 1993 26.7% of total consumption of maize in Mexico was as cattle feed, while 63.5% was for direct human consumption in various products, mostly as tortilla.[476]

The years 1995 and 1996 were good for domestic maize production, yielding 18.3 and 18.2 million metric tons, respectively. However, extraordinary imports were authorized at a time when international prices were at their highest level in years. In 1996 the volume of operations with industrial corn flour was distributed among the major firms in the following proportions: MASECA 70%, MINSA 27%, Agro-insa 2%, Hamasa 1%. [477] It is important to mention that during the NAFTA negotiations, yellow maize and white maize, two distinct commodities in the international market were treated as one and the same commodity. White maize is considered a distinct

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[473] Nadal Alejandro, "The Environmental and Social Impact of Economic Liberalization on Corn Production in Mexico", study for OXFAM Great Britain and the International World Wildlife Fund, sep. 2000

[474] For more information see annex 302.2 in schedule of Mexico, tariff item 1005.90.99.

[475] Ibid, Nadal Alejandro, supra note 473

[476] Ibid

[477] Ibid

commodity and commands on average price that is 25% higher than the price of yellow maize in the international market. However, under NAFTA they were considered as the same commodity.[478]

As has been seen, the TRQ system set out under NAFTA was not implemented as planned and all maize imports into Mexico since 1994 have been exempt from tariff payments. This means that maize producers have not received the level of transitionary protection intended to provide a breathing space for them to adjust to a more open trade regime. Public officials have justified this policy as a means of controlling prices and therefore reducing inflationary pressures. In 1993, as deregulation of the maize sector began, CONASUPO, -the state agency responsible for grain production, marketing and distribution- ceased to be the sole importer of basic grains.

As a result of these factors, perverse incentives acted in favour of private importers, some of whom (in the industrialized tortilla market like MASECA and MINSA among others) also received significant direct subsidies. The cost of the fiscal revenues foregone as a result of the government's failure to implement the TRQ system can be estimated at more than a billion dollars. [479]

It is important to note that due to a unilateral decision by the Mexican government, maize imports systematically exceeded the negotiated quota, and the extra imports were not charged at the corresponding tariff. The following table shows how maize imports systematically exceeded the negotiated quota.

[478] Ibid
[479] Ibid

Table 3.3 Maize: Market Acces into Mexio and NAFTA Quotas		
Year	**Negotiated Quota (Quantities in Metric Tons)**	*** Maize Imports**
1994 **206%**	**2,500,000**	***2,225,715,000**
1995	**2,575,000**	***2,634,359,000**
1996	**2,652,259**	***5,817,658,000**
1997	**2,731,817**	***2,469,194,000**
1998	**2,813,771**	****5,304,668,486**
1999	**2,898,184**	****5,491,772,600**
2000	**2,985,129**	****5,319,287,338**
2001	**3,074,682**	****6,141,853,179**
2002	**3,166,992**	****5,480,181,056**
2003	**3,261,929**	****5,728,829,295**
2004	**3,359,786**	****5,483,091,440**
2005	**3,460,579**	****5,706,750,847**
2006	**3,564,396**	****7,567,057,969**
2007	**3,671,327**	****7,908,375,836**
2008 **0%**	**----------**	****9,090,761,044**

Source * Ana de Ita[480] and ** INEGI

The allocation of the import quota is determined by a special committee under the leadership of SAGARPA and the Secretariat of Economy. Annually, the Federation Revenue Law for the Fiscal corresponding year publishes in D.O.F. the requirements and procedures for allocating quotas and additional quotas. The additional quotas are allocated through a mechanism based on domestic grain purchase commitments as a function of previous consumption and vary depending on whether the applicant is an industrial consumer or belongs to the livestock and balanced feed sector. The main importers of corn sit in this committee: flour mills, industrial plants and oil refiners, high corn fructose producers, livestock and poultry producers. Mex-

[480] De Ita Ana, "Catorce años de TLCAN y la crisis de la tortilla," Programa de las Américas, Reporte Especial, Washington, DC: Center for International Policy, 11 de noviembre de 2007.

ico's corn growers have never been part of the committee. The lack of adequate representation of corn growers in the committee helps explain why the tariff on imports beyond the tariff-free quota has not been charged. This means that the main protection mechanism that was designed to define the terms of the transition period was never used. Over the NAFTA period the domestic price of maize has fallen but the price of tortilla did not decreased, it has actually increased by 279%. The reasons for this are twofold: firstly, tortilla prices were subsidized until 1996, when manufacturers were able to transfer their increased costs to consumers; secondly, the Mexican tortilla market is a monopoly where the two largest companies GIMSA and MINSA account for 70% and 27% of the market respectively.[481] These companies operate like cartels, using their market power to set higher prices.

The Mexican government could have used NAFTA regulations to protect the maize sector until 2008, giving its farmers a longer adjustment period. However, it did the opposite i.e. since the inception of NAFTA in 1994 the imports of maize from the USA yearly exceeded the tariff free quota of maize imports. Hence, the planned fifteen-year transition period was compressed between January 1994 and August 1996, when prices fell 48% forcing Mexican producers to make a rapid adjustment.

Since January 1, 2008, agricultural trade between Mexico, Canada and USA has been completely free, with the end of the implementation period of the NAFTA. Currently, all U.S. and most Canadian products[482] will be able to enter Mexico without any duties. The same occurs with Mexico's exports to the other two countries. NAFTA's agricultural agreement provided in Chapter VII promotes the total liberalization of agriculture and forestry in the region. NAFTA commitments relating to agriculture between Mexico and the United States are the most radical of any trade agreement, since they include the liberalization of all agricultural and agri-food trade over a maximum period of fourteen years. NAFTA is the first treaty to treat two developed countries and an underdeveloped one as equals. [483]

[481] Ibid, Nadal Alejandro, supra note 473

[482] Canada excluded from its treaty dairy, poultry, and egg products, for which it retains a supply management system.

[483] Ibid, de Ita Ana, supra note 480

B. The Mexican Biosafety Law and the NAFTA/WTO Regimes

I. General Trade Rules

As mentioned before, it is complicated for Mexico to take measures to protect the environment, biodiversity, the human, plant and animal health and life concerning imports of GM maize because of the provisions provided in NAFTA/WTO regimes. Mexico must take into account the most favoured nation principle (MFN);[484] the national treatment on internal taxation and regulation;[485] and the general elimination of quantitative restrictions[486] when importing GMO's.

The fundamental principle of non discrimination contains two elements: (i) the principle of MFN treatment and (ii) the principle of national treatment. "Both can be found in all three major pillars of the WTO legal order: MFN treatment in Article I (1) GATT 1994[487], Article II GATS, and

[484] The most-favoured-nation principle of Article I of GATT is designed to ensure equality of treatment of like products originating or destined for the territories of all other contracting parties. This equal treatment must be accorded unconditionally and extends to customs charges and duties, to all rules and formalities connected with imports or exports, and to internal taxes, charges, and domestic regulation of a product's distribution, sale, and use.

[485] The national treatment principle of Article III of GATT applies broadly to all internal requirements applied to imported products, including taxes, charges, and all manner of regulations. For regulations, two standards must be met, one positive and one negative: they must be applied to imported products to accord treatment no less favourable than that accorded to like products of national origin (Art III(4)), and they must no be applied to afford protection to domestic production (Article III(1)), For internal taxes and charges, two negative criteria apply: they must not be in excess of those applied, directly or indirectly, to like domestic charges (Article III(2), or applied to imported or domestic products so as to afford protection to domestic production /Article III(1).

[486] The General Elimination of Quantitative Restrictions of Article XI states: No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licenses or other measures, shall be instituted or maintained by any contracting party on the imports of any product of the territory of any other contracting party or on the exports or sale for export of any product destined for the territory of any other contracting party."

[487] General Agreement on Tariffs and Trade (GATT 1994), Oct.30, 1947, 61 Stat. A-11 T.I.A.S.1700 U.N.T.S. 194, as modified by Marrakech Agreement of the World Trade Organization, Annex 1A, Legal Instruments of the Uruguay Round vol.1, 33 I.L.M. 1154 (1994)

Article 4 TRIPS, and national treatment in Article III GATT 1994, Art XVII GATS, and Article 3 TRIPS".[488]

Presently, when a state takes a measure to ban the import of a good, the international trade order comes into a play and imposes a number of disciplines.[489] "As a general rule, in order to effectively cover all trade barriers, any restriction of the import of goods falls under GATT XI, which provides for the elimination of quantitative restrictions".[490] Article III of GATT also prohibits any treatment of imported goods that is less favourable than that afforded to like domestic products.[491]

Article XI of GATT concerns more than quotas, it also extends to "other measures". The word "measures" was interpreted by the GATT Panel in the Japan Semi-Conductor case to refer not only to laws and regulations, but also more broadly even to non-mandatory government involvement.[492] Thus, Article XI does not deal with fiscal matters.[493] To understand the relationship between Article XI and Article III one must to do a test of both Articles: (i) "the measure in question should first be analyzed as to whether it is protected by Article III, if it fails the test of Article III, then Article XI is automatically applicable, and unless it falls under one of the exemptions[494] in

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[488] Stoll Peter Tobias and Schorkopf Frank, IV. Non-discrimination: Most Favoured Nation Treatment and National Treatment, p.48, World Economic Order, World Trade Law, Max Planck Commentaries on World Trade Law, 2006, Kononklijke Brill NV, Leiden, The Netherland.

[489] Ibid, Peter Tobias Stoll, supra note 22

[490] Ibid

[491] This may be the case where the measures do not discriminate on their face but formally apply to imported as well as domestic products. GATT, id, Article III:4 reads: "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no les favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use".

[492] Japan - Trade in Semi-Conductors, GATT BISD (35th Supp.), 115, para.106-09 (1989). The Panel set out a two part test for determining whether non-mandatory government requests could be regarded as "measure" within Article XI: whether there were sufficient incentives for the request s to take effect and whether the operation of the measures was dependent on government action. Non-binding "administrative guidance" by the Japanese government was ruled in the Semi-Conductor case to be within Article XI.

[493] J. Schoenbaum Thomas, International Trade and Environment Protection pp. 696-750 in: International Law and the Environment, second edition, Oxford, University Press, 2002.

[494] Article XI (2) excepts the three types of measures from the prohibition of Article XI (1): (a) export restrictions to relieve critical shortages of foodstuffs and other products essential to the exporting contracting party; (b) import or export restrictions necessary to the application of standards for grading or classifying commodities; and (c) import restrictions on ag-

that Article, the measure will violate the GATT".[495] An example of this can be found in the Canada Foreign Investment Review Act case.[496] "The GATT dispute resolution panel interpreted Article XI as regulating only measures affecting the imports or exports of a product, not internal requirements affecting imported products, which are left to Article III".[497]

According to Article III (4) of GATT 1994, members are permitted to impose an internal regulation on products imported from other members provided that it does not discriminate between "like" products. For example, if the GM-related trade measure is categorised as an internal regulation, and reviewed under Article III(4) of the GATT 1994, it is legitimate under that provision, unless it accords to the "like" imported products "less favourable treatment" than it accords to the "like" domestic products. In this case the crucial question is very similar to that under the TBT-Agreement, whether imported GMO's and products thereof are "like" their domestic counterparts.

Under the GATT, the "like product" test calls for a case-by-case determination in which a panel would assess and compare the physical properties of the product, the extend to which the products are capable of serving the same or similar end-uses, the extend to which consumers perceive and treat the products as alternative means of performing particular functions in order to satisfy a particular want or demand and the international classification of the products for tariff purposes.

It is important to highlight that to date there has been no determination by the WTO as to whether a particular LMO or LMO/FFPs and its non-GM equivalent are "like products". In the EC – Approval and Marketing of Biotech Products Case[498] the panel did not examine whether the biotech products at issue in that dispute were "like" their conventional counterparts and whether biotech products in general were safe or not. If a panel determines that the two products in question are different, then the importing country is under no obligation to treat the two products in the same way. If the products are found to be "like" then any difference in treatment

ricultural or fisheries products that are necessary to the enforcement of certain governmental policy measures.

[495] Ibid, Thomas J. Schoenbaum, supra note 493

[496] Canada, Administration of the Foreign Investment Review Act. GATT, BISD (30th Supp.) 140 paragraph 5.14 (1984).

[497] Ibid, Thomas J. Schoenbaum, supra note 493

[498] See EC-Approval and Marketing of Biotech Products. WT/DS291/R, WT/DS292/R, WT/DS293/R

that undermines the ability of the imported product to compete would violate the WTO's rules against discriminatory treatment.

Most panel and Appellate Body rulings on "like products" start their determination of likeness by quoting the report of a 1970 Working Party on Border Tax Adjustment (adopted by GATT contracting parties). The report suggested some criteria for determining whether products were "like": "the product's end-uses in a given market; consumers' tastes and habits, which change from country to country; the product's properties, nature and quality.[499] These criteria were rephrased and completed by the Appellate Body in the EC-asbestos case to comprise four categories of characteristics that the products involved might share: first; the physical properties of the products; second; the extent to which the products are capable of serving the same or similar end-uses, third; the extend to which consumers perceive the products as alternative means of performing particular functions; and fourth; the international classification of the products for tariff purposes.[500]

II. National Policy Exceptions

1. Interpretation of Article XX GATT 1994

The fundamental premise, between WTO members is that imported products must be treated no less favourably than domestic "like" products or imports from elsewhere. This means that it is neither applied in a way which constitutes an arbitrary or unjustifiable discrimination between states where the same conditions prevail, nor is it a disguised restriction on international trade. Once this hurdle is met, the Article goes on to recognise exceptionally the entitlement of states to act to protect human or other life or health, or conserve exhaustible natural resources, albeit that the consequence is trade restrictive according to Articles XX (b) and XX (g). [501]

Environmental and health objectives can accordingly be vindicated, although WTO bodies have shown a reluctance to accept a state's unilaterally imposed trading rules and procedures, where these are seen as inflexible impositions on trading opportunities of other states.[502] Furthermore, the important question as to what amounts to a "like product" and worthy of

[499] Working Party Report, Border Tax Adjustments, BISD18S/97, paragraph 18
[500] Stoll Peter Tobias, Rüdiger Wolfrum and Anja Seibert-Fohr (eds) WTO-Technical Barriers and SPS Measures, 2007 Koninklinjke Brill NV. Printed in Netherlands. Pp. 210-234
[501] Ibid Stallworthy Mark, page 16, supra note 164
[502] US-Shrimp/Turtle Products, 38 ILM 121 1999

trade protection prima facie requires that methods of process and production be excluded from being taken into account.[503]

In the Asbestos Case, it was the Appellate Body's view that there was an onus on Canada, as compliant, to establish that products made from alternative materials were "like products" in light of the widespread public awareness of the existence of risks posed by asbestos to health.[504]

Mexico may adopt national risk policies, if it meets a number of conditions i.e. the obligations of Articles I, III and IX may be derogated by using the exceptions set out in Article XX (b) or XX (g) of the GATT 1994. These exceptions may be used by Mexico and by each member to defend a measure that has been found to violate one of the GATT's primary obligations, such as its prohibition on import bans, or on the discriminatory treatment of a "like" product.

Regarding trade restrictions to protect resources beyond national jurisdiction under 1947 GATT there are the Tuna-Dolphin I Case[505] and the Tuna-Dolphin II Case.[506] Following this, the USA had banned imports of yellowfin tuna caught using methods that also kill dolphins, a protected species under the Marine Mammal Protection Act (MMPA). Both Tuna-Dolphin panels concluded that neither GATT Articles XX (b) nor Article XX (g) could justify the US tuna import ban. As to Article XX (b), both panels held that the ban failed the "necessity test". They rejected the US argument that "necessary means "needed", stating that necessary means that no other reasonable alternative exists and that a contracting party is bound to use among the measures available to it that which entails the least degree of inconsistency with the GATT. A trade measure taken to force other countries to change their environmental policies, and that would be effective only if such changes occurred, could not be considered necessary with the meaning of Article XX (b). Hence, both panels (Tuna-Dolphin I case the Tuna-Dolphin II case) similarly concluded that Article XX (g) was not applicable; they found the terms "relating to" and "in conjunction with in Article XX (g) meant primarily "aimed at" and held that unilateral measures to force other countries to change conservation policies cannot satisfy the primarily aimed at standard.

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[503] US- Tuna/Dolphin I & II, 30 ILM 1598 1992, 33 ILM 839 1994; cf. EC- Asbestos, 40 ILM 497 2001.

[504] Ibid, Stallworthy Mark, page 16, supra note 164

[505] US-Restrictions on Imports of Tuna, GATT, 30 ILM (1991) 1598,Tuna/Dolphin I Case

[506] US-Restrictions on Imports of Tuna, GATT, 33 ILM (1994) 839,Tuna/Dolphin II Case

Furthermore, the Tuna Dolphin II panel concluded that Article XX may have extra-territorial but not extra-jurisdictional effect. Thus, the Tuna Dolphin II panel's position on extra-territorial jurisdiction is based on the concept of nationality, under which a state may control the activities of its own citizens. The panel ruled that governments can enforce Article XX (g) restriction extra-territorially only against their own nationals and vessels.[507]

2. Interpretation of Article XX Chapeau

The introductory clause of Article XX is commonly named the "Chapeau" and it states:

> *Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:*
>
> *b) "necessary" to protect human, animal or plant life or health*
>
> *g) "relating to" the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.*

The Chapeau sets out the test for the manner in which a trade measure is applied. Three standards are stated in the chapeau: firstly, arbitrary discrimination, secondly, unjustifiable discrimination, and thirdly, a disguised restriction on international trade.

It is important to note that even if a measure falls within one of the exceptions in Article XX, the member would need to demonstrate that the application of its measure did not constitute: (i) arbitrary and unjustifiable discrimination between countries where the same conditions prevail; or (ii) a disguised restriction on international trade.[508] The significance of the Chapeau was emphasized by the WTO Appellate Body in the US Gasoline Standards Decisions in 1996.[509] Article XX's Chapeau is intended to prevent the abuse of the limited and conditional exceptions in Article XX.

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[507] Ibid, Tuna-Dolphin I, supra note 505, paragraph 5.20

[508] Ibid, Thomas J. Schoenbaum, supra note 493

[509] US- Standards for Reformulated and Conventional and Gasoline, Report of the Appellate Body, WT/DS2/AB/R (1996); 35 ILM (1996), 274

3. Exception of Article XX (b)

Article XX (b) of GATT 1994 deals with a broad range of sensitive issues like public health, disease control, food safety, consumer protection, animal welfare, and environmental policies and is obviously one of the most relevant exceptions of Art XX. Therefore, it figures prominently in the trade and environment debate.[510] It is incorporated into the provisions of the NAFTA regime according to Article 2101.1 and it states that the measures referred to in GATT Article XX (b) include environmental measures necessary to protect human, animal or plant health, and that GATT XX (g) applies to measures relating to the conservation of living and living-exhaustible natural resources. It is worth mentioning that Articles 103, 104 and Annex 104.1 of NAFTA provide for a list of Multilateral Environmental Agreements (MEAs) that take precedence over NAFTA, a list that include only: (i) CITES,[511] (ii) the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes[512] and their Disposal, (iii) the Montreal Protocol on Substances that Deplete the Ozone Layer,[513] and (iv) the agreement between USA and Mexico on Cooperation for the Protection and Improvement of the Environment in the Border Area.[514] Neither the CBD nor the BSP take precedence over NAFTA obligations, however, Mexico could request its NAFTA trading partners to have the CDB and the BSP added to the list of MEAs. In doing so, Mexico could protect not only its biodiversity but its maize, the staple food of Mexicans.

Article XX gives countries the legal means to balance their trade obligations with important non-trade objectives, such as health protection or the preservation of the environment, which form part of their overall national policies. Article XX (b) has been and is very likely further to be subject of several disputes under GATT1947 and WTO.

"Nevertheless, so far, only one WTO member has been successful in invoking this provision to justify exceptions to the basic GATT/WTO principles in the EC- Asbestos Case". In this case the question arises "whether the

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[510] Ibid, Stoll Peter Tobias, supra note 500, pp. 96-120

[511] Ibid, CITES, supra note 77

[512] Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 28 ILM (1989) 657. In force, 24 May 1992

[513] Protocol on Substances that Deplete the Ozone Layer, (Montreal), 26 ILM (1987),1550. In force 1 January 1989

[514] Agreement between the United States of America and the United Mexican States on Cooperation for the Protection and Improvement of the environment in the Border Area, signed in la Paz, Baja California Sur, August 14, 1983.

test imposed by Article XX (b) is too severe and whether the provision or its interpretation should be amended".[515]

In this EC – Asbestos Case the Appellate Body held that where there is a scientifically proven risk to health, WTO members have the right to determine the level of protection of health that they consider appropriate based either on the quality of the risk or on the quantity of the risk. The more vital the common interests or values pursued, the easier it would be to accept as necessary the measures designed to achieve those ends. In this case it found that there was no alternative means of eliminating the risk. The Appellate Body's approach to the application of Article XX (b) thus brings it closer to the proportionality or balancing analysis applied by the European Community and the USA when testing the necessity of restrictions on trade for environmental purposes.[516]

Thus, Article XX (b) envisages a three-step test, which requires: firstly, that the policy with respect to the measure for which the provision was invoked is within the range of policies designed to protect human, animal or plant life or health; secondly, that the measure for which the exception was being invoked was necessary to fulfil the policy objective; and thirdly, that the measures were applied in conformity with the requirements of the chapeau,[517] avoiding arbitrary and unjustifiable discrimination and/or a disguised restriction on international trade. The Appellate Body has held that a measure is necessary under Article XX (b) if no GATT consistent alternative is reasonably available and provided it entails the least degree of inconsistency with other GATT provisions.

4. Exception of Article XX (g)

Article XX (g) is another important exception designed to allow WTO members to take action to conserve exhaustible natural resources. For the application of Article XX (g) Mexico and each member need to meet the following criteria: firstly, the policy objective behind the measure must fall within the range of policies related to the conservation of exhaustible natural resources secondly, the measures must be related to the conservation of exhaustible natural resources; and thirdly, the measures must be made effective in conjunction with restrictions on domestic production or consumption.

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[515] Ibid, Stoll Peter Tobias, page 98, supra note 500

[516] Ibid, Thomas J. Schoenbaum, supra note 493

[517] Panel Report, US- Gasoline, WT/DS2/R, paragraph. 6.20; Panel Report, EC- Asbestos, WT/DS135/R, paragraph 8.167-8.169.

A measure is considered to be "related to" the conservation of natural resources, if there is a substantial relationship between the general structure and design of the measure at stake and the policy objective it purports to serve. The second criterion is met if "the means are, in principle, reasonably related to the end."[518]The third criterion, concerning the restrictions on domestic production or consumption requires the demonstration of an even handedness in the imposition of the trade restrictions. Restrictions on the production or consumption of imported LMO's must be in the context of similar restrictions on domestically produced LMO's.

C. Imports of GM Maize

As mentioned in the first two chapters, Mexico is a mega diverse country, a COD of different crops, especially of maize. Mexico is party to the CBD, to the BSP and is member of NAFTA and of the WTO[519] amongst others international organizations. Hence, Mexico has to comply with both commercial and environmental commitments. It is important to highlight that it is complicated for Mexico to comply with its environmental commitments due to the fact that it depends mainly on the trade with the USA. Mexico is the second biggest importer of US maize after Japan. As it is known, the USA is neither party to the CBD nor to the BSP and it probably will not be. Furthermore, it is the largest exporter of GMO's, as well as developer of biotech products worldwide. It exports close to 7 million metric tons/year[520] of maize[521] for FFPs to Mexico within NAFTA.

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[518] See US-Shrimp/Turtle Report of the Appelled Body, paragraph 136-142

[519] The WTO regime is constructed around the General Agreement on Tariffs and Trade (GATT), which was part of the post Second World War economic settlement, dating from 1947, and agreements, including the Sanitary and Phyto-Sanitary agreement (SPS), which sets out fairly detailed standards to be applied in the context of protection of the health and life of human and other species. Each of the agreements remains premised on GATT, under which a dispute involving a process through a Dispute Settlement Body has been granted, involving a process of complaint lodged before the WTO Panel, with appeals on points of law to an Appellate Body. The founding of the WTO and the entry into force of its rules on January 1, 1995 marked a turning point in the development of international economic relations. Its essential purpose is to liberalize markets, by removing unnecessary, discriminatory and protectionist barriers to free trade. Mexico has been a WTO member since 1st January 1995.

[520] Gálvez Amanda, M. Quirasco, A. Acatzi, J. Magaña, C. Moles, C. Peña, M. Castillo and M. Signori. "Detection and Quantification of GM Maize Varieties in Mexican Imports" in: Harmonisation Needs at International and Regional Level. First Conference on GMO's Analysis, June 2008
http://gmoglobalconference.jrc.ec.europa.eu/DetailedProgramme.htm

Currently, Mexicans consume 31 million tons of maize and produce only 21.8 million tons.[522] Hence, Mexico imports GM maize from the USA to cope with its domestic demand and therefore it is not in the position to give priority to environmental protection.

I. Harmonization of Labelling and Identification of GMO's Imports within NAFTA

Mexico, Canada and the USA (in an attempt to respect the different regulatory approaches in the three countries and the different levels of GMO's regulation) signed at the end of October 2003 a trilateral agreement[523] with respect to Article 18.2 (a) of the BSP. The agreement has a technical annex designed to guide harmonization of procedures for the imports of grains that "may contain" LMO's. The level of unintentional or adventitious mixing with transgenic grains was set at 5%, under which grains will be handled without the need to use the "may contain" label in the shipment's documentation. Simultaneous filing in the three countries of bulk grain imports and voluntary release into the environment for grain production as well as for experimental purposes was also proposed, requiring harmonization of procedures for applications. According to Article 18.2 (a), the accompanying documentation has to clearly identify that shipments "may contain" LMO's and that these are not intended for intentional introduction into the environment, as well as indicate a contact point for further information.

Theoretically, the BSP requires the exporting state to carry out a risk assessment. It does not leave the burden of doing so to the importing state. In practice, the major exporting states are industrialised countries that are developers of GMO's and are not party to the BSP such USA, Canada, and Australia with exception of Brasil and Paraguay, which are: developing countries, developer of GMO's and party to the BSP. Hence, they do not have the obligation to comply with the requirements of the BSP.

Importing states are regularly developing countries, that are party to the BSP but do not have the expertise, the technical and financial resources to implement the BSP fully. Here arises the question why developing countries signed and ratified the BSP when they did not have the capacity to comply with it. One scenario might be the political pressure other scenario might be the attempt to be subject of financial resources for capacity building

[521] Ibid, there is 80% of presence of GM maize varieties in Mexican imports.
[522] For more information see http://www.siap.gob.mx/
[523] Trilateral Inter-institutional Agreement: "Documentation Requirements for Living Modified Organisms for Food or Feed or for Processing (LMO/FFP's)".
online: http://bch.cbd.int/database/results.shtml?searchid=375559&page=1

provided by the Global Environmental Facility (GEF), or perhaps donations from international agencies or countries. Obviously, developing countries are not able to require more requirements of shipments containing GMO's since thus would imply that they have experts and laboratories at ports of entry which of course require huge investments. To sum up, to date, the BSP has been implemented by developed but not by developing countries.

II. Labelling and Identification Requirements of GMO's Imports

1. Analysis of the Trilateral Inter-institutional Agreement and its Addendum between the NAFTA Trading Partners

The trilateral inter-institutional agreement and its addendum are important documents for Mexico due to the fact that they are almost word for word the proposals of the International Grain Trade Coalition (IGTC), particularly where it comes to thresholds and the adventitious presence of GMO's. It is worth mentioning that they were signed between Mexico, a party to the BSP, and Canada and the United States, both non-parties to the BSP. It is important to highlight that at the MOP 3 in Cuiritiba, Brazil in March 2006 Mexico insisted on expressly excluding the protocol's documentation requirements from applying to trade between parties and non-parties in bilateral, multilateral or regional agreements. Following this, Mexico blocked the MOP 3 negotiations until the parties agreed to a clause stating that rules on labelling will not apply to transboundary movements between parties to the BSP and non-parties, a restatement of what in fact is international law but legitimating in legal terms what many observers considers a tripartite agreement between the three countries that contravened the spirit, if not the letter of the BSP.[524] Thus, trade between USA, Mexico and Canada does not have to abide by the labelling requirements of the BSP, even though Mexico has a legal right to require the same information on LMO's shipments from these non-parties as it requires from parties to the BSP, much as the EU has been doing.[525]

The aforementioned trilateral agreement focuses on the implementation of Article 18.2(a) of the BSP. As follow, it will be analyzed to determine, if this inter-institutional agreement and its addendum within NAFTA are

[524] A. Wise Timothy, Policy Space for Mexican Maize: Protecting Agrobiodiversity by Promoting Rural Livelihoods, GDAE Working Paper No. 07-01, February 2007, Global Development and Environment Institute, Tufts University.
Online: http://www.ase.tufts.edu/gdae/policy/research/MexicanMaize.html

[525] Ibid, A. Wise Timothy, supra note 524

compatible with both the provisions of the Mexican Biosafety Law and the provisions of the BSP.

a) Defining an Inter-institutional Agreement in Mexico

The Mexican legislation defines international agreements as treaties or as inter-institutional agreements.[526] Art 2.1 (a) of the Vienna Convention on the Law of Treaties[527] of 1969 defines "Treaty" as:

> *an international agreement concluded between states in written form and governed by international Law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation.*

Likewise, an "Inter-institutional agreement" is defined in the 1992 Mexican Law of Treaties[528] pursuant to Article 2 (II) as:

> *…an agreement ruled by international Law, put in writing by any decentralized body of federal, state or municipal administration and one or more foreign government bodies and international organizations, whatever their title, whether or not it derives from a previously approved treaty.*

As can be seen both a treaty and an inter-institutional agreement are ruled by international law. In other words, they are recognized as treaties and are therefore obligatory for the state as a whole even if they were made by an isolated authority and even without having passed through the Senate. Articles 6 and 7 of the Mexican Law of Treaties indicate that the authorities have the capacity to conclude inter-institutional treaties. The Mexican Law of Treaties of 1992 obliges the authorities and bodies to register inter-institutional agreements in the Secretariat of Foreign Relations.[529]

Regarding the hierarchy of inter-institutional agreements, it is worth mentioning that they are not part of the supreme legislation of the country but are in the fourth category i.e. below the constitution, below international agreements and below the general federal laws enacted by Congress.[530]

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[526] Nava Escudero Cesar, Guía Minima para la Enseñanza del Derecho Internacional Ambiental en México in: Boletin Mexicano de Derecho Comparado Número 113, Revista Juridica. Online: http://www.juridicas.unam.mx/publica/rev/boletin/cont/113/art/art8.htm

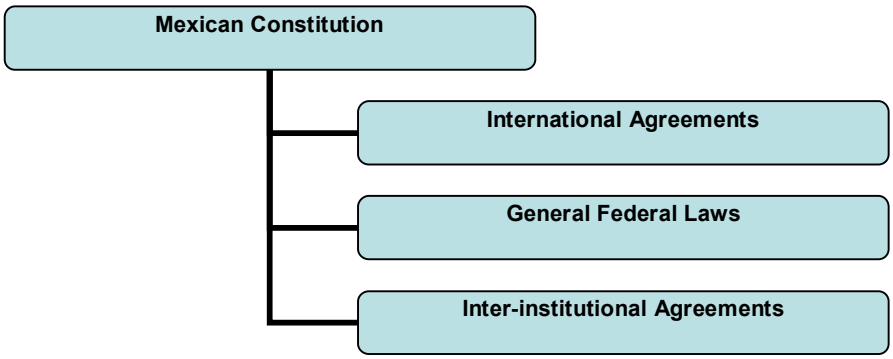
[527] Convention on the Law of Treaties (1969) Vienna, 8 ILM 689. In force since 27 January 1980. Published in the D.O.F. on February 14, 1975

[528] Ley sobre la Celebración de los Tratados, published in D.O.F. on January 02, 1992.

[529] Ibid, Article 7

[530] Nava Escudero, César, "Los acuerdos interinstitucionales ambientales", en derecho ambiental y ecología, México, año 2, núm. 12, abril-mayo de 2006.

Figure 3.1 Hierarchy of inter-institutional Agreements



b) The Trilateral Inter-institutional Agreement between the NAFTA Trading Partners

At the end of October 2003,[531] Mexico signed a trilateral agreement[532] with the USA and Canada with respect to documentation requirements of the BSP pertaining to LMO/FFPs provided pursuant Article 18.2 (a).[533] The Agreement was signed in order to clarify documentation requirements e.g. that they fulfil the objectives of the BSP[534] without unnecessarily disrupting commodity trade.

The trilateral agreement signed by the NAFTA trading partners is an inter-institutional agreement. Within Mexico it is not in force anymore firstly, because it was signed at the end of October 2003, i.e. almost two years before the Mexican Biosafety Law was enacted, published and entered into

[531] Ibid, Trilateral Inter-institutional Agreement, supra note 523

[532] The trilateral inter-institutional agreement was signed on October 29 by SAGARPA of Mexico, on October 23 by the U.S. Department of Agriculture and on October 20 by the Market and Industry Services Branch Agriculture and Agri-Food Canada.

[533] Article 18.2(a) of the BSP states: each party shall take measures to require that documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, clearly indentifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this protocol.

[534] Article 14 of the BSP enables parties to enter into agreements as long as they do not "result in a lower level of protection than that provided by the BSP." Article 24 extends the possibility of such agreements to non-Parties as long as such agreements are "consistent with the objective of the Protocol".

force. Secondly, because the Mexican Biosafety Law states pursuant to Article twelfth transitory:

> *All legal provisions contrary to this Law are hereby repealed*

Thus, the principle "lex posterior derogate legi priori" would be applied. It may also refer to the principle that later in time prevails. Additionally, there are some provisions of the inter-institutional agreement that are opposed to the Mexican Biosafety Law. Due to the fact that inter-institutional agreements have a hierarchy below federal and local Laws it is worth mentioning that the inter-institutional agreement is not in force anymore within Mexico. Nevertheless, the inter-institutional agreement was extended within NAFTA between October 31st and November 20th 2005. They decided to extend the period of the inter-institutional agreement by signing an addendum of the trilateral inter-institutional agreement to the documentation requirements for LMO/FFPs. The addendum has a single paragraph and states:

> *To extend the period during which the Documentation Requirements for Living Modified Organisms for Food or Feed, or Processing (LMO/FFPs) are in force, from the date this Addendum is signed, indefinitely until such time as any one of the participants decides to terminate it by notifying the other two participants in writing, 60 days in advance.*

Thus, the trilateral inter-institutional agreement was extended through the aforementioned addendum. It is important to highlight that Mexico signed this addendum with the aim to extend the inter-institutional agreement from 2003 in spite of the fact that they are neither compatible with the provisions of the Mexican Biosafety Law nor with the BSP. On the one hand, the Inter-institutional agreement is repealed because of the provision of Article twelfth transitory of the Mexican Biosafety Law. On the other hand the inter-institutional agreement and its addendum are in force despite the fact that they are governed by international rules.

Greenpeace[535] criticizes the trilateral inter-institutional agreement and argues that it would not have prevented the genetic contamination already experienced in Mexico and that it will only legitimize past, current and fu-

[535] Greenpeace, The United State's assault on multilateralism continues: The Case of Model Agreement pushed by the Miami Group. The original Miami Group included the US, Argentina, Canada, Australia, Chile, and Uruguay. New-Zealand and Brazil have now joined it to form the Miami+ group. Online:www.greenpeace.org

ture genetic contamination. Additionally, Greenpeace argues that the implementation of the trilateral inter-institutional agreement by Mexico, a party to the protocol, will constitute a clear case of non-compliance through non-fulfilment of BSP obligations, in particular according to Articles 14.1, 16.3, and in cases of re-export of imported LMO's, pursuant to Article 17.1.

2. The Trilateral Inter-institutional Agreement and its Addendum Regarding Imports of GM Maize within NAFTA

a) First Incompatibility between the Inter-institutional Agreement and the Mexican Biosafety Law

The inter-institutional agreement and its addendum are incompatible with the provisions of the Mexican Biosafety Law because the technical annex of the inter-institutional agreement states under section 4. "Applicability (a)"

> *The "may contain" documentation will be used for all transboundary movements of commodities intended for food or feed or for processing, where an LMO of that commodity species is authorized in, or sold from, a country of export, except:"*

Under number 2 of the implementation it states that the "may contain", when included, should state:

> *Cartagena Biosafety Protocol Provisions: This shipment may contain living modified organisms intended for direct use as food or feed or for processing that are not intended for intentional introduction into the environment*

This is the first incompatibility between the inter-institutional agreement and the Mexican Biosafety Law, because the latter requires more than just a "may contain" label. It requires all imported GMO's to be accompanied by an authorization granted by the Secretariat of Health. At ports, i.e. in Mexican territory, the Secretariat of Finance and Public Credit[536] does not allow the entry of GMO's[537] if the shipments do not have the aforementioned authorization.[538] However, imports from the USA neither have the "may contain" label nor indicate what kind of GMO destined for FFPs are contained in each shipment. Hence, Mexico does not know, if the LMO's have been authorized or not by the Mexican Secretariat of Health. Thus, the potential mixture imported into the country might then

[536] Ibid, Mexican Biosafety Law, supra note 332, Article 18(I)
[537] Ibid, Article 18(V)
[538] Ibid, Articles 5, 18, 91, 97

contain non-authorized varieties under the Mexican Biosafety Law i.e. prohibited varieties for commercialization. In short, the inter-institutional agreement provided for a very weak labelling scheme. Furthermore, due to the fact that the Mexican Biosafety Law relies on NOM's that have not yet been developed, the Secretariat of Finance and Public Credit does not require the practice of documentation at Mexican ports and this is a real problem for Mexico because Mexico is a COD of maize.

b) Second Incompatibility between the Inter-institutional Agreement and the Mexican Biosafety Law

This section 4, Applicability (a), has two exceptions, to the "may contain" label that states that the shipments will not use the label "may contain"

> *(ii) When the exporter and importer have contractually defined a "non-LMO shipment;" provided that such a shipment achieves a minimum of 95 percent non-LMO content, and that such definition does not conflict with regulations of the importing country.*

Thus, the exporter must only document that a shipment "may contain" LMO's for all shipments with more than 5% LMO content. For shipments requiring the "may contain" warning, the exporter is not obligated to identify the specific LMO's in the shipment. This invalidates one of the key provisions regarding safe handling of LMO's.

This points to another incompatibility between the inter-institutional agreement and the Mexican Biosafety Law since the latter requires all imported GMO's to be accompanied by an authorization granted by the Secretariat of Health, and there is a 0% threshold for unapproved events or varieties i.e. if the GMO's have an authorization, they can be imported to Mexico, and if not, the shipment must be restrained.

Following this, section 4, Applicability (b), states:

> *The adventitious presence of LMO's in a non-LMO shipment should not be considered a trigger for the "may contain" documentation*

The adventitious presence of LMO's in a non-LMO's shipment may have serious consequences for Mexico if it is GM maize to produce pharmaceutical products, because maize is open pollinated. Furthermore, in this regard, it is important to once again highlight that due to the fact that Mexico is a COD of maize, it has already been stated that the country prohibits

both experimentation and release of GM maize into the environment that has been modified to obtain pharmaceutical products, vaccines, industrial oils, plastics or any modification that limits or affects its properties as food. [539] Hence, Mexico must not allow an "adventitious presence of prohibited maize." It is worth mentioning that the adventitious presence of LMO's could be permitted, if it is an authorized event granted by the Secretariat of Health.

To sum up, the trilateral inter-institutional agreement and its addendum are not in force within Mexico but they are in force within NAFTA due to the fact that they are ruled by international Law. Thus, they are recognized and are obligatory for them. The identification of shipments may provoke conflicts regarding imports of GM maize if Mexico requires them to comply with the provisions included in its domestic Biosafety Law. This could be a possible scenario because within NAFTA, only Mexico requires to include in the shipments both identification of GMO's imports and the documentation of the approvals of the permits and/or authorizations of GMO's intended for use as FFPs or for voluntary release into the environment.[540] However, as mentioned above, current GM maize imports neither have documental information accompanying shipments nor labelling or identification. It may be seen as a trade restrictive measure and conflicts may arise within NAFTA/WTO if it does not conform to NAFTA/WTO regimes. Mexico may ban GM maize imports if Mexico can justify that the GM maize presents an unacceptable risk to human, plant, or animal health or life or to the conservation and sustainable use of biological diversity.

The inter-institutional agreement and its addendum violate the BSP[541] because they lead to a lower level of protection than the one provided by the BSP.[542] The labelling is weak due to the fact that it does not identify the specific LMO being shipped into Mexico. As can be seen, the attempt of the NAFTA trading partners with respect to the documentation requirements of the BSP pertaining to LMO/FFPs has failed because neither one is consistent with the objectives of the BSP nor are they consistent with the Mexican Biosafety Law.

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[539] Ibid, "Statement by Mexico on Transgenic Maize with Properties that Limit its Consumption as Food", supra note 73

[540] Ibid, Mexican Biosafety Law, supra note 332, Article 102

[541] Ibid, BSP, supra note 147, Article 24 (1) and 2 (2)

[542] Ibid, Article 14

III. Imports Bans within the Agreement on Technical Barriers to Trade (TBT Agreement)[543] *and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)*[544]

1. The TBT Agreement

Import bans are strictly regulated by the WTO-Agreements such as GATT, SPS-Agreement and TBT-Agreement. They would require any importing party to demonstrate that any particular import ban has a rational basis, is in support of a legitimate policy objective, is no more restrictive than necessary to achieve that objective, and is not by means affecting any product in international trade, including GMO's. Thus, the TBT and the SPS Agreements were adopted to further the objectives[545] and to elaborate rules for the application of the provisions[546] of the GATT. The NAFTA and the WTO regimes will ensure that measures are not more restrictive than necessary. At the most basic level, both the WTO agreements and NAFTA share the common purpose of ensuring that measures that affect trade in products do not discriminate on the basis of a product's country of origin in a manner that harms imports and that is necessary to achieve the purpose for which they were designed.[547]

a) Labelling

Labelling requirements relating to food, nutrition claims and concerns, quality and packing regulations, are normally subject to the TBT-Agreement. Hence, technical regulations should not create unnecessary obstacles to international trade and be more trade-restrictive than is necessary to fulfil a legitimate objective taking into account the risks that non-fulfilment would create. Measures should not discriminate between imported products and "like" products of domestic or foreign origin. In the current investigation, it would be important to know, what will occur, If GMO's and GM products are considered "like" products in relation to conventional

[543] Agreement on Technical Barriers to Trade (TBT Agreement), Article 2.2, Apr. 15, 1994, WTO Agreement, Annex 1A, in results of the Uruguay Round of Multilateral Trade Negotiations (1994)

[544] Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), Article 5.6 n.3, Dec.15, 1993, WTO Agreement, Annex 1A, in Results of the Uruguay Round of Multilateral Trade Negotiations, vol. 27 (1994), 33 I.L.M. 1144. (15 April, 1994), Annex IA

[545] Ibid, TBT Agreement, supra note 543, Preambel, 2nd recital

[546] Ibid, SPS Agreement, supra note 544, Preambel, 8th recital

[547] Ibid, TBT Agreement , Articles 2.1, 2.2, supra note 542, SPS Agreement, Articles 2.2, 2.3 supra note 543, GATT, supra note 487, Articles I, III, and XX

products. If this should be the case, then there are no grounds for applying any special treatment to them, including mandatory labelling schemes.[548]

b) Technical Regulations

Regarding technical regulations, members are to accord treatment "no less favourable" to products originating in the territory of any other member of the WTO, than that accorded to like products of national origin and to like products originating in any other country. The concept of "like products" is a relevant aspect of the TBT-Agreement. The principle of non-discrimination, as set out in Article 2.1 of the TBT-Agreement incorporates elements of the most-favoured-nation[549] and the principle of national treatment.[550] Thus, Article 2.1 may be seen as a combined and shortened version of Articles I and III of GATT 1994. In examining whether a measure is consistent with Article 2.1, two steps may be followed: first, the determination of whether or not the two products or sets of products are "like"; secondly, if both products are "like", the establishment of no less favourable treatment between them.[551]

However, the Appellate Body made it clear in Japan-Alcoholics Beverages II- probably the most important case in relation to "like products" that the concept of like product may have different meanings in the different provisions in which it is used. The image of an accordion was given to designate the concept of "likeness" as it is a relative one that stretches and squeezes in different places as different provisions of the WTO agreement are applied. The interpretation of the concept of "likeness" will vary according to the particular provision in which the term "like" is encountered as well as by the context of and the circumstances that prevail in any given case to which that provision may apply.

In the EC-Asbestos case, the Appellate Body warned against the automatic transposition of the interpretation of "likeness" under the first sentence of Article III (2) to other provisions where the phrase "like products" is used.[552] Given, however, that the like product provision of the TBT-Agreement appears to be a logical extension of the non-discrimination obligations and that Article III (4) GATT 1994 specifically deals with regulatory discrimination, it is likely that GATT non-discrimination disputes, in particular those dealing with Article III (4) GATT 1994 may provide guidance

[548] Ibid, Zarilli Simonetta, supra note 25
[549] Ibid, GATT 1994, supra note 487, Article I
[550] Ibid, Article III
[551] Ibid, Stoll PeterTobias, supra note 500, Pp. 210-234
[552] EC-Asbestos Case, WT/DS 135/AB/R, footnote 50

in the interpretation of the term "like products" appearing in various places in the TBT-Agreement, in particular Article 2.1.

For instance, if the claimant contends that a technical regulation is incompatible with Article 2.1 of the TBT-Agreement because it subjects imported genetically modified products to less favourable treatment than conventional products of national or foreign origin, the panel, in order to determine incompatibility with Article 2.1 would have to establish, inter alia, that the genetically modified and conventional products involved are "like products". In this context, it seems that the issue to consider is whether a genetically engineered product that sufficiently resembles a conventional product in outward characteristics would be considered substantially equivalent to the conventional product. If this was the case, the two products would therefore be regarded as equally safe and should be treated in the same way. However, this issue of "like products" remains open.[553]

The TBT Agreement applies to all measures affecting the trade in any products that are technical regulations[554] or technical standards,[555] as long as those measures do not fall under the SPS-Agreement. While SPS measures may be imposed only to the extent necessary to protect human, animal and human health from food-borne risks or from pests or diseases, governments may introduce TBT regulations when necessary to meet a number of legitimate objectives, including the prevention of deceptive practices, the protection of human health or safety, animal or plant life or health or the environment.

c) The Process and Production Methods

States may also regulate process and production methods (PPM's) as long as they adhere to the disciplines covered by the SPS-Agreement according to Annex I (1) and pursuant to Articles 2 (2) and Annex I (1) of the TBT Agreement. A good example of a PPM of this type is the practice of catching tuna by setting fishing nets on schools of dolphins without taking precautions to spare the dolphins. When the USA banned import of tuna caught by such methods, two GATT dispute settlement panels declared this action inconsistent with GATT norms on the ground that it discriminated between "like" products. A state can not therefore adopt different treatment for two

[553] Ibid, Zarilli Simonetta, supra note 25

[554] Ibid, TBT-Agreement, supra note 543, Annex I(1), Technical regulations are documents that lay down product characteristics that are mandatory in character (such as trade restrictions on products containing certain substances).

[555] Ibid, TBT-Agreement, supra note 543, Annex I (2), Technical Standards are those that are non-mandatory in character (such a voluntary labelling schemes).

products with the same physical characteristics based upon how the products have been produced or harvested.[556]

d) The Eco-labelling

Labelling of environmental aspects of goods and services (eco-labelling)[557] emerged as an international issue in the trade context, following Mexico's complaint that the US 1990 Dolphin Protection Consumer Information Act (allowing Dolphin Safe labels to be placed on tuna products provided that dolphins had not been killed) was incompatible with the GATT. Although there have been no subsequent GATT or WTO Committee on Trade and the Environment ruling on the propriety of eco-labelling schemes under GATT/WTO rules, with particular focus on the compatibility with the WTO rules of mandatory labelling requirements for genetically modified organisms, the matter is now governed for its parties, in respect to LMO's, by the BSP, which requires LMO's intended for FFPs to be identified to show that they "may contain" LMO's and are not intended for intentional release into the environment. [558] However, the USA is not party to the BSP and considering that it is in first place in the cultivation and development of biotech-crops it will certainly continue to invoke for not mandatory labelling of these products.

To sum up, under the TBT Agreement, member states pledge that technical regulation will not be allowed to create unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more restricted than necessary to fulfil a legitimate objective. They have to be based on science and on non-discriminatory rules. This is a problem regarding imports of GMO's since biotechnology has only recently developed and its impact on ecosystems is difficult to ascertain and may be difficult to reverse. Hence, the application of the precautionary principle is crucial.

2. The SPS Agreement

The SPS-Agreement's main goal is to prevent domestic sanitary or phytosanitary measures from having unnecessary negative effects on international trade and being misused for protectionist purposes. It allows countries to protect food safety and animal and plant health and to take priority over

[556] Ibid, J. Schoenbaum Thomas, supra note 493

[557] The theory behind eco-labels is that if consumers are informed, the marked and consumer choice can be relied upon to stimulate the production and consumption of environmentally friendly products.

[558] Sands Philippe, Principles of International Environmental Law, page 861, second edition, 2003, Cambridge University Press

trade. It governs all measures which may directly or indirectly affect international trade in any products that are applied with the policy objective of protecting animal or plant life or health within the territory of the member from risks arising "inter alia", from pests, diseases or contaminants.

A country that is banning or otherwise restricting imports of GMO's or GM products may be infringing its trade obligations under the WTO but it may, however, invoke a number of provisions to justify its trade-restrictive measure. The country imposing the trade restrictive measure has to prove that it is necessary to protect human, animal or plant life or health and that it is based on scientific principles and that it is maintained with sufficient scientific evidence. If the measure is applied on a provisional basis, it must seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time. Nevertheless, if the justification of the trade-restrictive measure is not safety, the SPS-Agreement is not applicable and not violated.

a) Measures for Health and Safety Protection

The SPS Agreement[559] establishes the conditions governing sanitary and phytosanitary measures enacted by Members, amplifying Article XX (b) of GATT 1994 and confirming that measures consistent with the SPS Agreement are deemed to meet the requirements of that Article."[560] Thus, SPS measures are defined in Annex A to the SPS Agreement as:

> *Any measure applied:*
>
> *(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;*
>
> *(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuff;*
>
> *(c) to protect human life and health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or*

[559] Ibid, SPS Agreement, Article 2.4, supra note 544
[560] Ibid, Sands Philippe, page 977, supra note 558

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport, of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

To date, there have been four relevant cases within the WTO Panels and the Appellate Body which raised issues under the SPS Agreement: (i) the Australian Salmon;[561] (ii) Japanese Varietals[562]; (iii) Beef Hormone Case;[563] and (iv) the EC- Measures Affecting the Approval and Marketing of Biotech Products.[564]

In 1998, in the Beef Hormone Case, the European Community invoked the precautionary principle to justify its claim that it was entitled to prohibit imports of beef produced in the USA and in Canada with artificial hormones, where the impacts of human health were uncertain[565]. "The community argued that the precautionary principle was already a general customary rule of international law or at the least a general principle of law that it applied to both the assessment and management of a risk, and that it informed the meaning and effect of Articles 5.1 and 5.2 of the SPS Agreement."[566] The USA denied that the precautionary principle represented a rule

[561] Australia – Measures Affecting Importation of Salmon, Report of the Appellate Body, WT/DS18/AB/R, 20, October 1998. The Salmon dispute arose out of a Canadian complaint regarding Australia's prohibition on the importation of fresh, chilled or frozen salmon from Canada.

[562] Japan – Measures Affecting Agricultural Products, WT/DS76/R, 27 October 1998 and WT/DS76/AB/R, 22 February 1999. This case was about a complaint by the USA relating to the requirement imposed by Japan for testing and confirming the efficacy of the quarantine treatment for each variety of certain agricultural products.

[563] EC– Measures Concerning Meat and Meat Products. Beef Hormone Case, WTO Appellate Body (1997) WT/DS26/AB/R

[564] European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R

[565] Ibid, Sands Philippe, pages 277-278, supra note 558

[566] See Report of the Appellate Body, 16 January 1998, WT/DS48/AB/R, paragraph 16

of customary international law and that it had any legal status at all, thus, the USA refers to a precautionary approach, as provided in the SPS-agreement 5.7. Canada referred to a precautionary approach as an emerging principle of international Law, which may in the future crystallize into one of the "general principles of law recognized by civilized nations", within the meaning of Article 38 (1) (c) of the ICJ Statute. Concerning this matter the WTO Appellate Body said:

> *Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle, at least outside the filed of international environmental law, still awaits authoritative formulation.*

The WTO Appellate Body agreed with the USA and Canada that the precautionary principle did not override Articles 5.1 and 5.2 of the SPS-Agreement, although it considered that it was reflected in the preamble to Articles 3.3 and 5.7 of the SPS-Agreement, which did not exhaust the relevance of the principle. [567] The Appelllate Body also addressed the preparation and content of the risk assessment. It concluded that the EC's measures were not based on a risk assessment that reasonably supported or warranted the import prohibition. The various scientific studies the EC has adduced were too general in nature. Accordingly, the measures were inconsistent with Article 5.1 and consequently also with Article 3.3[568]

b) Import Restraint under the SPS Agreement

"WTO member states have the right to take sanitary and phytosanitary measures that are necessary for the protection of human and animal health." [569]

However, the measures may only be taken if they fulfil six specific requirements:

First, SPS-measures must not be more trade-restrictive than required to achieve their appropriate[570] level of protection.[571]

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[567] Ibid, Sands Philippe, page 227, supra note 558

[568] Ibid, pagina 981

[569] Ibid, J. Schoenbaum Thomas, supra note 493

[570] "Appropriate" is the level of protection deemed appropriate by the member state, see Annex A paragraph 5

Second, any SPS measure shall be applied only to the extent necessary to protect human, animal or plant life and health.[572]

Third, a measure must be based upon scientific principles and sufficient scientific evidence. However, even without sufficient scientific evidence, provisional standards can be applied.

Fourth, Measures must be based upon a risk assessment process taking into account available scientific evidence and economic factors, including the objective of minimizing negative trade effects.[573]

Fifth, Article 2(3) of the SPS-Agreement repeats the requirements of the Chapeau of Article XX that the measure must not arbitrarily or unjustifiably discriminate between members and must not be a disguised restriction on international trade. Moreover, with the objective of achieving consistency, Article 5(5) also prohibits arbitrary or unjustifiable distinctions in the levels of sanitary and phytosanitary protection considered appropriate.

Sixth, there is an obligation at least to consider adopting international standards if they are scientifically justified or required by the member state's own unilaterally determined higher level of protection[574]

The AppelIate Body insisted that these requirements are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision. Whenever one of these requirements is not met, the measure at issue is inconsistent with Article 5.7 of the SPS-Agreement.[575]

D. Conclusion

The findings of this chapter identify the complicated situation for Mexico as a NAFTA/WTO member and as party to the BSP. Since the inception of NAFTA in 1994 Mexico has had the possibility to protect maize within the 15 years transition period and to support Mexican farmers, however, as can been seen, Mexico exceeded levels in the TRQ established within NAFTA. In short, the quota set out under NAFTA was not implemented. All maize imports into Mexico have been exempt from tariff payments and the maize imports from the USA contain 70% of GM maize that is neither accompanied with a label nor with any identification. Thus, GM imports of maize may contain varieties unapproved in Mexico. However, it remains to

[571] Ibid, SPS-Agreement, supra note 544, Article 5(6)
[572] Ibid, Article 2(2)
[573] Ibid, SPS Agreement, supra note 544, Article 5
[574] Ibid, Article 3
[575] Japan – Measures Affecting Agricultural Products II, WT/DS76/AB/R, paragraph. 90.

be seen if Mexico will retrain GM maize imports as it is obligated to do according to the provisions of the Mexican Biosafety Law but not by the trilateral inter-institutional agreement signed by the NAFTA trading partners.

Mexico must comply with the principles provided within NAFTA/WTO regimes and must not apply measures that are contrary to the principle of non-discrimination or are at least trade restrictive. By applying technical standards, they must be non-discriminatory and not be more trade restrictive than necessary to realize a legitimate objective. Governments are also encouraged to seek equivalence of technical matters and mutual recognition of conformity assessment procedures to reduce the restrictiveness of the measure. NAFTA and the WTO seek to establish free trade regarding GMO's by eliminating national level measures that may create trade barriers such as the provisions provided in Article 5.7 of the SPS-Agreement. However, the regimes do allow states to enact national protective measures to preserve human and animal health as well as natural resources based on scientific evidence. Disputes may be expected under the TBT- Agreement regarding technical regulations and standards with such a mandatory labelling. Relating to GMO's, a core question is whether such measures result in a disguised restriction on trade, on the basis that "like products" are treated less favourably than others. Indeed assertions that GM and non-GM products are "like products" may prove hard to challenge in the WTO context given the paucity of existing scientific evidence. As can be seen only the Asbestos Case has been successful in invoking Article XX (b). The Appellate Body held that where there is a scientifically proven risk to health, WTO members have the right to determine the level of protection of health they consider appropriate based either on the quality of the risk or on the quantity of the risk. Hence, the more vital the common interests or values pursued, the easier it would be to accept as necessary the measures designed to achieve those ends.

Summary

The Protection of Maize under the Mexican Biosafety Law

Chapter I:

1. The findings of this chapter identify the development of biotechnology and show successful cases concerning mainly red and green biotechnology. Both the adoption of biotech-crops and the number of biotech countries planting biotech crops (from 6 in 1996 to 25 in 2008) have rapidly increased in the last two decades. In 2008, 125 million hectares were cultivated with transgenic crops. Currently, maize has the most events approved (44) followed by cotton (23), canola (14) and soybean (8).

2. The first maize hybrids with a degree of drought tolerance are expected to be commercialized in the USA (Nebraska and Kansas) in 2012. These may well be the first commercial transgenic varieties to address a problem of great concern to Mexico, namely, the cultivation of GM maize in arid zones. However, it is necessary that the authorizations of permits, for the release of GM maize into the environment are granted only for use outside of the restricted areas such as: (i) the centres of origin and diversity, (ii) the GMO-free zones and; (iii) the national protected areas. Furthermore, biosafety measures and monitoring must be in place before the release can take place in order to avoid an introgression.

3. The outcome of this research shows the crucial importance of maize for Mexico and the importance to protect, preserve, and to minimize the loss of its diversity, while avoiding introgression in a COD. The contamination of maize in the north of Oaxaca in 2001 indicated that the lack of control and monitoring at borders, when GM maize was imported from the USA without label or identification, was probably the cause of maize contamination. This illustrates the complexity of managing biosafety in Mexico.

Chapter II:

4. The findings of this chapter show that the risks associated with biotechnology were first addressed in the 1992 Convention on Biological Diversity (CBD), which focused on the protection of biological diversity at

the time when biodiversity became an issue in international environmental policy as a law. The issue of biotechnology was also addressed internationally within the 2000 Cartagena Protocol on Biosafety (BSP) which set out a comprehensive regulatory regime to ensure "the safe transfer, handling and use of LMO's that may have adverse effects on the conservation and sustainable use of biological diversity taking into account risks to human health, and specifically focusing on transboundary movements".

5. The findings of this research show the opposing positions of the USA and the EU with regard to GM crops. The difference between the positions of the USA and the EU is rooted in divergent concepts of caution. While the USA regulates product safety independently of the technology, through product liability, the EU has created specific separate regulations for biotechnology.

6. The creation of CIBIOGEM in Mexico was crucial to coordinate biosafety and biotechnology policies throughout the country. Also, the promulgation of the Mexican Biosafety law was another achievement since it incorporates into a single homogenous law much dispersed existent legislation. Nevertheless, the implementation of the law is difficult as it relies on NOM's, which have not yet been developed. In addition, Mexico lacks adequate human, technical and financial resources, this in turn, is a hurdle to undertake an appropriate risk assessment and risk management of GMO's. The application of the precautionary approach will also be difficult since the Law subjects its application to the provisions and administrative procedures established in the Law, notwithstanding the fact that the Law does not provide guidelines to do so. Hence, the findings of this research show that Mexico will face a potential conflict since it is party to the BSP and a Member of the WTO. On the one hand, the BSP allows the application of the precautionary approach even in the face of "lack of scientific uncertainty due to insufficient scientific information". On the other hand, the SPS Agreement allows for the application of the precautionary approach "where there is insufficient scientific evidence" but only on a provisional basis. Thus, it may be difficult for Mexico to decide how to apply the precautionary approach i.e. in the light of the BSP or in the light of SPS Agreement. However, the application of the precautionary approach in Mexico is crucial to the granting of authorizations of permits of experimental release of GM maize into the environment since the impact on ecosystems is difficult to ascertain and may be difficult to reverse, especially in a COD of maize.

7. The Mexican Biosafety Law currently provides for the protection of maize. However, to achieve adequate protection the implementation of the law is crucial. The Mexican Biosafety Law can protect maize - the staple food of Mexicans – only if (i) the centres of origin and the centres of genetic diversity are established before authorizations of permits for experimental release of GM maize into the environment takes place; (ii) the Secretariat of Finance and Public Credit requires identification and labelling of GM maize imports at borders; (iii) the NOM's required for the implementation of the Law are issued; (iv) the precautionary approach of granting authorizations of permits for the release of GM maize into the environment is applied, (v) SAGARPA and SEMARNAT take into account the reports from CONABIO (even though they are only for informative purposes) before deciding whether authorizations of permits for the release of GM maize into the environment may take place, (vi) Mexico monitors both the GMO's imports and the releases of GM maize into the environment and; (vii) Mexico invests at least 1% of GDP in science and technology (as provided in Articles 1, 9 and 9-bis of the Science and Technology law) in order to promote biotechnology in the country and to obtain benefits of biotechnology.

Chapter III:

8. The findings of this investigation identify the complicated situation for Mexico as a NAFTA/WTO member and as party to the BSP, since the USA and Canada are not Party to the BSP. Hence, if a dispute arises before the WTO, the provisions of the BSP namely the precautionary approach will not be taken into consideration – an example of this was seen in the EC-Biotech case (Measures Affecting the Approval and Marketing of Biotech Products) between the EU and the USA, Canada and Argentina.

9. Another outcome of this research shows that since the inception of NAFTA in 1994 Mexico has had the possibility to protect maize within the fifteen years transition period and to support Mexican farmers. However, as has been shown, in 1996 maize imports have actually exceeded the TRQ's established by NAFTA for the transition period.

10. Although the Mexican Biosafety Law requires a mandatory labelling of imported GMO's, maize imports from the USA have neither labels nor do they carry an identification. Thus, GM maize imports may contain unapproved varieties for Mexico, and should therefore be restrained at borders since, according to the provisions of the Mexican Biosafety Law, there is

a 0% threshold for unapproved GMO's i.e. if the GMO's have an authorization they can be imported, if not they must be restrained. Notwithstanding, it remains unclear whether Mexico will indeed restrain GM maize imports at borders since Mexico, Canada and the USA signed a trilateral inter-institutional agreement with respect to Article 18. 2 (a) of the BSP, which allows a "non LMO shipment" if such shipment achieves a minimum of 95% non-LMO content. The agreement is ruled by international law and is therefore in force, even though it is inconsistent with both the Mexican Biosafety Law and the BSP.

11. The findings of this research also show that the NAFTA/WTO regimes allow states to enact national protective measures based on scientific evidence to preserve human and animal health (Article XX b) as well as natural resources (Article XX g). However, as has been discussed in this study, only the French ban on imports of Asbestos has been successful in invoking Article XX (b) because France scientifically proved the threats (lung cancer) that asbestos may cause to human health.

12. To date, there has been no determination by the WTO as to whether a GM and a non-GM are "like products". In the event that the panel determines that GM and non-GM are different, then the importing party does not have to treat both in the same way. However, if the panel determines that they are "like products" then any difference in treatment that undermines the ability of an imported product to compete with a domestic product would violate the WTO's rules against discriminatory treatment.

Bibliography

Acevedo Gasman Francisca, Huerta Ocampo Elleli, Barrios Pérez Alejandra y Oliveros Galindo Oswaldo, "El análisis de riesgo a la biodiversidad: la experiencia de Conabio pp161-180 en: Bioseguridad en la aplicación de la biotecnología y el uso de los organismos genéticamente modificados, CIBIOGEM, PNUD, GEF, primera edición, México, 2008

Agreement between the United States of America and the United Mexican States on Cooperation for the Protection and Improvement of the environment in the Border Area, signed in la Paz, Baja California Sur, August 14, 1983.

Agreement on the Application of Sanitary and Phytosanitary Measures, Article 5.6 n.3, Dec.15, 1993, WTO Agreement, Annex 1A, in Results of the Uruguay Round of Multilateral Trade Negotiations, vol. 27 (1994), 33 I.L.M. 1144 (1994).Agreement on the Application of Sanitary and Phytosanitary Measures" (15 April, 1994).

Agreement on Technical Barriers to Trade (TBT), Art. 2.2, Apr. 15, 1994, WTO Agreement, Annex 1A, in Results of the Uruguay Round of Multilateral Trade Negotiations (1994).

Alvarez-Buylla Roces Elena, "Aspectos Ecológicos, Biológicos y de agrobiodiversidad de los Impactos del Maíz Transgénico" en: Ciencia, ambiente y mercado: un debate abierto, pp 181-218, siglo xxi s.a. de c.v. en coedición con el centro de inestigaciones interdisciplinarias en ciencias y humanidades, unam, primera edición 2004.

Alvarez Morales Ariel. Pp 90-96, 2000, "Mexico: Ensuring Environmental Safety While Benefiting from Biotechnology." In G.J. Persley and M.M. Lantin, eds., Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, D. C., 21-22 October 1999. Washington: Consultative Group on International Agricultural Research.

Alvarez Morales Ariel y Jofre Garfias Alba E, „Manejo y Control de Riesgos Aplicado a los OGMs páginas 145-159 en: Bioseguridad en la aplicación de la biotechnología y el uso de los organismos genéticamente modificados, CIBIOGEM/PNUD/GEF, primera edición, México, 2008.

Alvarez Morales Ariel, pp 90-96, 2000, "Mexico: Ensuring Environmental Safety While Benefiting from Biotechnology".

Aguirre G. A., M. R. Bellon and M. Smale. 1998. A regional Analysis of Maize Biological Diversity in Southeastern Guanajuato, Mexico. CIMMYT Economics Working Paper 98-06. Mexico, D. F.;

American Society of Agronomy, Madison, WI. Pp. 1-31; Shaw, R.H. 1988. Climate requirement. In: G.F. Sprague and J.W. Dudley (eds.) Corn and Corn Improvement. Amer. Soc. Agron. Mafison, WI. Pp. 609-633.

A. Wise Timothy, Policy Space for Mexican Maize: Protecting Agrobiodiversity by Promoting Rural Livelihoods, GDAE Working Paper No. 07-01, February 2007, Global Development and Environment Institute, Tufts University.
Online: http://www.ase.tufts.edu/gdae/policy/research/MexicanMaize.html

Barrios Pérez Alejandra, Gama López Susana, Oliveros **Galindo Oswaldo y Acevedo Gasman Francisca,** "Sistema de informacion de organismos modificados (SIOVM), páginas 181-206 en: Bioseguridad en la aplicación de la biotechnología y el uso de los organismos genéticamente modificados, CIBIOGEM/PNUD/GEF, primera edición, México, 2008.

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, Mar. 22, 1989, 28 I.L.M. 657, 1673 U.N.T.S. 57.

Benson. G. O. and R. B. Pearce. 1987. Corn Perspective and Culture. In: S. A. Watson and P. E. Ramstad (eds.). Corn: Chemistry and Technology. Amer. Assoc. of Cereal Chemistry. St. Paul, MN. Pp 1-29.

Benz, B. F. 1986. Racial systematics and the evolution of Mexican maize. In: L. Manzanilla (ed.). Studies in the Neolithic und Urban Revolutions. B.A.R. International series 349. pp. 121-136.

Bericht der Enquête-Kommission" Chancen und Risiken der Gentechnologie", BT-Dr.s. 10/6775, S 7.

Betancour Rodríguez, Andres, 2001,Instituciones de Derecho Ambiental, Madrid.

Birnie Patricia, Boyle Alan and Redgwell Catherine, International Law and the Environment, chapter 11 "Conservation of Nature, Ecosystems and Biodiversity" pp 583-649, third edition, Oxford University Press, 2009.

Bolivar Zapata Francisco G., "Biotechnología Moderna para el Desarrollo de México". En ciencia, ambiente y mercado: un debate abierto, pp 261-268, siglo xxi s.a. de c.v. en coedición con el centro de inestigaciones interdisciplinarias en ciencias y humanidades, unam, primera edición, México, 2004.

Bolivar Zapata Francisco G., compilador y editor: autores Carlos F. Arías Ortíz... et al. – 2da Ed. México, D.D. El Colegio Nacional, 2007. 718 p. Coedición con: Academia Mexicana de Ciencias; UNAM, Instituto de Biotechnología: CONACTY: CIBIOGEM. "Fundamentos y casos exitosos de la biotechnología moderna".

Butler, L.J. (1995), "The Regulation of Agricultural Biotechnology in the USA." *Biotechnology and Development Monitor*, No. 24, p. 26.

Calva José Luis, "El modelo de desarrollo agropecuario impulsado mediante la Ley Agraria y el TLC", en: J. L. Calva, Aternativas para el campo mexicano, México, PUAL-UNAM-Friedrich Ebert Stiftung-Fontanamara, 1993. **Canada**. "Administration of the Foreign Investment Review Act", GATT BISD (30th Supp.), 140, Para. 5.14 (1984).

Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 39 ILM (2000), 1027. In force 29 December 1993. It was published in D.O.F. on May 07, 1993.

Chauvet Michelle. El Desarrollo Agrícola y Rural del Tercer Mundo en el Contexto de la mundialización: "La agricultura transgénica: Esperanza ó amenaza para la sustentabilidad?", 2004, UNAM, pp 511-521.

CIBIOGEM, 2003 Agreement entitle "Documentation Requirements for Living Modified Organisms (LMO's) for Food, Feed and Processing. Internal Document of the Government of Mexico, Canada and the U.S. Restricted Document.

CIMMYT 1994. World Maize Facts and Trends. Maize Seed Industries Revisited: Emerging Roles of the Public and Private Sectors. Mexico, D. F.

Código Penal Federal publicado en el Diaro Oficial de la Federación el 14 de agosto de 1931, última reforma publicada en el D.O.F. el 26 de junio del 2008.

Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea mays*): Key Food and Feed Nutrients, Anti- Nutrients and Secondary Plant Metabolites, No. 6, 2002, ENV/JM/MONO(2002)25

Constitución Politica de los Estados Unidos Mexicanos publicada en el Diario Oficial de la Federación el 5 de febrero de 1917, última reforma publicada en el D.O.F el 18 de junio del 2008.

Convention on Biological Diversity (CBD) 31 ILM (1992),818. In force 29 December 1993. It was published in the D.O.F. on May 07, 1993

Convention on International Trade in Endangered Species **of Wild Fauna and Flora**, (1973), Washington 993 UNTS 243. In force 1 July 1975

Convention on the Law of Treaties, (Vienna) 8 ILM (1969) 689. In force 27 January 1980. It was published in the D.O.F. 14 February 1975

Cotero Garcia Marco, "Regulacion de los organismos genéticamente modificados en México, páginas 313-320 en: Bioseguridad en la aplicacion de la biotecnologia y el uso de los organismos genéticamente modificados, CIBIOGEM/PNUD/GEF, primera edición, México, 2008.

Dasilva, Edgar J. "The colours of Biotechnology": Science, Development and Humankind. Electron. J. Biotechnol. Dic., 2004, Vol. 7, No. 3, pp-1-2. ISSN 0717-3458. [1]

De Pina García Juan Pablo, "La diversidad del maíz y los riesgos de la experimentación transgénica" en: Revista de Geografía Agrícola número 38 enero-junio 2007 pp 111-120, Universidad Autónoma Chapingo, Dirección de Centros Regionales Universitarios, Coordinación de Revistas Institucionales, México, 2007.

Dispute Settlement Panel, European Communities Measures Affecting the Approval and Marketing of Biotech Products WT/DS291/27, WT/DS292/21 and WT293/21, (2003)

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration. *OJ L 106, 17.4.2001, p. 1–39*

Decreto Ley No. 190 sobre Seguridad Biológica de Cuba de 1999

D.O.F., Tomo DCXXXVIII No. 20, México, D.F., miercoles 29de Noviembre de 2006, primera sección p.71.

Doebley, J. M. M. Goodman and C. W. Stuber. 1987a. Patterns of isozyme variation between maize and Mexican annual teosinte. Econ. Bot. 41(2):234- 246.

Dobley J. Goodmann J, Stuber CW. 1985. Isozyme variation in the races of Maize from Mexico. American Journal of Botany 72(5): 629-639; Doebley J., Stec A, Wendel J., Edwards M. 1990. Genetic and morphological analysis of a maize-teosinte F2 population: Implications for the origin of maize. PNAS, volumen 87; paginas 9888-9892; Dobley J., Stec A. 1991. genetic analysis of the morphological differences between maize and teosinte. Genetics, Volumen 129; páginas 285-295; Dobley J. 1992.

Mapping the genes that made maize. Treds in Genetics, Volumen 8, número 9; págnas 302-307.

Dyer-Leal, G. and A. Yúñez-Naude (2003), "NAFTA and Conservation of Maize Diversity in Mexico", paper presented at the 2nd North America Symposium of CEC on Assessing the Environmental Effects of Trade, 14 February, Mexico City.

Eckard Boege y Victor Manuel Toledo: Biodiversidad, Recursos Genéticos y Areas Naturales Protegidas, pp 191-213. Agenda para el Desarrollo, vol. 14, 2007, Editorial Porrúa.

Ellstrand, N. C. H. C. Prentice and J. F.Hancock. 1999. Gene Flow and Inrogression from Domesticated Plants into their wild Relatives. Ann. Rev. Ecol. Syst. 30, Pp. 539-563.

Enquete-Kommision, „ Chancen und Risiken der Gentechnik", BT-Dr.s. 10/6775, s.7

Erbgut Wilfried and Schlanke Sabine, Gentechnikrecht, pp.435-366. in Umweltrecht, 2. Auflage, Nomos Verlagsgesellschaft Baden-Baden, 2008

Espinoza Gutierrez Elvira y Signorini Marcelo, Codex Alimentarius y los organismos geneticamente modificados pp. 275-286 en: Bioseguridad en la aplicacion de la biotecnologia y el uso de los organismos genéticamente modificados, CIBIOGEM/PNUD/GEF, primera edición, México, 2008.

European Communities, Measures Affecting the Approval of Biotech Products, Request for Consultations, on May 20, 2003 online:http://docsonline.wto.org:80/DDFDocument s /t/G/TBT/ D28.doc

Evans, M. M. S. and J. L. Kermicle, 2001. Teosinte crossing barrier 1, a locus governing hybridisation of teosinte with maize. Theor. Appl. Genet. 103, Pp. 259-265

FAO, **1992**, Maize in Human Nutrition. FAO: food and nutrition series, No. 25. FAO, Rom

FAO/WHO 1996: Biotechnology and food safety, Report of a joint FAO/WHO consultation. FAO Food and Nutrition Paper 61, Food and Agriculture Organization of the United Nations, Rome.

FAO, 1997: Biotechnology and Food Safety, Food and Nutrition Paper 61, FAO, Rom.

FAO/WHO (2000): Safety aspects of genetically modified foods of plant origin.

FAO/WHO consultation 29 May – 2 June 2000. WHO, Geneva, Switzerland

Galinat, W.C. 1988. The Origin of Corn in: G.F. Sprague and J. W. Dudley (eds.) Corn and Corn Improvement. Agronomy Monographs No. 18. American Society of Agronomy, Madison, WI. Pp. 1-31

Gálvez Mariscal Amanda, 2000. Biotechnologia Agricola en México: aspectos de regulación, Crónica Legislativa, H. Cámara de Diputados, núm. 13, 3ª. epoca, del 1 de marzo al 30 de abril, pp 80-82.

Gálvez Mariscal Amanda, In: Gene Flow "What does it Mean for Biodiversity and Centers of Origin", Panel 6, page 26, México 2004, by Offset Reboson.

Gálvez Mariscal Amanda, M. Quirasco, A. Acatzi, J. Magaña, C. Moles, C. Peña, M. Castillo and M. Signori. "Detection and Quantification of GM Maize Varieties in Mexican Imports" in: Harmonisation needs at international and regional level. First Conference on GMO's Analysis, June 2008.http://gmoglobalconference.jrc.ec.europa.eu/DetailedProgramme.htm

Gálvez, M. Quirasco, A. Acatzi, J. Magaña, C. Moles, C. Peña, M. Castillo and M. Signori. "Detection and Quantification of GM Maize Varieties in Mexican Imports" in: Harmonisation Needs at International and

Regional Level. First Conference on GMO's Analysis, June 2008. Available online: http://gmoglobalconference.jrc.ec.europa.eu/DetailedProgramme.htm

Gálvez Mariscal Amanda, "Learning about Biosafety in Mexico:between competitiveness and conservation" in: 62 Int. J. Biotechnology, vol.7 nos. 1/2/3, 2005, Inderscience Enterprises Ltd.

Gálvez Mariscal Amanda, UNAM, Experiences and Lessons Learned: Mexico pp 5-6 in: Bio-safety Protocol news, December 2007.

Gálvez Mariscal Amanda, Principios básicos de biología molecular y biotecnología Pp 87-112 en: Bioseguridad en la aplicación de la biotecnología y el uso de los organismos genéticamente modificados, CIBIOGEM, PNUD, GEF, primera edición, México, 2008

General Agreement on Tariffs and Trade (GATT), Oct.30, 1947, 61 Stat. A-11 T.I.A.S.1700 U.N.T.S. 194, as modified by Marrakech Agreement of the World Trade Organization, Annex 1A, Legal Instruments of the Uruguay Round vol.1, 33 I.L.M. 1154 (1994)

Genetic Modification: an overview for non-scientists, Report of the New Zealand Royal Commission on Genetic Modification, Wellington, 2001, page 363.

Gesetzt zur Regelung der Gentechnik (Gentechnikgesetz – GenTG) v. 20.6.990. BGBI. I S. 108

Gesetzt zur Neuordnung des Gentechnikrechts vom 21.Dezember 2004, BGBI. 2004 I S. 186

Green Peace, The United States's assault on multilateralism continues: The Case of Model Agreement pushed by the Miami Group. The original Miami Group included the US, Argentina, Canada, Australia, Chile, and Uruguay. New-Zealand and Brazil have now joined it to form the Miami+ group.

Gupta Aarti and Robert Falkner, "The Influence of the Cartagena Protocol on Biosafety: Comparing Mexico, China and South Africa. In: Global Environmental Politics, November 2006, Vol. 6, No. 4 Pages 23-55.

Guruswamy Laksman D., International Environmental Law in a Nutshell, chapter one, "Sources and Forms of International Environmental Law" pp. 1-30, second edition, 2003 by West, a Thomson Business.

Gutiérrez-Nava, M. L., C. A. Warren, P. León and V. Walbot. 1998. Transcriptionally active MuDR, the regulatory element of the mutator transposable element family of Zea mays, is present in some accessions of the Mexican land race Zapalote Chico. Genetics 149, pp. 329-346

Halauer, A.R. 2000. Potential for Outcrossing and Weediness of Genetically Modified Insect Protected Corn. APHIS-USDA

Harlan, J. R. 1992. Crops and man. American Society of Agronomy, Inc. Crop Science Society of America, Inc. Madison, WI. USA. Pp. 284, Second Edition.

Hernández –Xolocotzi, E. 1972. Exploración etnobotánica en maíz. Fitotecnia Latinoamericana 8 (2):46-51. reimpreso en: E. Hernández X. 1987. Xolocotzia, Tomo II. UACH. Chapingo, Mexico. Pp.751-756.

Herrera Estrella Luis and Martinez Trujillo Miguel, "Plantas Transgénicas: Potencial, Uso actual y Controversias." En ciencia, ambiente y mercado: un debate abierto, pp 29-50, siglo xxi s.a. de c.v. en coedición con el centro de investigaciones interdisciplinarias en ciencias y humanidades, unam, primera edición 2004.

Herrera Juan Antonio, Carlos Hinojosa, Gloria Hagelsieb y René Salinas, "Mexico's Environmental Law in the GMO era", pp. 121-156 en: Mexican Law Review, new series, Volume I, number 1, UNAM, Instituto de Investigaciones Jurídicas, July-Decemeber 2008.

Hoisington, D., G. M. L. Morris. 1998. Varietal Development, Applied Biotechnology en: M. L. Morris (ed.) Maize Seed Industries in Developing Countries, Lynne Rienner Publishers, Inc. and CIMMYT, Int. Pp. 77-102.

Hubert Carton de Grammont, "Politica Neoliberal, estructura productiva y organización socialde los productores: una visión en conjunto", en:

Antonio Yunez-Naude, los pequeños productores rurales en México: Las reformas y las opciones, México, El Colegio de México, 2000.

ISAAA Brief 39-2008: Executive Summary Global Status of Commercialized Biotech/GM Crops: 2008. The First Thirteen Years, 1996 to 2008.

ISAAA Brief 35-2006: Executive Summary, Global Status of Commercialized Biotech/GM Crops: 2006.

Japan – Measures Affecting Agricultural Products, WT/DS76/R, 27 October 1998, and WT/DS76/AB/R, 22 February 1999.

Japan - Trade in Semi-Conductors, GATT BISD (35th Supp.), 115, paragraph 106-09 (1989).

Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Safety Standards, held in Geneva, Switzerland, 13-17 March 1995. Cartagena Protocol on Bio-safety, at Article 1

José Luis Solleiro, Rosario Castanion y Silvia Almanza. El Desarrollo Agrícola y Rural del Tercer Mundo en el Contexto de la mundialización: "Hacia una politica y regulación de organismos genéticament modificados para la agricultura y la alimentación en México.", 2004, Unam, pág. 523-544.

Jugenheimer RW, 1976, Corn improvement, seed production, and uses. John Wiley & Sons, Inc, New York, USA **Jurisprudence:** Novena Epoca; Instancia:Pleno; Fuente; Semanario Judicial de la Federación y su Gaceta; Tomo: X, Noviembre de 1999; Tesis P.LXXVII/99; Página:46; Jurisprudence: Novena Epoca; Instancia:Pleno; XXV Abril de 2007; Tesis P.IX; tesis Aislada, Registro no. 172650

Jurisprudence: Novena Epoca; Instancia: Pleno; Fuente; Semanario Judicial de la Federación y su Gaceta; Tomo: X, Noviembre de 1999; Tesis P.LXXVII/99; Página: 46; Jurisprudence: Novena Epoca; Instancia: Pleno; XXV Abril de 2007; Tesis P.IX; tesis aislada, registro no. 172650

Kermicle, J. L. and J. O. Allen, 1990, Cross-incompatibility between maize and teosinte. Maydica 35, Pp 399-408

Kinderlerer Julian. „Regulation of Biotechnology: needs and burdens for developing Countries."

Kinderlerer, Julian, Kummer, Katharina and Tapper, Richard (2003). An Explanatory Guide to the Cartagena Protocol on Biosafety. IUCN, Gland, Switzerland and Cambridge, UK. Xvi + 295pp.

Klopfer Michael, Umweltschutzrecht, Gentechnikrecht, s. 447-470, 2008, C.H. Beck Verlag

Kubli-García Fausto, Capitulo V, Bioseguridad de Organismos Genéticamente Modificados en México, Pp 191-241 en: Régimen jurídico de la bioseguridad de los organismos genéticamnete modificados, Instituto de Investigaciones Jurídicas, UNAM, primera edición 2009. Online:http://www.bibliojuridica.org/libros/libro.htm?l=2637

Kuiper, H. 2003. The use of profiling methods for identification and assessment of unintended effects in genetically modified foods. National Academy of Sciences Workshop on identifying unintended health effects of genetically engineered foods, February 6-8, 2003. Washington, D.C.

La Convención de Viena sobre el derecho de los tratados fue publicada en el Diario Oficial de la Federación el 14 de febrero de 1975.

Ley sobre la Celebración de los Tratados, publicada en el Diario Oficial de la Federación el 02 de Enero de 1992.

Ley de Bioseguridad de Organismos Genéticamente Modificados publicada en el Diario Oficial de la Federación el 18 de marzo del 2005

Ley de Bioseguridad ó ley número 8.974 de Brasil de 1995

Ley de Biodiversidad de Costa Rica de 1998

Ley de Diversidad Biológica de Veneuela del 2000

Ley de Ciencia y Technología publicada en el Diario Oficial de la Federación el 5 de junio del 2002, última reforma publicada en el D.O.F el 21 de agosto del 2006.

Ley de Desarrollo Rural Sustentable publicada en el Diario Oficial de la Federación el 7 de diciembre del 2001, última reforma publicada el 02 de febrero del 2007 en el D.O.F.

Ley de Desarrollo Rural Sustentable publicada en el D.O.F. el 7 de dicimebre del 2001, ultima reforma publicada el 02 de febrero del 2002

Ley de Planeación publicada en el Diario Oficial de la Federación el 05 de enero de 1983, última reforma publicada en el D.O.F el 13 de junio del 2003

Ley No. 27104 o Ley de Prevención de Riesgos derivados del Uso de la Biotecnología de Perú de 1999.

Ley Federal de la Administración Pública Federal publicada en el Diario Oficial de la Federación el 29 de diciembre de 1976, última reforma publicada en el D.O.F el 1 de octubre del 2007.

Ley Federal de Sanidad Vegetal publicada en el Diario Oficial de la Federación el 5 de enero de 1994, última reforma publicada en el D.O.F. el 18 de noviembre del 2008.

Ley Federal de Producción, Certificación y Comercio de Semillas publicada en el Diario Oficial de la Federación el 15 de junio del 2007.

Ley Federal de Protección al Ambiente publicada en el D.O.F. el 11 de enero de 1982.

Ley Federal de Metrología y Normalización, publicada en el Diario Oficial de la Federación el 01 de julio de 1992, última reforma publicada en el D.O.F. el día 28 de julio del 2006.

Ley General de Desarrollo Forestal Sustentable publicada en el Diario Oficial de la Federación el 25 de febrero del 2003, última reforma publicada en el D.O.F el 24 de noviembre del 2008.

Ley General del Equilibrio Ecológico y la Protección al Ambiente publicada en el Diario Oficial de la Federación el 28 de enero de 1988, ultima reforma publicada en el D.O.F el 16 de mayo del 2008.

Ley General de Salud, publicada en el Diario Oficial de la Federación el 07 de febrero de 1984, ultima reforma publicada en el D.O.F el 05 de enero del 2009.

Ley General de Vida Silvestre publicada en el Diario Oficial de la Federación el 03 de julio del 2000, ultima reforma publucada en el D.O.F el 14 de octubre del 2008.

Ley para Prevenir y Controlar la Contaminación Ambiental publicada en el D.O.F. el 23 de marzo de 1971

López Herrera Agustín, Best Practices and Lessons Learned from the UNDP-GEF Capacity Building Project fort he Implementation of the National Biosafety Framework of Mexico, pp. 5-6 in: Biosafety Protocol News, Volume 3/Issues 5, December 2008

Losey. J. E., L.S. Rayor and M. E. Carter. 1999. Transgenic pollen harms monarch larvae. Nature 339, pp. 214.

Louette, D. 1996. Intercambio de semillas entre agricultores y flujo genético entre variedades de maíz en sistemas agrícolas tradicionales. In Serratos, J. A. M. C. Willcox, and F. Castillo (eds). Flujo genético entre maiz criollo, maíz mejorado y teocintle: Implicaciones para el maíz trangénico. CIMMYT. México, D. F. Pp 60-71.

Louette, D. 1997. Seed exchange among farmers and gene flow among maize varieties in traditional agricultural systems in: A. Serratos, M.C. Willcox and F. Castillo (eds.). Gene Flow among Maize Landraces, Improved Maize and Teosinte. Implications for Transgenic Maize. CIMMYT, Mexico, D. F. pp. 56-66.

Louette, D. and M. Smale. 1998. Farmers' Seed Selection Practices and Maize Variety Characteristics in a Traditionally-Based Mexican Community. CIMMYT Economics Working Paper No. 98-04. México, D.F.: CIMMYT.

Mackenzie, Ruth, Burhenne-Guilmin, Francoise, La Viña, AntonioG.M. and Werksman, Jacob D. In Cooperation with Ascencio, Alfonso, Kinderlerer, Julian, Kummer, Katharina and Tapper, Richard (2003).

An Explanatory Guide to the Cartagena Protocol on Bio-safety. IUCN, Gland, Switzerland and Cambridge, UK. Xvi + 295pp.

Mannion A. M. and Bowly S.R., Chapter 9 "Biotechnology and Genetic Engineering: New Environmental Issues" in: Environmental Issues in the 1990s, pp147-160, Ed by John Wiley Sons Ltd, England 1995.

Mangelsdorf, P. C. and R. G. Reeves. 1939. The origin of indian corn and ist relatives. Texas Agric. Expt. Sta. Bull. 574.

Mangelsdorf, P.C. 1974. Corn, Its Origin, Evolution and Improvement. Harvard University, Press, Cambridge, MA.

Massieu Trigo Yolanda y Chauvet Michelle, IV. La agricultura transgénica y los recursos fitogenéticos en México, aspectos sociales pp.75-112 en: Cultivos transgénicos para la agricultura latinoaméricana, primera edición, FCE, SEP, CONACYT, México, 2008

Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994).

Matsuoka, Y., Y. Vigouroux, M. M. Goodman, J. Sanchez G., E. Buckler and J. Doebley. 2002. A single domestication for maize shown by multilocus microsatellite genotyping. Proc. Natl. Acad. Sci. USA 99: 6080-6084.

Mendel Georg, Versuche über Pflanzenhybriden, vorgelegt in den Sitzungen vom 8. Februar und 8. März 1865, gedruckt in den Verhandlungen des naturforschenden Vereins in Brünn. IV. Band. Abhandlungen 1865, Brünn, 1866. Im Verlage des Verein. S. 3-47

Michelle Chauvet and Amanda Gálvez, "Learning About Biosafety in Mexico: between competitiveness and conservation", Int. J Biotechnology, Vol. 7, Nos. 1,2 and 3: 62-71,2005, Inderscience Enterprice Ltd.

Morris, M. L. 1998. Overview of the world maize economy. In: M. L. Morris (ed.) Maize Seed Industries in Developing Countries. Lynne Rienner Publishers, Inc. and CIMMYT, Int. pp. 13-34

Nadal, A. 1999. El maíz en México: Algunas implicaciones ambientales del Tratado de Libre Comercio de América del Norte en: Evaluation de los efectos ambientales del Tratado de Libre Comercio del Norte. Comisión para la Cooperación Ambiental. Montréal, Quebec, Canada. Online: http://www.cec.org

National Institute of Ecology (INE), Environmental Impact Assessment: Achievements and Challenges for Sustainable Develpment 1995-2000; General Directorate of Law and Environmental Impact.

Norman, M. J. T., C. J. Pearson and P. G. E. Searle. 1995. The ecology of tropical food crops. Cambrigde University Press, Cambridge, Great Britain. Pp. 126-144, second edition.

North American Free Trade Agreement (NAFTA) Washington, 8 and 17 December 1992; Ottawa, 11 and 17 December 1992, Mexico City, 14 and 17 December 1992, in force 1 January 1994, 32 ILM 289 (1993) and 32 ILM 605 (193).

Nava Escudero César. Memorias del Segundo Encuentro Internacional de Derecho Ambiental, 2004, "La Seguridad de la Biotechnología: La Normatividad Internacional Vis-a-vis, la Regulación Nacional Mexicana", página 439-470. SEMARNAT-INE-PNUMA.

Nava Escudero César, "Guía Minima para la Enseñanza del Derecho Internacional Ambiental en México" in: Boletin Mexicano de Derecho Comparado Número 113, Revista Juridica.

Nava Escudero César, "Los Acuerdos Interinstitucionales Ambientales", en Derecho Ambiental y Ecología, México, año 2, núm. 12, abril-mayo de 2006.

Nava Escudero César. "El Principio de Precaución en el Derecho Internacional Ambiental en: Derecho Ambiental y Ecología, México, Año 1, número 2, Agosto-Septiembre de 2004.

Nava Escudero César, "El principio de precaución en el derecho internacional ambiental" en: Estudios Ambientales, Instituto de Investigaciones Jurídicas, UNAM, primera edición 2008.
Online: http://www.bibliojuridica.org/libros/6/2641/pl2641.htm

New Zeeland Royal Commission on Genetic Modification, Genetic Modification: "An Overview for Non Scientist", Wellington 2001, page 363.

NOM-056-FITO-1995 por la que se establecen los requisitos fitosanitarios para la movilización nacional, importación y establecimiento de pruebas de campo de organsimos manipulados mediante la aplicación de ingenieria genética publicado en el Diario Oficial de la Federación el 11 de Julio de 1996.

North American Agreement on Environmental Cooperation, Sept. 14, 1993, Can.-Mex.-U.S.,32 I.L.M. 1480 (1994).

North American Free Trade Agreement, Dec. 17,1992, Can.-Mex.-U.S.,32 I.L.M. 298(1994).

OECD, 1996: Recombinant DNA Considerations. Safety considerations for industrial, agricultural and environmental applications of organism derived by DNA techniques (The Blue Book), Paris, OECD.

OECD, 1993, Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles. OECD, Paris; OECD, 2001, Consensus Documents, OECD Inter-Agency Network for Saftey in Biotechnology. OECD, Paris.

OECD, 1993: Safety Evaluations of Foods derived by Modern Biotechnology: Concepts and principles. Paris, OECD

OECD, 1992: Safety Considerations for Biotechnology; OECD, 1993 Safety Considerations for Biotechnology: Scale-up of crop plants. OECD, 1993: Traditional Crop Breeding Practices: An historical Review to serve as a Baseline for Assessing the role of modern biotechnology; OECD, 1995: Safety Considerations for Biotechnology: Scale-up of micro-organisms as bio- fertilizers.

OECD, 2005, Agriculture, Trade and the Environment "The Arable Crop Sector", Chapter 2, pp 57-97, Paris.

OECD, 2005, Agriculture, Trade and the Environment, "The Arable Crop Sector" chapter 1, pp. 33-55, Paris. OECD, 2005, Agriculture, Trade

and the Environment "The Arable Crop Sector", chapter 1, Pp 33-55 Paris.

OECD, 2006, "Agricultural Policies and Commodity markets", Chapter 5 Pp 15-138 in: Agricultural and Fisheries Policies in Mexico", Recent Achievements, Continuing the Reform Agenda, OECD, Paris.

OECD, 2006, "Safety Assessment of Transgenic Organisms", Volume 1, OECD Consensus Documents, Volume 1, Seccion 3 maize (zea mays subsp. Mays) pp. 47-71, Paris.

Ojeda Mestre Ramón, "La legitimación activa para el juicio de amparo en materia ambiental" pp. 50-54 en Gaceta Ecológica INE-SEMARNAT México número 60, 2001.

Ortega-Pazcka, R., C. Solano S., F. Aragón C. Y J. Bustamante L. 1988. Trabajos recurrentes de colecta de maíces nativos de Oaxaca. Resúmenes del XII Congreso de Fitogenética. 18-22 de Julio, 1988. Chapingo Mexico. Pp. 218.

Ortega-Pazcka, R. 1973. Variación de maíz y cambios socioeconómicos en Chiapas, Mex. 1946-1971.Tesis de M. C. Colegio de Postgraduados Chapingo, Mexico. 199 pp.

Ortíz Garcia Sol y Ezcurra Exequiel, protocolo de cartagena: Bioseguridad en la aplicacion de la biotecnologia y el uso de los organismos geneticamente modificados, pags, 313-320 CIBIOGAM-PNUD- GEF , 1 edicion 2008. pag 363-274

Ortíz Garcia Sol. El uso de los organismos genéticamente modificados en México: retos y estrategias para su regulación. Conferencia presentada el 09 de octubre del 2007, Universidad Autonoma de la Ciudad de México. CIBIOGEM

Ortíz Garcia Sol, Herramientas de la bioseguridad, páginas 115-130, en: Bioseguridad en la aplicacion de la biotecnologia y el uso de los organismos genéticamente modificados, CIBIOGAM/PNUD/GEF, primera edicion, México, 2008.

Ortíz Garcia Sol, et al., Replay to Cleveland et al.'s "Detecting (transgene flow tolandraces in centers of crop origin: lessons from the case of maize in Mexico." Environmental Bio-safety Research 2005. 4: p. 209-215;

Ortíz García Sol, et al., Absence of detectable transgenes in local landraces of maize in Oaxaca, Mexico (2003–2004). Proceedings of the National Academy of Science, 2005. 102: p. 12338-12343.

Ortiz Garcia Sol y Adriana Otero Arnaiz, México como el centro de origen del maíz y elementos sobre la distribución de parientes silvestres y variedades o razas de maíz en el norte de México. Coordinación del rograma de Bioseguridad del Instituto Nacional de Ecología. Revista de Geografía Agrícola número 38 enero-junio 2007 pp 141-152, Universidad Autónoma Chapingo, Dirección de Centros Regionales Universitarios, Coordinación de Revistas Institucionales, México, 2007.

Panel Report, US- Gasoline, WT/DS2/R, para. 6.20; Panel Report, EC-Asbestos, WT/DS135/R, para 8.167-8.169.

Persley G. J., Pp 3-21, 2000. "Agricultural Biotechnology and the Poor: Promethean Science" In G.J. Persley and M.M. Lantin, eds., Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, D. C., 21-22 October 1999. Washington: Consultative Group on International Agricultural Research Alvarez Morales Ariel. Pp 90-96, 2000, "Mexico: Ensuring Environmental Safety While Benefiting from Biotechnology." In Persley G. J. and M.M. Lantin, eds., Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, D. C., 21-22 October 1999. Washington: Consultative Group on International Agricultural Research

Persley G,, J, and M.M. Lantin, eds., Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, D. C., 21-22 October 1999. Washington: Consultative Group on International Agricultural Research.

Plan Nacional de Desarrollo 2007-2012. Online: http://pnd.calderon.presidencia.gob.mx/index.php?page=documentos-pdf

Pollak, L.M. and P. J. White. 1995. Corn as a Food Source in the United States: Part I. Historical and Current Perspectives. Cereal Foods World. Amer. Assoc. of Cereal Chemists. St. Paul. MN. Pp. 749-754.

Poy Solano Laura, "México, entre las naciones que menos recursos destinan a ciencia y tecnología", en la Jornada, sección sociedad y Justicia, México, 18 de enero del 2007, pág 45.

Protocol on Substances that Deplete the Ozone Layer, (Montreal), 26 ILM (1987),1550. In force 1 January 1989

Prall Ursula, Gentechnikrecht s. 483 in: Hans-Joachim Koch, Umweltrecht, 2. Auflage, München 2007, Carl Heymanns Verlag.

Quist, D. and I. Chapela. 2001. Transgenic DNA introgressed into traditional maize landrace in Oaxaca, Mexico. Nature 414: 541-543.

Reglamento de Bioseguridad de Bolivia de 1997

Reglamento de Control Sanitario de Productos y sevicios publicado en el Diario Oficial de la Federación el 09 de agosto de 1999, ultima reforma publicada en el D.O.F el 06 de abril del 2006.

Reglamento de la Ley del Equilibrio Ecológico y la Protección al Ambiente en Materia de Evaluación del Impacto Ambiental, publicado en el Diario Oficial de la Federación el 30 de mayo del 2000.

Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados publicado en el Diario Oficial de la Federación el 19 de marzo del 2008, última reforma publicada en el D.O.F el 06 de marzo del 2009.

Reglamento de Insumos para la Salud publicada en el Diario Oficial de la Federación el 04 de febrero de 1998.

Reglamento de la Ley General de Salud en Materia de Investigación para la Salud publicada en el Diario Oficial de la Federación el 06 de enero de 1987.

Reglamento de la Ley General de Salud en Materia de Publicidad publicada en el Diario Oficial de la Federación el 04 de Mayo del 2000, última reforma publicada en el D.O.F. el 06 de abril del 2006.

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. OJ L 268, 18.10.2003, p. 24–28

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23

Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms. OJ L 287, 5.11.2003, p. 1–10 .

Report of the World Commission on Environment and Development: Our Common Future 1987, The Brundland Report Convention on Biological Diversity, supra note at the fifth preamble recital.

Ribeiro Silvia, "Cultivos Transgénicos: Contexto Empresarial y Nuevas Tendencias" En ciencia, ambiente y mercado: un debate abierto, pp 67-87, siglo xxi s.a. de c.v. en coedición con el centro de investigaciones interdisciplinarias en ciencias y humanidades, UNAM, primera edición, México, 2004.

Rivera Herrejón María Gladys, "El sector maicero y la política agrícola en México durante los noventa", Pp. 287-316 en: El Desarrollo Agrícola y Rural del Tercer Mundo en el Contexto de la mundialización, 2004, UNAM

Rooney L. W. and S. O. Serna-Saldivar. 1987. Food uses of whole corn and dry milled fractions. In: S. A. Watson and P. E. Ramstad (eds.). Corn: Chemistry and Technology. Amer. Assoc. of Cereal Chemistry. St. Paul, MN. Pp. 399-429.

Rubio Blanca, "La politica agropecuaria neoliberal y la crisis alimentaria", en José Calva, El campo mexicano: ajuste neoliberal y alternativas, México, Juan Pablos-CIETAAM, UACH, 1997

Sands Philippe, Principles of International Environmental Law, 19 International Trade and Competition pp. 940-1019, second edition, 2003, Cambridge University Press.

Schoenbaum Thomas J., International Trade and Environment Protection pp 696- 750 in: International Law and the Environment, second edition, Oxford University press, 2002.

Shaw, R.H. 1988. Climate requirement. In: G.F. Sprague and J.W. Dudley (eds.) Corn and Corn Improvement. Amer. Soc. Agron. Mafison, WI. Pp. 609-633.

Simonetta Zarilli, "International Trade in Biotechnology Products and Multilateral Legal Frameworks". –In: Biological Resource Management in Agriculture, "Challenges and Risks of Genetically Engineered Organisms", OECD Paris, 2004, pp. 29-45

Solleiro José Luis, Castanion Rosario y Almanza Silvia. El Desarrollo Agrícola y Rural del Tercer Mundo en el Contexto de la mundialización: "Hacia una politica y regulación de organismos genéticament modificados para la agricultura y la alimentación en México.", 2004, UNAM, pág. 523-544

Smith, B. D. 1995. The emergence of Agriculture. Scientific American Library, New York. Pp. 231;

Stallwortly Mark, Understanding Environmental Law, 6.3 law risk and GMO's, pp 147-172, first edition, published by Thomson, Sweet & Maxwell, London, 2008

Stockholm Declaration on the Human Environment, U.N. Doc. A/CONF/48/14/REV.1 (1972), reprinted in 11 I.L.M. 1417 (1972).

Stoll Peter Tobias, "Controlling the Risks of Genetically Modified Organisms: The Cartagena Protocol on Bio-safety and the SPS Agreement, In: Yearbookof International Environmental Law 10 (1999), 82-119.

Stoll Peter Tobias, Rüdiger Wolfrum and Anja Seibert-Fohr (eds) WTO-Technical Barriers and SPS Measures, 2007 Koninklinjke Brill NV. Printed in Netherlands. Pp. 96-120

Stoll Peter Tobias and Schorkopf Frank, World Economic Order, World Trade Law, Max Planck Commentaries on World Trade Law, 2006, Kononklijke Brill NV, Leiden, The Netherland.

Téllez Kuenzler Luis, La modernización del sector agropecuario y forestall, México, FCE, 1994; y SARH, el sector agropecuario en las negociaciones del TLC, México 1992.

Tovar Millán Patricia, La ley general del equilibrio ecológico y la protección al ambiente y bioseguridad, pags 287-312 en: Bioseguridad en la aplicación de la biotechnología y el uso de los organismos genéticamente modificados, CIBIOGEM/PNUD/GEF, primera edición, México, 2008.

Tsaftaris, A. S. 1995. The Biology of Maize (Zea mays, L.). Document XI/754/95 European Commission.

Turrent-Fernández, A., N. Gómez-Montiel, J. L. Ramírez Díaz, H. Mejía-Andrade, A. Ortega-Corona and M. Luna-Flores. 1997. Plan de investigaciones del sistema maíz-tortilla en los Estados Unidos Mexicanos. Internal Document, INFAP- SAGAR.

United Nations Conference on Environment and Development: Rio Declaration on Environment and Development (Rio Declaration), Rio de Janeiro, June 14, 1992,(1992) 31 *ILM* 874.

United Nations Convention on Biological Diversity, June 5,1992, 31 I.L.M. 818,823 (1992).

United Nations Conference on Environment and Development: Rio Declaration on Environment and Development.

United Nations Convention on Biological Diversity.

US-Schrimp/Turtle Report of the Appelled Body, paragraph 136-142.

US- Standards for Reformulated and Conventional and Gasoline, Report of the Appellate Body, WT/DS2/AB/R (1996); 35 ILM (1996), 274

Vavilov, N. I. 1951. The origin, variation, immunity and breeding of cultivated plants. Translated from the Russian by K. Starr Chester. The Ronald Press Co. New York. Pp. 94.

Vega-Segovia, M. L. and R. Ferrera-Cerrato. 1996ª. Microorganismos del rizoplano del maiz y frijol inoculados con mutantes de Rhizobium y Azospirillum en: J. Pérez-Moreno anf R. Ferera-Cerrato (eds.). Avances de Investigación, Área de Microbiología de Suelos. PROEDAF-IRENAT, Colegio de Postgraduados. Montecillo, Estado de México. Pp. 9-17.

Villalobos Arámbula Víctor Manuel, "Los transgénicos: Oportunidades y amenazas", primera edición 2008, Mundi-prensa, impreso en Madrid.

Von Moltke, K. 1988. "The Vorsorgeprinzip in West German Environmental Policy": In Royal Commission on Environmental Pollution, Twelfth Report. Best Practical Environmental Option. Cmnd 310. London: HMSO.

Watson, J. D. y F. H. C. Crick, 1953, Molecular Structure of Nucleic Acids. "A structure for Deoxyribonucleic Acid", Nature, 171, pages 737-738

Weale, A., 1992, The New Politics Of Pollution. Manchester University Press: London.

White, P. J. and L. M. Pollak. 1995. Corn as a Food Source in the United States: Part II. Processes, Products, Composition and Nutrient Values.
Cereal Foods World. Amer. Assoc. of Cereal Chemists. St. Paul. MN. Pp. 756-762.

Wilkes, H.G. 1977 Hybridisation of Maize and Teosinte, in Mexico and Guatemala and the Improvement of Maize. Economic Bonaty 31, Pp. 254-293

Wright, S. Sydney Brenner, 1978 in Molecular Politics – Developing American and British Regulatory Policy for Genetic Engineering 1972-1982, University of Chicago Press, 1994, p.76.

WHO 1991: Strategies for Assessing the Safety of Foods Produced by Biotechnology. Report of a joint FAO/WHO Consultation, WHO, Geneva.

Who, 1995, Application of the Principles of Substantial Equivalence to the Safety Evaluation of Foods or Food Components from Plants Derived by the Modern Biotechnology. Report of the WHO workshop. World Health Organization, Geneva; WHO/FAO, 2000 Safety Aspects of Genetically Modified Foods of Plant Origin. Report of a joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, 29 May- 2 June, 2000.

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