LAW ON BIOSAFETY OF GENETICALLY MODIFIED ORGANISMS

MEXICO

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LAW ON BIOSAFETY OF GENETICALLY MODIFIED ORGANISMS

FIRST TITLE
General Dispositions

CHAPTER I
Objective and Aims

ARTICLE 1.- The present law is of public order and social interest. It has the purpose of regulating the activities of confined usage, experimental release, release within a pilot program, commercial release, trading, importation and exportation of genetically modified organisms with the aim of preventing, avoiding or reducing the possible risks that these activities might entail to human health or to the environment and to biological diversity or to the health of animals, plants and aquatic organisms.

ARTICLE 2.- To fulfill its object, this ordinance has the following aims:

I. To guarantee an adequate and efficient protection of the human health, biological diversity and health of animals, plants and aquatic organisms with respect to the adverse effects that the undertaking of activities with genetically modified organisms might entail;

II**.** To define the principles and national policy in the matter of biosafety of GMOs and in the instruments for its application;

III. To determine the competences of the various dependencies of the Federal Public Administration in the matter of biosafety of GMOs;

IV. To establish the foundations to enter into treatises or coordination agreements between the Federation and the governments of the federative entities, by means of the competent Secretaries, for the better fulfillment of the object of this Law;

V. To establish the foundations for the working of the Inter-secretarial Commission for the Biosafety of Genetically Modified Organisms. The Secretaries integrating this commission must collaborate in a coordinated way, within the field of their competences, in relation to the biosafety of genetically modified organisms;

VI. To establish the administrative procedures and criteria for the evaluation and monitoring of the possible risks that the activities with genetically modified organisms might entail on human health, environment, biological diversity or on the health of animals, plants and aquatic organisms;

VII. To establish the regimen of licenses for the undertaking of activities concerning the experimental release, release within a pilot program and commercial release of genetically modified organisms, including their importation to undertake such activities;

VIII. To establish the regimen of notifications for the undertaking of activities of confined usage of genetically modified organisms in the cases in which this Law makes reference;

IX. To establish the regimen of authorizations of the Secretary of Health of the genetically modified organisms determined in this Law;

X. To create and develop the National System of Information on Biosafety and the National Registry on Biosafety of Genetically Modified Organisms;

XI. To lay the foundations for the establishment, case by case, of geographical areas free of GMOs in which it is prohibited or is restricted the undertaking of activities with determined genetically modified organisms, as well as the crops which Mexico is considered to be center of origin, particularly maize. The latter will be in a regimen of special protection;

XII. To lay the foundations for the contents of the Mexican official norms in the matter of biosafety;

XIII. To establish control measures to guarantee biosafety, as well as the corresponding sanctions in the cases of non-fulfillment or violation of the dispositions in this Law, its rules and regulations and the Mexican official norms derived from it;

XIV. To establish the mechanisms for the public participation in aspects of biosafety matter of this Law, including the access to information, participation of private, social and productive sectors through the Mixed Advisory Council of the CIBIOGEM, and the public consultation on the applications for GMOs release to the environment, and

XV. To establish the instruments to promote scientific and technological research in biosafety and biotechnology.

ARTICLE 3.- For the effects of this Law the following definitions are rendered:

I. *Accident*: Involuntary release of genetically modified organisms during their utilization, which may pose, based on technical criteria, possible risks to human health, environment and biological diversity.

II. *Activities*: Confined usage, experimental release, release within a pilot program, commercial release, trading, importation and exportation of genetically modified organisms, according to this Law.

III. *Authorization*: It is an administrative act by which the Secretary of Health, within its realm of competence according to this Law, authorizes that genetically modified organisms expressly determined in this Law, can be used for trading and imported for trading, as well as their utilization with public health or bioremediation purposes.

IV. *Bioremediation*: Process using genetically modified organisms for degrading or disintegrating contaminants affecting resources and/or natural elements, to transform them into simpler components rendering them less harmful or innocuous to the environment.

V. *Biosafety*: Actions and measures – assessment, monitoring, control and prevention-- that must be undertaken when dealing with activities concerning genetically modified organisms with the purpose of preventing, avoiding or reducing the possible risks such activities may cause to human health, environment and biological diversity, including innocuousness aspects of these organisms destined for human use or consumption.

VI. *Modern biotechnology*: It is considered the application of *in vitro* techniques of nucleic acids, including recombinant deoxyribonucleic acid (DNA and RNA) and the direct injection of nucleic acids into cells and organelles, or the fusion of cells beyond the taxonomic family, exceeding the natural physiological barriers of reproduction or recombination; these are not techniques commonly

used in traditional reproduction and selection, and are used to originate genetically modified organisms, and will be determined in the Mexican official norms derived from this Law.

VII. *Case by case*: Individual evaluation of genetically modified organisms supported with the scientific and technical evidence available. The evaluation considers, among other aspects, the receptor organism, release area and the characteristics of the genetic modification, as well as the existent background concerning the activities carried out with the organism in question and the benefits compared with alternative technological options to solve a specific problem.

VIII. *Center of origin*: It is a geographical area of the national territory where a process of domestication of a determined species took place.

IX. *Center of genetic diversity*: It is a geographical area of the national territory in which morphological and genetic or both types of diversities exist of some determined species. This area lodges populations of wild relatives and constitutes a genetic reservoir.

X. *Trading*: It is the introduction into the market of genetically modified organisms to be distributed and consumed as products or merchandises, without having the intention of releasing them into the environment, independent of its lucrative character and of the legal title under which it is made.

XI. *CIBIOGEM*: Inter-secretarial Commission for the Biosafety of Genetically Modified Organisms.

XII. *CONACyT*: National Council for Science and Technology.

XIII. *Biological diversity*: The variability of living organisms no matter their source, which include, among other things, terrestrial and marine ecosystems, as well as other aquatic ecosystems and the ecological complexes lodging them; it includes the diversity within each species, among the species and that of the ecosystems.

XIV. *Innocuousness*: Health assessment of genetically modified organisms, for human use or consumption, or for the processing of foods for humans, and whose finality is to guarantee that such organisms are free of risks or harmless for the health of the population.

XV. *Release*: The introduction into the environment of a genetically modified organism or a combination of them without the adoption of contention measures, such as physical barriers, or a combination of these with chemical or biological barriers, to limit their contact with the population and environment.

XVI. *Commercial release*: It is the introduction, intentional and permitted into the environment of a genetically modified organism or a combination of them, without the adoption of contention measures such as physical barriers, or a combination of these with biological or chemical barriers, to limit their contact with the population and the environment. This introduction has commercial, production, bioremediation, and industrial purposes, or others different from experimental release and release within a pilot program, in the terms and conditions issued in the respective license.

XVII. *Experimental release*: It is the introduction, intentional and permitted, into the environment of a genetically modified organism or a combination of them, in which contention measures have been adopted, such as physical barriers, or a combination of these with chemical or biological barriers, to limit their contact with

the population and the environment. This introduction is exclusively for experimental purposes, in the terms and conditions within the respective license.

XVIII. *Release within a pilot program*: It is the introduction, intentional and permitted, into the environment of a genetically modified organisms or a combination of them, with or without contention measures, such as physical barriers or a combination of these with chemical and biological barriers, to limit their contact with the population and the environment. This introduction is previous to the commercial release of such organism or group of organisms, within the authorized areas and in the terms and conditions contained in the respective license.

XIX. *Environment*: The set of natural and artificial elements or those induced by man allowing the existence and development of human beings and other living organisms that interact in a determined space and time, outside the facility areas, or outside the realms where genetically modified organisms are used in a confined manner.

XX. *Organism*: Any live biological entity capable of reproducing itself or of transferring or replicating genetic material. Included in this concept are sterile organisms, microorganisms, virus, viroids -- cellular or not cellular--. Human beings are not considered organisms for the effects of this Law.

XXI. *Genetically modified organism*: Any living organism, human beings exempted, having acquired a new genetic combination, originated through the specific use of modern biotechnological techniques defined in this Law, as long as the techniques used are the ones established in this Law or in the Mexican official norms derived from it.

XXII. GMO or GMOs: genetically modified organism or organisms.

XXIII. *Step by step*: Methodological approach in which all GMO to be commercially released must be previously submitted to satisfactory tests concerning risks studies, assessment of risks and reports of the results applicable to the undertaking of activities of experimental release and release within a pilot program of the determined organisms, in the terms of this Law.

XXIV. *License*: It is the administrative act issued by SEMARNAT or SAGARPA, within their fields of their respective competences according to this Law, necessary for undertaking the experimental release, release within a pilot program, commercial release and importation of GMOs to carry out such activities, in the cases and conditions established in this Law and in the Mexican official norms derived from it.

XXV. *Products containing genetically modified organisms*: Refers to those products for commercialization containing one or some genetically modified organisms in its composition.

XXVI. *Derived products*: Are those products having genetically modified organisms as raw material in their production process, including extracts, provided that in their composition for commercialization live genetically modified organisms are not present, and, therefore, lack the capacity of transferring or replicating their genetic material.

XXVII. *Registry*: National Registry on Biosafety of Genetically Modified Organisms.

XXVIII. *Residues*: Any debris originated in the confined usage of genetically modified organisms, including the genetically modified organisms themselves.

XXIX. *Secretaries*: Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food, Secretary of the Environment and Natural Resources and the Secretary of Health, in relation to their respective fields of competence established in this Law.

XXX. *SAGARPA*: Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food.

XXXI. *SEMARNAT*: Secretary of the Environment and Natural Resources.

XXXII. *SHCP*: Secretary of Finance and Public Credit.

XXXIII. *SSA*: Secretary of Health.

XXXIV. *Confined utilization*: Any activity in which the genetic material of an organism is modified or, once done, this modified organism is cultivated, stored, employed, processed, transported, traded, destroyed or eliminated, as long as in the undertaking of these activities physical barriers are employed, or a combination of these and chemical or biological barriers, with the aim of limiting in an effective manner its contact with the population and the environment. For the effects of this Law, the facilities area or the realm of confined usage is not a part of the environment.

XXXV. *Authorized zones*: The areas or geographical regions that must be determined, case by case, pending a resolution of a license, are those in which genetically modified organisms, once analyzed, may be released to the environment.

XXXVI. *Restricted zones*: Centers of origin, centers of genetic diversity and natural protected areas inside which the undertaking of activities with genetically modified organisms are restricted, in the terms of this Law.

ARTICLE 4.- It is matter of this Law the biosafety of all GMOs obtained or produced through the application of modern biotechnology techniques referred in the present ordinance, that are used for purposes related to agriculture, livestock, aquatic organisms, woods and forests, industry, commerce, of bioremediation and any other, with the exceptions established in this Law.

ARTICLE 5.- It is also matter of this Law the authorization of GMOs destined for human usage or consumption, or the processing of foods for humans to be used in trading and imported for trading. Likewise, it is a matter of this ordinance the authorization of GMOs, different from the former, destined to a public health cause or for bioremediation.

ARTICLE 6.- The following are excluded from the realm of application of this Law:

I. Activities of confined usage, experimental release, release within a pilot program and commercial release, trading, importation and exportation of GMOs, when the genetic modification of such organisms is obtained through traditional mutagenic or cellular fusion techniques --these include protoplasts of plant cells--, where the resulting organisms may be also produced with traditional multiplication methods or *in vivo* or *in vitro* cultures, provided these techniques exclude the utilization of genetically modified organisms as receptor or parental organisms;

II. The utilization of *in vitro* fertilization techniques, conjugation, transduction, transformation or any other natural process, as well as polyploid induction, as long

as no molecules of recombinant deoxyribonucleic acid (DNA), nor genetically modified organisms are employed;

III. The production or processing of medicines and pharmacological agents with GMOs originated from confined processes whose regulation corresponds to the General Law of Health;

IV. The health control of derived products and confined productive processes in which GMOs intervene authorized by this Law, for human or animal usage and consumption. These products and processes are subject to the dispositions in the General Law of Health and its rules and regulations applicable to all products and processes;

V. The human genome, human stem cell cultures, modification of human stem cells and the biosafety in hospitals, whose regulation corresponds to the General Law of Health, and to the International Treatises in which the United Mexican States is a participant;

VI. The collection and profit of biological resources regulated by the General Law for the Ecological Balance and the Protection of the Environment, General Law for the Wild Life, and the International Treatises in which Mexico is a participant, and

VII. The intellectual property of biotechnological products and processes are subject to the Law of Industrial Property, Federal Law of Plant Varieties and the International Treatises in which Mexico is a participant.

ARTICLE 7.- The activities, organisms and products subject to the scope of this Law, will not require, in matters of biosafety and innocuousness, of other permits, authorizations, notifications and, in general, requirements, administrative procedures and restrictions other than those established in this ordinance.

The following issues are exempted from the dispositions in the above paragraph:

I. The measures that in matters of general health correspond to the Secretary of Health in the terms of the General Law of Health and its regulations, except in relation to the administrative procedures and expedition of authorizations that this Law regulates;

II. The measures that in matters of health of animals, plants and aquatic organisms correspond to the Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food, in the terms of the Federal Law of Animal Health, the Federal Law of Plant Health, the Law of Fisheries, the Law of Sustainable Rural Development, and to the additional applicable dispositions, and

III. The measures that in environmental matters correspond to the Secretary of the Environment and Natural Resources in terms of the General Law for Ecological Balance and the Protection of the Environment, the General Law for Wild Life, the General Law for Sustainable Forest Development and of other laws applicable in such matter, except those related to:

A) The evaluation of the environmental impact and the study of risks regulated in Section V, Chapter IV of the First Title and in Chapter V of the Fourth Title, of the General Law for Ecological Balance and Environmental Protection, and

B) The administrative procedures and expedition of licenses and other control and monitoring instruments that this Law regulates.

ARTICLE 8.- In absence of an expressed disposition in the present ordinance, it will remain what is established in the Federal Law of Administrative Procedures.

CHAPTER II
Principles in Biosafety Matters

ARTICLE 9.-For the formulation and conduction of the biosafety policy and for the expedition of the rules and regulations and the Mexican official norms derived from this Law, the following principles must be complied:

I. The Mexican Nation is possessor of one of the wealthiest biodiversities in the world. Its territory holds areas defined as centers of origin and genetic diversity of species and varieties that must be protected, utilized, potentiated and exploited in a sustainable manner, since this country is a valuable reservoir of molecules and genes for the its sustainable development;

II. The State has the obligation of guaranteeing the right of every person to live in an adequate environment for his nourishment, health, development and well being;

III. GMOs biosafety has the objective of guaranteeing an adequate level of protection in the field of confined usage, experimental release, release within a pilot program, commercial release, trading, importation and exportation of such organisms resulting from modern biotechnology that may have adverse effects for the preservation and sustainable utilization of the environment and biological diversity, as well as affecting human health and the health of animals, plants and aquatic organisms;

IV. With the aim of protecting the environment and biological diversity, the Mexican State must adopt the cautionary scope in agreement with its capacities and taking into consideration the compromises established in international treatises and agreements in which the United Mexican States is a participant. In cases of severe or irreversible damage, the lack of absolute scientific certitude must not be the reason for deferring the adoption of effective measures as a function of the costs paid in preventing the degradation of the environment and biological diversity. Such measures will be adopted in conformity with the previsions and administrative procedures established in this Law;

V. The protection of human health, environment and biological diversity demand that attention is drawn to the control and handling of the possible risks derived from GMOs activities, by means of a previous assessment of such risks and the monitoring posterior to their release;

VI. The knowledge, opinions and experience of the scientists, particularly Mexican scientists, constitute a valuable element for guidance, so that the regulation and administration of GMOs activities are supported on studies and dictates having scientific foundations. Therefore, scientific research and technological development on biosafety and biotechnology must be encouraged;

VII. With regards to the confined use of GMOs with the following purposes: teaching, scientific and technological research, industrial and commercial, the

dispositions in this Law must be observed, as well as the rules and regulations and the Mexican official norms derived from it. Norms and prevention principles established by the institutions, centers or companies --public and private-- carrying out such activities must also be observed;

VIII. The possible risks that GMOs activities may entail to human health and biological diversity will be evaluated case by case. Such assessment must be supported by the best scientific and technical evidence available;

IX. The release of GMOs to the environment must be carried out “step by step”, that is, every GMO destined to be released commercially must be previously subject to satisfactory tests in agreement with risk studies, risk assessment and reports of results applicable to the undertaking of activities of experimental release and release within a pilot program of such organism, in the terms of this Law;

X. Adverse effects that GMO release may cause to biological diversity must be monitored, having also in mind the possible risks posed to human health;

XI. The administrative procedures to obtain licenses and authorizations for undertaking GMOs activities must be efficacious and transparent; the issuing of regulations and Mexican official norms derived from this Law must comply with the compromises established in international treatises and agreements in which the United Mexican States is a participant, in a way that their contents and capacities are compatible with such treatises and agreements;

XII. It is necessary to promote the technological development and scientific research on genetically modified organisms that may contribute to satisfy the needs of the Nation;

XIII. For the analysis of solutions to particular problems, the benefits and the possible risks originated by the use of GMOs will be assessed, case by case. This assessment may also include the evaluation of the risks from the alternative technological options to contend with the specific problem for which the GMO was designed. Such comparative analysis must be supported by scientific and technical evidence, as well as by the background dealing with use, production and consumption and may be an additional element together with the risk assessment study to decide, in a casuistic manner, the release to the environment of a determined GMO;

XIV. The appropriate capacity and normativity must be available to avoid the accidental release into the environment of GMOs coming as residues from any type of process in which such organisms have been involved;

XV. The application of this Law, the administrative processes and criteria for the evaluation of possible risks that the activities regulated by this Law must ensue, the instruments for controlling these activities, their monitoring, the regulations and Mexican official norms derived from this Law, inspection and surveillance procedures to verify and corroborate the compliance of this ordinance and of the dispositions derived from it, the implantation of security measures and those of urgent application, and the employment of sanctions for violations to the precepts of this Law and of the dispositions emanating from it, are the means by which the Mexican State acts in a cautious and prudent manner and based on scientific and technical foundations to prevent, reduce and avoid the possible risks that the activities with GMOs may originate to human health or to the environment and biological diversity;

XVI. The biosafety of products related to agriculture, livestock, fisheries and aquatic organisms is closely related to the health of plants, animals and aquatic organisms. Therefore, the adopted policy in these matters must comprise aspects related to the environment, biological diversity, as well as the health of humans, plants and animals;

XVII. The Mexican State will cooperate in the sphere where the exchange of information and investigation of the socio-economical effects of GMOs takes place, especially in indigenous and local communities;

XVIII. The Mexican State will guarantee the public access to the information regarding the biosafety and biotechnology referred to in this Law, in accordance with the issues established in this ordinance and with the dispositions applicable to the access to government public information, and

XIX. The experimentation with GMOs or any other organism with the purpose of elaboration and/or usage of biological weapons is prohibited in the national territory.

CHAPTER III
On the Competence in the Matter of Biosafety

ARTICLE 10.- The competent authorities in the matter of biosafety are the following:

I. SEMARNAT;

II. SAGARPA, and

III. SSA

The Secretary of Finance and Public Credit is endowed with the faculties established in this Law, in relation to the importation of GMOs and products containing them.

ARTICLE 11.- SEMARNAT plays the role of exercising the following faculties with respect to the activities with any type of GMO, unless determined GMOs corresponding to SAGARPA;

I. Participation in the formulation and enforcement of the general policy on biosafety;

II. Assessment and evaluation, case by case, of the possible risks that the activities with GMOs may cause to the environment and to biological diversity, based upon risk studies and reports of results elaborated and presented by the interested parties, in the terms of this Law;

III. Resolution and expedition of licenses for the undertaking of activities related to the release of GMOs to the environment, as well as to establish and ensure a follow-up of the conditions and measures that such activities must comply, in accordance to the dispositions of the present ordinance, including GMO release for bioremediation;

IV. Monitoring of the effects that the GMO release, permitted or accidental, may cause to the environment and to biological diversity, in accordance with the dispositions in this Law and the Mexican official norms derived from it;

V. Participation in the elaboration and expeditions of the lists referred to in this Law;

VI. Suspension of the effects of licenses, when scientific and technical information is available from which it can be deduced that the licensed activity poses higher risks to the ones foreseen, that may affect negatively the environment and biological diversity, or the health of humans, animals, plants or aquatic organisms. The two last suppositions must be expressly requested by the SAGARPA or SSA, according to its competence in this Law, and based on technical and scientific elements;

VII. Enact and enforce the pertinent security measures or measures of urgent applications, based on scientific and technical evidence, as well as on the precautionary approach, in the terms of this Law;

VIII. Inspection and surveillance of the fulfillment of this Law, its rules and regulations and the Mexican official norms derived from it;

IX. Imposition of administrative sanctions to persons violating the precepts of this Law, its rules and regulations and the Mexican official norms derived from it, without detriment, in a determined case, of the corresponding punishments when the acts or omissions result in crime, as well as the consequent civil and environmental responsibility, and

X. Other faculties that this Law confers to SEMARNAT.

ARTICLE 12.- It corresponds to SAGARPA the exercise of the faculties conferred to it by this Law when they concern activities with GMOs in the following cases:

I. Plants that are considered agricultural specimens, including seeds and any other organism or product considered within the realm of application of the Federal Law of Plant Health, with the exception of wild and forest specimens regulated by the General Law of Wild Life and the General Law for Sustainable Forestry Development, respectively, and those that lie within any protection regime by Mexican official norms derived from these laws;

II. Animals that are considered livestock and any other considered within the field of application of the Federal Law for Animal Health, with the exception of wild species regulated by the General Law for Wild Life and those that lie within any protection regime by Mexican official norms derived from these laws;

III. Phytozoosanitary raw materials, as well as for animal and plant nutrition;

IV. Fishing and aquatic related species, with the exception of those that lie within any protection regime by Mexican official norms;

V. GMOs that are used for immunization to protect and avoid the dissemination of animal diseases;

VI. GMOs that are fungi, bacteria, protozoans, virus, viroids, spiroplasms, phytoplasms, and other microorganisms, that have agricultural, livestock, aquatic or phytozoosanitary productive ends, and

VII. Additional organisms and products that are determined by the regulations of this Law.

ARTICLE 13.- In the cases established in the previous article, it corresponds to SAGARPA the exercise of the following attributions:

I. Participation in the formulation and application of the general policies of biosafety;

II. Assessment and evaluation, case by case, of the possible risks that the activities with GMOs could provoke to the health of animal, vegetable and aquatic

species, as well as to the environment and to the biological diversity, based on studies of risk and the report of results that are made and presented by the people interested, in the terms of this Law;

III. Resolutions and expedition of licenses for the realization of activities with GMOs, as well as to establishing and following up the conditions and measures that these activities must comply with in accordance to the dispositions of the present ordinance;

IV. Undertaking the monitoring of the effects that the permitted or accidental liberation of GMOs could cause to the health of animals, plants and aquatic species, and to the biological diversity, in conformity with the dispositions in this Law and the official Mexican norms that derive from it;

V. Participation in the elaboration and expedition of the lists referred in this Law;

VI. Suspension of licenses, when in possession of supervening scientific and technical information from which it may be asssumed that the permitted activity supposes risks superior to those foreseen, that can negatively affect the health of animals, plants or aquatic species, the biological diversity, or human health. These last two assumptions, at the express demand of SEMARNAT or the SSA, depending on their competence regarding this Law, with support of scientific and technical elements;

VII. Enactment and application of security measures or measures of urgent application, based on scientific and technical foundations and in a precautionary approach, in the terms of this Law;

VIII. Inspection and surveillance of the compliance of the present Law, its regulations and the official Mexican norms derived from it;

IX. Imposition of administrative sanctions to the persons infringing the precepts of this Law, its regulations and the official Mexican norms derived from it, without detriment, in its case, of the corresponding punishment when the acts or omissions resulting in infractions to this ordinance also constitute a crime, and of the civil responsibility that could result, and

X. Other attributions conferred by this Law.

ARTICLE 14.- In the cases that the knowledge, administrative procedures and resolution of a license application concerning wild and forestry species correspond to SEMARNAT, this institution must send the respective file to SAGARPA so the latter may manifest the corresponding opinion.

ARTICLE 15. In the cases in which SAGARPA has competence, SEMARNAT will be concerned with the following:

I. To issue the corresponding biosafety dictate, previous to the resolution of SAGARPA, as a result of an analysis and assessment of the risks based on the study undertaken and presented by the interested parties, in relation to the possible risks that the activity with GMOs may cause to the environment and to biological diversity, in cases dealing with the application of licenses for the experimental release of such organisms, or based on the reports of results and the adjunct information provided by the interested parties together with the license applications for the release within a pilot program and for commercial release;

II. To request SAGARPA the suspension of the effects of the licenses that such secretary issues, when available scientific and technical information suggests that

the permitted release may originate higher risks to the previously calculated that may affect negatively the environment and biological diversity, and

III. To exercise the faculties established in fractions I, II, IV, V, VII and VIII of Article 11 of this Law.

The biosafety dictate referred to in fraction I of this article will have a binding character, previous to the granting of the licenses whose issue corresponds to SAGARPA, and will come out in the terms of Article 66 of this Law.

ARTICLE 16.- It corresponds to SSA the exercise of the following faculties in relation to GMOs;

I. To participate in the formulation and application of the general policy on biosafety;

II. To evaluate, case by case, the studies carried out by the interested parties on the innocuousness and possible risks of GMOs subject to authorization in the terms of the Title Fifth of this Law;

III. To resolve and issue the authorizations of GMOs referred to in the previous fraction;

IV. To participate in the elaboration and issue of lists referred to in this Law;

V. To enact and enforce the pertinent security measures or those of urgent application, based on technical and scientific evidence, as well as with a precautionary approach, in the terms of this Law;

VI. To request SEMARNAT or SAGARPA, as is convenient, with support on technical and scientific elements, the suspension of the effects of the licenses related to release to the environment of GMOs, when the available information may suggest that the activity permitted by these Secretaries entails higher risks than the ones foreseen that may affect human health;

VII. To inspect and to watch the compliance of the present Law, its rules and regulations and the Mexican official norms;

VIII. To impose administrative sanctions to persons infringing the precepts of this Law, its rules and regulations and the Mexican official norms derived from it, without detriment, in a determined case, of the penalties corresponding to acts or omissions considered infractions to this ordinance also be constitutive of crime, and of the civil responsibility that may entail, and

IX. Other faculties that this Law confers.

The SSA will undertake surveillance actions --health and epidemiological—of GMOs and products containing them, as well as products derived from them, in conformity with the General Law of Health and its regulative dispositions.

ARTICLE 17.- In the case of accidental release of GMOs, the Secretaries will act in coordination so that, in the fields of their respective competences according to this Law, implement the necessary measures to avoid negative affectations to biological diversity, and health be it human, animal, plant and of aquatic organisms, whatever is the case.

ARTICLE 18.- The SHCP must exercise the following faculties with respect to the importation of GMOs and products containing them:

I. To examine in entry customs within the national territory that imported GMOs to be released to the environment or comprehended in the finalities established in Article 91 of this Law, comply with the respective license and/or authorization, according to each case, in the terms of this ordinance;

II. To examine that the documentation accompanying GMOs imported to this country, provide the identification requirements established in the Mexican official norms derived from this Law;

III. To participate, in a joint manner with the Secretaries, in the expedition of Mexican official norms concerning the storing or deposit of GMOs or products containing them in the customs precincts within the national territory;

IV. To notify immediately to SEMARNAT, SAGARPA and/or SSA on possible infractions to the precepts of this Law, in the matter of importation of GMOs, and

V. To refuse access into the national territory to GMOs or products containing them, in the cases in which such organisms or products lack a license and/or authorization, according to each case, for its importation, in agreement with this Law.

The SHCP will exert the previous faculties, without detriment of the ones conferred to this institution by the customs legislation, in relation to the importation of merchandises.

CHAPTER IV
On Coordination and Participation

ARTICLE 19.- The CIBIOGEM is an Inter-secretarial Commission that has the aim of formulating and coordinating the policies of the Federal Public Administration relative to the biosafety of GMOs. This institution will exert the functions established in the regulatory dispositions derived from this Law, in accordance with the following bases:

I. The CIBIOGEM will be integrated by the heads of the subsequent Secretaries: Agriculture, Livestock, Rural Development, Fisheries and Food; Environment and Natural Resources; Health; Public Education; Finance and Public Credit, and Economy, as well as by the General Director of CONCyT;

II. The Presidency of CIBIOGEM will rotate among the heads of the following Secretaries: Agriculture, Livestock, Rural Development, Fisheries and Food; Environment and Natural Resources, and Health. The presidency will have its exercise, functions an duration determined by the corresponding regulatory dispositions. It will have a Vice-presidency as well, whose head will be the General Director of CONACyT, who will preside the sessions in the absence of the President, will also assist the Commission and the Executive Secretary in their functions and will undertake activities that the CIBIOGEM commends to him in the terms established in the regulatory dispositions derived from the present Law;

III. The CIBIOGEM may ask other dependencies to participate, with voice, in the agreements and decisions concerning issues related to its object. It can also invite members of the Advisory Council;

IV. The CIBIOGEM will have an Executive Secretary appointed by the President of the Republic, nominated by the General Director of CONACyT and approved by the CIBIOGEM. His attributions and faculties will be determined in the regulatory dispositions derived from this ordinance. He will execute and see the fulfillment of the agreements of the proper Commission and will carry out other functions commended to him.

V. The Executive Secretary of CIBIOGEM will exhibit an organic structure approved in the terms of the applicable dispositions and will be considered an administrative unit as function of CONACyT, and in conformity with the Organic Law of this latter parastatal entity, and

VI. The CIBIOGEM will include a Technical Committee integrated by the coordinators, general directors or their equivalences competent in the matter appointed by the heads of the dependencies and entities conforming the CIBIOGEM. Such Committee may propound the creation of specialized sub-committees to deal with specific issues and will have the attributions determined by the regulatory dispositions derived from this Law.

ARTICLE 20.- The Scientific Advisory Council of CIBIOGEM is created. It will be a compulsory consultation organ of the CIBIOGEM itself to deal with technical and scientific aspects in modern biotechnology and biosafety of GMOs, It will be integrated by a group of experts in various disciplines, members of centers, research institutions, academies and scientific societies of renowned prestige. They will act in a personal manner, independent of the institution, association or company to which they belong or in which they work. These experts will expressly manifest in a commitment letter, at the moment of their designation as members of the Scientific Advisory Council, not to have any conflict of interests.

The selection of the members to the Scientific Advisory Council will be made through a public convocation issued jointly by CONACyT and the Technological and Scientific Advisory Forum foreseen in the Law of Science and Technology. Among the functions of the Advisory Committee are the formulation of scientific protocols, analyses and methodologies, and technical dictates, liable to remuneration. The specific functions of the Advisory Council and the mechanisms for the renewal of its members so that this is done in a progressive and escalating manner will be established in the regulatory dispositions derived from this Law. The technical dictates issued by the Scientific Advisory Council must be taken into consideration by the CIBIOGEM when adopting decisions.

ARTICLE 21.- The Mixed Advisory Council of the CIBIOGEM is created. It will be an auxiliary organ for advice and opinion of CIBIOGEM itself. It will be integrated by representatives of associations, chambers or companies of the private, social and productive sectors. Its fundamental function will be to know and express an opinion on social and economical aspects, as well as issues relative to regulatory and promotion policies. It will also express its views on the priorities of normalization and improvement of administrative procedures and legal proceedings in the matter of biosafety of GMOs. The specific functions of the Mixed Advisory Council of CIBIOGEM and the mechanisms for the incorporation of its members will be established by CIBIOGEM.

ARTICLE 22.- The CIBIOGEM will issue its rules of operation establishing the mechanisms of participation so that members and representatives of the academic, scientific, technological, social and productive sectors with renowned prestige and experience in subjects related directly to activities matter of this Law, can contribute via opinions, studies and consultations concerning the understanding and evolution of the policies on biosafety and promotion of the research on biosafety and biotechnology, as well as to collect opinions, studies and consultations related to such matters.

ARTICLE 23.- CONACyT will include in its budget the necessary resources for the development of the activities of the CIBIOGEM, Executive Secretary and the Scientific Advisory Council, in agreement with the assignations authorized in the terms of the applicable dispositions. Such assignations will be administrated and exercised by the Executive Secretary of the CIBIOGEM.

The programs, projects, financial supports, as well as other actions undertaken in the implementation of the present law and other dispositions in the matter, in which economic resources of Federal origin must be exercised, will be subject to the availability of resources assigned for this purpose in the Federal Expenses Budget of the corresponding annual income, and they must comply with the applicable dispositions in revenue matters.

ARTICLE 24.- The Secretaries may establish technical and scientific committees to provide them with support in the resolution of files concerning license applications and authorizations, as well as notifications. The regulative dispositions of this Law will determine the foundations for the organization and functioning of such committees.

CHAPTER V
On the Coordination with the Federative Entities

ARTICLE 25.- The Federation, by means of the Secretaries in their realm of competence and in the terms of the applicable dispositions, and CIBIOGEM been informed, may celebrate treatises or coordination agreements with the governments of the federative entities, with the following aims:

I**.** To establish a concurrent collaboration for the monitoring of the risks caused the activities related to the release of GMOs to the environment may cause, be it experimental release or within a pilot program, that are determined in such treatises or agreements, and

II. In its case, to undertake surveillance actions to comply with the dispositions of this Law.

ARTICLE 26.- The treatises or coordination agreements subscribed between the Federation and the governments of the federative entities for the purposes referred to in the previous article, must conform to the applicable dispositions and to the following bases:

I. The matters and activities constituting the object of the treatise or agreement must be defined with precision;

II. The aims of the treatises or agreements must be congruent with the policy in the matter of biosafety;

III. The assets and resources that each part contributes must be described, making clear their specific destination and its form of administration, to achieve the former, the Federation will contribute by strengthening the financial capacities and institutions;

IV. The necessary means, procedures and resources contributed by the competent Secretaries will be determined, so that the governments of the federative entities carry out the actions and activities matter of the treatises and coordination agreements;

V. The time interval in which the treatise or agreement is in force will be specified, as well as the forms of completion and solution of controversies, and in its case, its renewal;

VI. The definition of the organ or organs that must undertake the actions resulting from the treatises or coordination agreements;

VII. The determination of the actions for promoting and participating jointly in the support of scientific and technological research on biosafety and biotechnology;

VIII. The establishment of the obligation of presenting detailed reports on the compliance of the object of the treatises and coordination agreements, and

IX. Other stipulations that the interested parties consider necessary for the correct compliance of the treatise or agreement must be enclosed.

The agreements this article makes reference must be published in the Federal Official Gazette and in the official diffusion organ of the respective local government.

ARTICLE 27.- The governments of the federative entities will have access to the information inscribed in the National Registry on Biosafety of Genetically Modified Organisms. Likewise, the CIBIOGEM, by means of its Executive Secretary, will notify the applications for the licenses of commercial release of GMOs to the environment to the governments of the federative entities where such activity will take place, so that they have knowledge of the situation and may manifest an opinion in the terms of this Law. The notification must be issued within the 20 days following the reception of the corresponding application license by the CIBIOGEM for its inscription in the Registry.

CHAPTER VI
On the Promotion of Scientific and Technological Research on Biosafety and Biotechnology

ARTICLE 28.- The Federal Executive will promote, support and strengthen the scientific and technological research in the matter of biosafety and biotechnology through policies and instruments established in this Law and in the Law of Science and Technology. In the matter of biotechnology, this support will be oriented to encourage projects of research and development and innovation, training of specialized human resources, and strengthening of groups and infrastructure in universities and institutions of higher education and public research centers. These projects must solve specific productive needs of the country and must benefit directly national producers.

In the matter of biosafety, research will be promoted to gain sufficient understanding to allow the assessment of possible risks GMOs may cause to the environment, biological diversity and health of humans, animals, plants and aquatic organisms. The research in this matter will also create the socioeconomic considerations of the effects of such organisms in the preservation and utilization of the biological diversity, and to assess and verify the information provided by the interested persons. Likewise, an impulse will be given to create human, institutional and related to infrastructure capacities to assess and monitor risks.

ARTICLE 29.- To achieve the fostering of scientific and technological research in the matter of biosafety and biotechnology a program for the development of biosafety and biotechnology will be established. CONACyT will be in charge of the formulation of this program based on the proposals presented by the Secretaries and the other dependencies and entities of the Federal Public Administration that support or undertake scientific research and technological development. In such process the opinions and proposals from the scientific, academic, and technological communities, as well as from the productive sector will be taken into consideration, and will be convened by the Scientific Advisory Forum and by the CIBIOGEM.

Such program will be a part of the Special Program of Science and Technology established in the Law of Science and Technology.

ARTICLE 30.- The program for the development of biosafety and biotechnology must comprise, at least, diagnoses, policies, strategies and general and sectorial actions related to:

I. Scientific research;

II. Technological innovation and development;

III. Training of researchers, technologists and high level professionals;

IV. Support to public research centers;

V. Scientific research projects, as well as innovation and technological development projects oriented to solving national problems and dealing with activities that will yield benefits to national producers related to agriculture, livestock, forestry and aquatic organisms.

VI: New centers of research and technological transference in fundamental areas of national development, in accordance with local and regional necessities of preservation and protection of the environment, or of production related to rustic crops, agriculture, livestock, and industry;

VII. Dissemination of scientific and technological knowledge;

VIII. National and international collaboration;

IX. Strengthening of a culture in biosafety, and

X. Decentralization and regional development.

The Federal Executive, by means of the competent Secretaries, will ensure that the seed companies belonging to peasant and producer organizations have at their disposal, in a preferential and accessible manner, the results of the scientific and innovative research as well as the technological development comprised in the Program for the development of biosafety and biotechnology.

ARTICLE 31.- CONACyT will constitute the Fund for the Promotion and Support of the Scientific and Technological Research on Biosafety and Biotechnology in accordance with the Law of Science and Technology. This fund will receive all revenue resources contributed by the dependencies and entities for this purpose, as well as third person resources and earnings derived by from rights determined by the revenue dispositions, derived from actions undertaken in application of this Law.

SECOND TITLE
On Licenses

CHAPTER I
Common Dispositions

ARTICLE 32.- A license will de required for the undertaking of the following activities:

I. Experimental release to the environment, including the importation of one or more GMOs to carry this activity;

II. Release to the environment within a pilot a program, including the importation of GMOs to carry this activity, and

III. Commercial release to the environment, including the importation of GMOs to carry this activity.

ARTICLE 33.- Once the corresponding Secretaries receive a license application to release GMOs to the environment, provided it complies with the information and requirements established in this Law, must send it to the Registry for its respective inscription and publicity. Once the former has been done, the Secretary to which the resolution of the license application for the release of GMOs to the environment corresponds, will make the application available to the public, for consultation, and must obey the preventive measures on confidentiality established by this Law. Such Secretary may use any convenient means to make available to the public the respective license application.

Any person, including the governments of the federative entities where the respective release is supposed to take place, can manifest an opinion, supported technically and scientifically, in a period no longer than 20 lawful days starting on the date the respective application is available to the public in the terms of this article.

The manifestation of opinions, in conformity with the previous paragraph, will be taken into consideration by the corresponding Secretaries for the establishment of additional biosafety measures, in case that the license expedition for GMO release to the correspondent environment is issued, in the terms of this Law.

ARTICLE 34.- The corresponding Secretary will issue its resolution, properly founded and motivated, once the information and documentation provided by the interested person is analyzed, as well as the dictate or the opinion manifested by the Secretaries having this capacity in conformity with this Law and, when it proceeds, the authorization of the GMO issued by the SSA in the terms of this ordinance. The corresponding Secretary can in its resolution do the following:

I. Issue the license to undertake the activity of the corresponding release to the environment, and may establish monitoring, control, prevention and security measures additional to the ones propounded by the interested person in the application license, or

II. Deny the license in the following cases, when:

A) The application does not comply with the requirements established in this Law or in the Mexican official norms for the granting of the license;

B) The information provided by the interested person, including the relative to the possible risks that the GMO may cause is false, incomplete or insufficient, or

C) The corresponding Secretary reaches the conclusion that the risks of determined GMOs will affect in a negative manner human health or biological diversity, or the health of animals, plants or aquatic organisms, causing them severe or irreversible damage.

ARTICLE 35.- The terms established by this Law for the resolution of a license application to release GMOs to the environment, be it experimental or within a pilot program, will be capable of extension, in the case the interested person lacks the authorization issued by the SSA in the terms of this ordinance, provided such authorization be a requirement for the issuing of the respective license.

ARTICLE 36.- The licenses for the experimental release of GMOs to the environment, within a pilot program or commercially, will have the effects of importation licenses of such organisms to be released in experimental form, within a pilot program or commercially, depending on the case, in the terms and conditions established in the licenses themselves. The former, without detriment that the importation of the determined GMOs must be subject to the phytosanitary or aquatic related regime established in the legislation of the corresponding matter.

ARTICLE 37.- Monitoring, prevention, control and security measures of the possible risks in the utilization of a GMO that the corresponding Secretary establishes in the license, may comprise, among others, the following aspects:

I. GMO handling;

II. Security measures so that the possible risk is maintained within the limits of tolerance accepted in the assessment, and

III. Monitoring of the corresponding activity, in relation to the possible risks such activity may originate.

ARTICLE 38.- The Secretary issuing the license may modify the monitoring, control and prevention measures, request the interested person the implementation of new measures, as well as to interrupt or cancel such license, granting previously an audience with the interested persons, when it has scientific or technical information available from which it may be concluded that the activity may imply higher or lower risks than those foreseen originally in the corresponding studies. The former must be established in the licenses issued by the competent Secretaries.

ARTICLE 39.- The holder of the license is compelled to obey and comply the monitoring, prevention, control and security measures established in the license, as well as the dispositions of this ordinance, its rules and regulations and the Mexican official norms derived from it, that are applicable to the determined release. Non-compliance of the measures and dispositions referred to in this article, will originate a determination of the respective responsibility and the application of the corresponding sanctions in agreement with this Law.

ARTICLE 40.- The importation of GMOs or products containing them is not allowed in the cases that such organisms are prohibited in the country of origin, or are classified in the lists as not allowed for their commercial release or importation for such activity.

ARTICLE 41.- It is forbidden to undertake activities with GMOs or any other organism whose end-product be the fabrication and/or utilization of biological weapons.

CHAPTER II
Requirements to obtain licenses

SECTION I
Licenses for the experimental release to the environment

ARTICLE 42.- License applications for the experimental release of GMOs to the environment, including their importation for this activity, must be accompanied by the following information:

I. Characterization of the GMO, in which it must be considered what is established in the official Mexican norms derived from this Law for each case;

II. Identification of the zone where GMOs are to be experimentally released, including the specifications about the total area in which the release will take place:

III. A study of the possible risks that the release of GMOs could have on the environment and on the biological diversity. Furthermore, in those cases in which SAGARPA has competence, the study must include possible risks that the liberation of such organisms could cause to the health of animals, plants or aquatic organisms;

IV. The measures and procedures for monitoring the activity and biosafety that will be carried out when the activity takes place and those after the release;

V. In its case, the preceding GMO release information from other countries;

VI. In its case, the considerations, concerning the risks of available alternative technologies to treat the problem for which the genetically modified organism to be released was built, will be presented, and

VII. The information determined, for each case, by the Mexican official norms derived from this Law.

It is a requirement to get a license for experimental release to the environment to have the GMO authorization issued by SSA in accordance with this Law, when such organism is destined for public health purposes or for bioremediation. The interested person may start the procedures to obtain such license from the competent Secretary, but it will not be issued until it is proved in the respective file the authorization granted by SSA.

ARTICLE 43.- Besides what is established in the previous article, the persons interested in the importation of GMOs for their experimental release into the environment, must enclose with their application the information and documentation granting that the GMO is permitted under the legislation of the country of origin, at least for its release in an experimental stage, enclosing for such effects the authorization or official documentation that supports such situation.

ARTICLE 44.- The resolution to a license application for the experimental release of GMOs must be issued in a maximum term of six months starting the following day that the Secretary issuing the resolution receives the application, and given that the information is complete.

ARTICLE 45.- In the case that, after the granting of a license, at the time of the experimental release of an GMO to the environment, one of the following situations is present:

I. Any modification is produced in the release that may increase of diminish the possible risks to the environment and biological diversity, or

II. New scientific and technical information becomes available about such risks.

In these cases, the holder of the license is obliged to:

A. Inform immediately to the corresponding Secretary of such situation;

B. Revise the monitoring and biosafety measures specified in the documentation, and

C. Adopt the necessary biosafety measures.

ARTICLE 46.- The holder of the license for experimental release to the environment, must inform to the Secretary issuing it, by means of a report, the results of the release or releases performed in relation to the possible risks to the environment and biological diversity. The characteristics and contents of the report to which this article refers to will be established in the Mexican official norms derived from this Law.

ARTICLE 47.- The holder of the license is obliged to inform immediately to the corresponding Secretary, of any situation that in the licensed release could increase or diminish the possible risks to the environment, the biological diversity and/or human health.

ARTICLE 48.- The corresponding Secretary may limit the effect of the license for the experimental release to the environment considering the elements in the file.

ARTICLE 49.- The experimental release of GMOs to the environment will be performed under the protection and according to the terms and conditions established in the license. In the case that such license includes various releases of the same GMO in the same geographical area established in the license, in the license itself a notification requirement for each release may be stipulated.

SECTION II

License for the release to the environment within a pilot program

ARTICLE 50.- The application of a license to carry out the release of a GMO to the environment within a pilot program, including its importation for this activity, must be accompanied by the following information:

I. The license for the experimental release of a determined GMO;

II. Reference and considerations on the report of the results of the experimental release or releases in relation to the possible risks to the environment and biological diversity, and additionally, to the health of animals, plants and aquatic organisms in the cases in which SAGARPA is the competent institution in accordance with this Law;

III. Information relative to the following:

A) The total amount of GMO to be released;

B) Handling conditions given to the GMO, and

C) Identification of the zones where the GMO is to be released, including a specification of the area or total areas where the release will take place.

IV. Monitoring and biosafety measures to be undertaken during and posterior to the release of such activity, and

V. The information that for each case is determined by the Mexican official norms derived from this Law.

The former is with the purpose that the corresponding Secretaries have available the information allowing them the analysis and assessment of the possible risks to the environment and biological diversity, or to the health of animals, plants or aquatic organisms, just as it corresponds in agreement with this Law.

It will be a requirement to obtaining the license for the release to the environment within a pilot program that the applicant has the authorization of the SSA for the determined GMO in accordance with this Law, when such organism is to be for human use or consumption. The interested person could start the administrative procedures to obtain such license in the competent Secretary, but this will not be granted until the person gives proof of the authorization from the SSA in the respective file.

ARTICLE 51.- The interested persons in the importation of GMOs to be released to the environment within a pilot program, besides the conditions established in the previous article, must enclose with their application the information and documentation proving that the GMO is authorized in agreement with the legislation of the country of origin, at least for its release in this type of stage, enclosing for these effects the authorization and official documentation supporting this situation.

ARTICLE 52.- The resolution to a license application for the release of GMOs to the environment within a pilot program must be issued in a maximum term of three months starting on the following day the Secretary in charge of the resolution has received the license application and the information enclosed by the interested person is complete.

The validity of the license will be determined by taking into consideration the elements in the file.

ARTICLE 53.- The holder of the license to release to the environment within a pilot a program must inform, in a report, to the Secretary issuing the license, the results of the release or releases in relation to the possible risks to the environment and biological diversity. The characteristics and contents of the report referred in this article will be established in the Mexican official norms derived from this Law.

ARTICLE 54- The holder of the license will be obliged to inform immediately to the corresponding Secretary, of any situation in which the undertaking of the authorized release may increment or diminish the possible risks to the environment, biological diversity and/or human health.

SECTION III
Licenses for the commercial release to the environment

ARTICLE 55.- The license application to undertake the commercial release of GMOs to the environment, including its importation for this activity, must be accompanied by the following information:

I. The licenses for the releases, experimental and within a pilot program, of the determined GMO;

II. The reference and considerations on the reports with the results of the experimental release and release in a pilot program that had been carried out, in the terms of the licenses referred in the former fraction;

III. Specific instructions and recommendations for the storage, transport, and in its case, handling;

IV. In its case, the conditions for its release and trading;

V. In its case, the presentation of the considerations on the risks of the available alternative technologies to contend with a problem for which the GMO to be released was designed;

VI. In its case, the information the solicitant has available on data or results related to the trading of the determined GMO in other countries, and

VII. The additional information determined by the Mexican official norms derived from this Law.

The former with the aim that the corresponding Secretaries have the information available to perform the analysis and assessment of the possible risks to the environment and biological diversity or to the health of animals, plants and aquatic organisms, as the case may be according to this Law.

ARTICLE 56.- The interested persons in the importation of GMOs for commercial release, besides what is established in the previous article, must enclose the information and documentation proving that the GMO is authorized for its trading in accordance with the legislation of the country of origin, and for this matter must include the authorization or official documentation supporting this situation.

ARTICLE 57.- The resolution of the license application for the commercial release to the environment must be issued in the term of four months starting on the following day the Secretary making the resolution receives the license application, and the information provided by the interested person is complete.

ARTICLE 58.- The activities and importations subsequent to the license of commercial release to the environment will be carried out in accordance with the terms and conditions established in the license, and without requiring further licenses. It is understood that the subsequent importations are carried out in the same terms and conditions established in the respective license for commercial release, when the same GMO is involved, and the release area is unchanged. The former is independent from the monitoring, liability to inspection and surveillanceactionc these activities and importations may have, in the terms of this Law.

ARTICLE 59.- The license for the commercial release to the environment of a determined GMO, underlies the authorization for trading such organism and the products containing it, in the terms of this Law.

CHAPTER III
Study and assessment of risks

ARTICLE 60.- The assessment of risks is a process in which , case by case, and based on studies, supported scientifically and technically, carried out by the

interested persons, the possible risks or effects of the experimental release of GMOs to the environment may cause to the latter and to the biological diversity, as well as to the health of animals, plants and aquatic organisms.

The possible risks to human health will be the matter of risk studies to obtain the authorization of a determined GMO, in the terms of this Law.

ARTICLE 61.- To undertake the study and assessment of the risks, the following guidelines must be complied:

I. They must be done case by case, in a transparent manner and based on scientific principles and with a precautionary approach, in the terms of this Law, taking into consideration the counseling of experts;

II. They will be undertaken in the relevant fields of specialization;

III. The lack of knowledge or scientific consensus will not be necessarily interpreted as indicator of a determined level of risk, absence of risk, or the existence of an acceptable risk;

IV. They must have as a minimum layer the possible risks that might be imposed by the release of genetically unmodified host organisms or of parental organisms, if they were to be released in that environment;

V. The receptor organism, genetic modification –including the genetic construction and the insertion method--, and the environment into which the GMO will be released must be taken into consideration, and

VI. The nature and the degree of detail of the information they contain may vary from one case to the other, depending on the determined GMO, its predetermined use, and the probable receptor environment.

ARTICLE 62.- The basic stages to follow for the study and the assessment of risks are the following:

I. The identification of new characteristics associated with the GMO that may exert possible risks in the biological diversity;

II. The assessment that these possible risks may actually occur, considering the level and the type of exposition of the GMO;

III. The assessment of the consequences in the case that the possible risks actually happened;

IV. The estimate of a global possible risk the GMO might represent, based on the evaluation of the probability that the possible risks and the identified consequences actually happen, and

V. The recommendation whether the possible risks are acceptable or may be handled, or not, including the determination of the strategies for the handling those possible risks.

ARTICLE 63.- When there is uncertainty in relation to the level of possible risks GMOs may cause to the biological diversity, the corresponding Secretaries will require, within the administrative procedure to obtain a license for the activity of releasing a determined GMO to the environment, additional information on concrete matters in relation to the risk study, or they will adopt appropriate strategies for the handling of the risk and/or monitoring of the GMO in the receptor environment.

In case of imminent danger causing serious or irreversible damage, the uncertainty associated with the level of the possible risks the GMOs may cause to biological diversity or to human health, will not be used as a reason for the

corresponding Secretary to delay the adoption of efficacious security measures that hinder the negative affectation to the biological diversity or human health. In the adoption of these measures, the corresponding Secretary will take into consideration the available scientific evidence to lay a foundation or criterion for the establishment not only of the measure or measures, but also of the administrative procedures established in this Law, and the commercial normativity comprised in international treatises and agreements that the United Mexican States have subscribed.

ARTICLE 64.- The interested person may present additional to the study of possible risks, other studies or considerations not only analyzing the GMO contribution to the solution of environmental, social, productive or other problems, but also the existent socio-economical considerations with respect to GMOs release to the environment, as well as an assessment of the risks of the alternative technological options to deal with the specific problem for which the GMO was designed. These analyses must be supported by technical and scientific evidence, the antecedent related to its use, production and consumption, and may be considered by the competent Secretaries as additional elements to be considered in the decision concerning the experimental release to the environment, and the subsequent releases of a determined GMO to the environment be it within a pilot program or commercially, respectively.

ARTICLE 65.- The characteristics and requirements of the assessment studies of the possible risks will be established in the Mexican official norms derived from this Law.

CHAPTER IV
On Dictates

ARTICLE 66.- The dictates issued by SEMARNAT will be solely required when dealing with GMO activities related to experimental release, release within a pilot program or commercial release which are in the competence of SAGARPA. Such dictates must be issued in a 60 day term starting on the day the SEMARNAT receives the administrative file remitted by SAGARPA. Such period comprises the issuing of the corresponding dictate, as well as its remission to SAGARPA. SAGARPA will issue the license for the GMO release to the corresponding environment, provided that SEMARNAT issues a favorable dictate.

CHAPTER V
On the Reconsideration of Negative Resolutions

ARTICLE 67.- The interested persons to whom the corresponding Secretary has denied a license, may ask such Secretary for a reconsideration of the respective resolution, when it is considered the following:

I. A modification of the circumstances has occurred that may influence the results of the studies on possible risks in which the resolution was based upon, or

II. New pertinent scientific or technical information is available from which one may infer that the identified possible risks are not the ones originally foreseen.

The competent Secretary may issue a resolution within the next two months. In case of not doing so, the reconsideration must be taken as rejected.

ARTICLE 68.- The reconsideration referred to in the previous article does not constitute any resource or means of defense, and may be promoted by the interested persons independently that they assert the resource of impugnation established in this Law against the resolution affecting them.

CHAPTER VI
On the Revision of Licenses

ARTICLE 69.- The corresponding Secretary, at any moment and based on new technical or scientific information concerning the possible risks that GMOs may cause to public health or to the environment and biological diversity, may revise the granted licenses, and in its case, withdraw its effects or revoke such licenses, in accordance with the procedures established in the regulatory dispositions derived from this Law, and when the following causes may be present:

I. A modification in the circumstances of the activities that may influence the results of the assessment study of the possible risks in which the license was based upon, or

II. Additional technical or scientific information is available that may modify any of the conditions, limitations or license requirements.

CHAPTER VII
Confidentiality

ARTICLE 70.- The interested persons may state clearly in the license application the information that must be considered confidential in accordance with the regime of industrial property or copyright. The correspondent Secretary will subject itself to what is established in the laws in the matter and will refrain to register or facilitate the information to third persons, as well as the data protected under such laws.

ARTICLE 71.- The following information will not be considered confidential:

I. The general description of the GMOs;

II. The identification of the interested person or the person responsible for the activity;

III. The aim and the place or places of the activity;

IV. The systems and measures concerning biosafety, monitoring, control and emergency, and

V. The studies on the possible risks to human health or to the environment and biological diversity.

The access to information referred to in the previous fractions will be ruled, in addition, by the applicable dispositions in the matter of access to government public information.

CHAPTER VIII
Exportation of GMOs destined to be released to the environment in other countries

ARTICLE 72.- The interested persons in exporting GMOs to be released to the environment in other countries will notify per se, in accordance to what is determined in the regulatory dispositions derived from this Law, their intention to export such organisms to the competent authorities of the respective country. Such notification will take place only in the cases in which the international treatises and agreements subscribed by the United Mexican States establish this requirement for the exportation to the respective country. The information enclosed, by the interested person, to the notification referred to in this article, must be accurate, creditable and adjusted to the dispositions established in such international treatises and agreements.

THIRD TITLE
On the Confined Utilization and Notifications

CHAPTER I
Confined Utilization

ARTICLE 73.- The confined utilization of GMOs may have the following purposes: teaching, scientific and technological research, industrial and trading.

ARTICLE 74.- The persons undertaking activities of confined utilization subject to the requirement of presentation of notification in the terms of this Law, must comply with the following:

I. To keep a notebook registering the activities of confined usage; this notebook must be provided to the corresponding Secretaries when they solicit it;

II. To apply the confinement measures whose execution must be adapted to the most recent and advanced scientific and technical understanding in the matter of handling of risks, treatment, final disposal and elimination of GMO residues originated in the undertaking of the activity, and

III. In the case of confined usage for teaching purposes or for scientific and technological research an internal biosafety commission must be integrated, as well as the application of sound practices of scientific research and the fulfillment of biosafety rules defined by the internal biosafety commission. The latter will be in charge of the security of the facilities and of the good practices and security in the handling of GMOs used for the determined activity.

The Mexican official norms derived from this Law will establish:

A) The requirements and general characteristics included in the registry notebook referred to in this article, for every type of activity;

B) The requirements and the characteristics relative to GMO confinement, treatment, final disposal, destruction and residue elimination;

C) Handling conditions required for each form of confined utilization of such organisms, and

D) Actions to be undertaken in the case of an accidental GMO release.

ARTICLE 75.- The storage or deposit of GMOs or products containing them, carried out in customs precincts within the national territory will be subject to the dispositions of the respective Mexican official norms issued jointly by the competent Secretaries, with the participation of the SHCP.

ARTICLE 76.- The transport of GMOS or products containing them, as well as the transit of such organisms and products in the national territory, when their final destination is another country, will be regulated by the Mexican official norms issued jointly by the competent Secretaries, with the participation of the Secretary of Communications and Transport.

CHAPTER II
On notifications

ARTICLE 77.- The notification is the communication presented in official format that the subjects named in this Law must present to the SEMARNAT or SAGARPA, whichever is convenient in accordance with this ordinance, related to the confined utilization of GMOs in the cases established in this chapter.

ARTICLE 78.- The notifications must be presented to SEMARNAT or SAGARPA, in accordance to the attributions bestowed to them by this Law, in the official formats issued for this effect. The contents of the formats will be determined by such Secretaries, with the previous approval of the Federal Commission for Regulatory Improvement. In such formats the information and documentation the interested person must present will be determined. The formats must be published in the Federal Official Gazette.

ARTICLE 79.- The following require a presentation of notification:

I. GMOs handled, originated and produced for teaching purposes or for scientific and technological research;

II. The integration of the internal biosafety commissions, including the name of the person or persons responsible of such commissions;

III. The first time a laboratory or facility is used for teaching or for scientific and technological research in which GMOs are handled, originated or produced;

IV. The production of GMOs for industrial processes, and

V. The first time specific facilities are used for the GMO production referred to in the previous fraction.

ARTICLE 80.- It also requires the presentation of a notification the importation of GMOs to be used in a confined way for industrial or commercial purposes, solely when the following suppositions are assembled:

I. GMOS not requiring a license, given that they will be exclusively used in a confined manner, and therefore, are not imported to be released to the environment, and

II. GMOs not requiring sanitary authorization given that they will not be for human use or consumption of for public health aims.

ARTICLE 81.- The subjects who must present to the corresponding Secretary the respective notification are the following:

I. In the cases referred to in fractions I, II and III, Article 79, the person responsible for the internal biosafety commission of the institution, center or company where the teaching, scientific and technological research activities are undertaken, in which a determined GMO is produced and originated;

II. In the cases referred to in fraction IV and V, Article 79, the legal representative of the company where the determined GMOs are produced, and

III. In the case referred to in the previous article, the GMO importer.

ARTICLE 82.- It is exempted from the presentation of a notification the confined used or the importation for this activity, in the case that the determined GMO is exempted of such requirement in the lists issued by the Secretaries in accordance with this Law.

ARTICLE 83.- The confined utilization of GMOs and the importation of such organisms for this activity may be carried out starting when the internal commission of biosafety or the importer, as the case may be, presents the respective notification to the corresponding Secretary.

ARTICLE 84.- Once the notification is presented, the corresponding Secretary may determine, in a specific case, and based upon scientific and technical evidence that:

I. In consideration of the genetically modified organism and the possible risks involved in its handling, the activity must be cancelled;

II. According to the situation, it can resolve that the confined utilization requires the adoption and implementation of additional biosafety measures to the ones stated by the interested person in the notification. These measures will be determined by the corresponding Secretary, and must be fulfilled and complied with by the interested person to continue with the activity, or

III. The prohibition of the confined utilization of a determined genetically modified organism or its importation for this activity.

The determined resolution may be impugned through the appeal resource established in the present ordinance.

ARTICLE 85.- The persons, whose activity of confined release are required of the presentation of a notification, are compelled to fulfill and comply with the other dispositions in the present ordinance and in the Mexican official norms derived from it, whenever it is applicable.

FOURTH TITLE
Restricted Zones

CHAPTER I
Centers of origin and of genetic diversity

ARTICLE 86.- The species for which the United Mexican States are center of origin and of genetic diversity, as well as the geographical areas where they are located, will be jointly determined by agreements subscribed by the SEMARNAT and SAGARPA, based on the information found in their archives or in their data

bases, including those provided, among others, by the National Institute of Statistics, Geography and Informatics; National Institute of Research on Forestry, Agriculture and Livestock; National Institute of Ecology; National Commission for the Understanding and Use of Biodiversity, and National Forestry Commission, as well as the agreements and international treatises relative to these matters. The SEMARNT and SAGARPA will establish in the agreements they issue, the necessary measures for the protection of such species and geographical areas.

ARTICLE 87.- To determine the centers of origin and of genetic diversity, the following criteria will be taken into consideration:

I. Centers of genetic diversity must be considered those regions that currently lodge populations of wild relatives of the determined GMO, including different breeds or varieties, which constitute a genetic reservoir of this material, and

II. In the case of crops, the geographical regions in which the determined organism was domesticated provided these regions are centers of genetic diversity.

ARTICLE 88.- In the centers of origin and of genetic diversity of animal and plant species, the release of GMOs will be only allowed, when these GMOs are different from the native species, as long as their release does not cause any negative affectation to human health or to biological diversity.

CHAPTER II
On the Activities with GMOs in Natural Protected Areas

ARTICLE 89.- In the natural protected areas created in accordance with the dispositions in the matter, solely GMO activities with the purpose of bioremediation will be allowed, in the cases of the presence of plagues or contaminants jeopardizing the existence of animal, plant or aquatic species, and the GMOs were created to avoid or attack such situation, as long as the necessary scientific and technological elements are available giving support to the environmental benefit that is expected, and when these activities are authorized by SEMARNAT in the terms of this Law.

For the effects of the matter disposed in the previous paragraph, it is forbidden to undertake activities with GMOs in the nucleus of the zones of the natural protected areas.

In the case that some center of origin or of diversity is located in a natural protected area, the declaratory of creation and the handling programs of such areas will be modified in the terms of the legislation in this matter, in accordance with the fulfillment of the determinations referred to in Article 86 of the present Law.

CHAPTER III
Zones Free of GMOs

ARTICLE 90.- Zones free of GMOs may be established for the protection of organic agricultural products and others of interest to the soliciting community, in agreement with the following general guidelines:

I. The free zones will be established when GMOs of the same species to the ones resulting from production processes yielding organic agricultural products coincide, and when it is scientifically and technically demonstrated that their coexistence is not viable or that they would not comply with the normative requirements for their certification;

II. Such zones will be determined by SAGARPA by means of agreements to be published in the Federal Official Gazette, with a previous dictate from CIBIOGEM, and the opinion of the National Commission for the Understanding and Utilization of Biodiversity, taking into consideration what is established in the Mexican official norms relative to organic agricultural products;

III. The determination of free zones will be carried out based on the following requirements:

a) A written application must be elaborated by the interested communities, through a legal representative;

b) Such application must be accompanied by a favorable opinion of the governments of the federal entities and the municipal governments of the places or regions to be determined as free zones, and

c) Evaluations must be undertaken in relation to the effects that GMOs may cause to production processes of organic agricultural products or to biodiversity. These evaluations must demonstrate, scientifically and technically, that their coexistence is not viable or that they do not comply with the normative requirements for their certification, in accordance to the Mexican official norms issued by SAGARPA. These aforementioned assessments will be carried out in agreement with the Mexican official norms established by this Secretary.

IV. The SAGARPA will establish in the agreements the security measures to be adopted in the zones free of GMOs to guarantee the adequate protection to organic agricultural products.

FIFTH TITLE
On the Protection of Human Heath in relation to GMOs

CHAPTER I
On GMO Authorizations

ARTICLE 91.- GMOs subject to authorization are the following:

I. Those destined for human utilization or consumption, including grains;

II. Those destined for the processing of foods for human consumption;

III. Those having a public health aim, and

IV. Those destined for bioremediation.

For the effects of this Law, GMOs will also be considered for human use or consumption when though they are for animal utilization may be directly used for human consumption.

ARTICLE 92.- The application for a GMO authorization must be accompanied by the following requirements:

I. The study of the possible risks that the use or consumption by humans of the determined GMO might have on human health, including scientific and technical information related to its innocuousness, and

II. Other requirements determined in the Mexican official norms derived from this Law.

The guidelines, criteria, characteristics and requirements of the studies on the possible risks that GMOs might have on human health will be determined by the SSA in the Mexican official norms issued in accordance to this Law.

ARTICLE 93.- In the case of applications of GMO authorizations to allow its importation for the purposes laid down in importation in Article 91 of this Law, the interested person must enclose, besides what is established in the previous article, the information and documentation demonstrating that the GMO is authorized in conformity with the legislation of the country of origin. If this is not the case, the interested will declare the inexistence of such situation and exhibit the consideration elements the SSA may use as foundations to resolve the authorization application.

ARTICLE 94.- Once the SSA receives an authorization application, and provided that it complies with all the information and requirements established in this Law, it will remit it to the Registry to be respectively inscribed and publicized.

ARTICLE 95.- The authorizations must be issued in a time not longer than six months beginning at the time the SSA receives the authorization application from the interested person and provided that the information in the application is complete.

ARTICLE 96.- The SSA will issue its resolution once it has analyzed the information and documentation provided by the interested person. In its resolution, such Secretary may, in a founded and rational manner:

I. Issue the authorization, or

II. Deny the authorization in the following cases:

A) When the application does not comply with the requirements, established in this Law or in the Mexican official norms, necessary for the granting of the authorization;

B) When the information provided by the interested person be false, incomplete or insufficient, or

C) When the SSA concludes that the risks that these organisms might present will negatively affect human health, with the possibility of severe or irreversible damage.

The SSA will base its resolutions in accordance with the sustained scientific and technical identification of the possible risks the GMOs could originate, and the real possibility of affectation to human health by these organisms.

ARTICLE 97.- The GMOs authorized by the SSA may be freely commercialized and imported for their trading, as well as products containing such organisms and products derived from them. The latter without detriment that such

authorized organisms, the products that contain them, and the products derived from them remain subject to the general sanitary control regime established by the General Law of Health and its regulations and, in the case that they may be applicable to them, the corresponding phytozoosanitary requirements.

ARTICLE 98.- The dispositions related to the Second Title will be applicable to the administrative procedure of authorization, with regard to the Reconsideration of the Negative Resolutions, Revision of Licenses and Confidentiality.

CHAPTER II
Additional dispositions

ARTICLE 99.- The packing of GMOs and the products containing them, for human use or consumption, will be ruled by the Mexican official norms issued by the SSA together with the Secretary of Economy, in conformity with the General Law of Health and its regulative dispositions, and with the Federal Law on Metrology and Normalization.

ARTICLE 100.- The development, production, commercialization and, in general, the processing of GMOs with therapeutic effects, in addition to what is established in this Law, will be subject to the dispositions laid down in the General Law of Health and other ordinances applicable to medicines and pharmacological agents.

SIXTH TITLE
Labeling and Identification of GMOs

ARTICLE 101.- GMOs or products containing genetically modified organisms, authorized by the SSA given their innocuousness in the terms of this Law and to be used directly for humans, must guarantee the explicit reference of genetically modified organisms and indicate in the label information regarding their food composition or their nutritious properties, in those cases where these characteristics are significantly different from the respective conventional products, and in addition must comply with the additional general labeling requirements in accordance to the Mexican official norms issued by the SSA, in agreement with what is established in the General Law of Health and its regulatory dispositions, with the participation of the Secretary of Economy.

The information indicated in the labels, in agreement with what is established in this article, must be true, objective, clear, understandable, and useful for the consumer and based on scientific and technical information.

The labeling of GMOs in the form of seeds or vegetative material for sowing, cultivation and agricultural production will be subject to the Mexican official norms issued by SAGARPA with the participation of the Secretary of Economy. With respect of this type GMO, it will be compulsory to inscribe in the label that it is a genetically modified organism, as well as the characteristics of the acquired genetic combination and its implications relative to special crop conditions and

culture requirements. The changes in reproductive and productive characteristics must also be included.

The evaluation in the conformity of such Mexican official norms must be carried out by the SSA, SAGARPA and the Secretary of Economy in the field of their respective competences, and the accredited and approved persons in agreement with what is established in the Federal Law on Metrology and Normalization.

ARTICLE 102.- The information requirements that must be contained in the documentation accompanying GMOs imported in accordance with this Law will be established in the Mexican official norms derived from the present ordinance, considering in their issue the final purpose these organisms will be given and what is established in international treatises subscribed by the United Mexican States. The Mexican official norms referred to in this article will be jointly issued by SAGARPA, SSA and the Secretary of Economy. In the case that GMO importation is aimed for release to the environment, the Mexican official norms referred to in this article will be issued by the indicated Secretaries jointly with SEMARNAT.

SEVENTH TITLE
On GMO lists

ARTICLE 103.- GMO lists, issued and published in agreement with this Law, will be the following:

I. GMOs having a license for its commercial release or its importation intended for this activity;

II. GMOs not having a license to be released commercially or its importation intended for this activity;

III. GMOs having an authorization issued by the SSA, and

IV. GMOs to be used in a confined manner in teaching and scientific and technological research purposes.

GMO lists referred to in this article will be issued and published by the competent Secretaries with the periodicity established in the regulatory dispositions derived from this Law and in agreement with what is established in the present Title. The aim of these lists is to reveal to interested persons or public in general the outcome of the resolutions issued as a consequence of the applications for licenses and authorizations.

ARTICLE 104.- The GMO lists referred to in fractions I and II of the previous article will be elaborated considering the results of the evaluations, case by case, and issued jointly by SEMARNAT, SSA and SAGARPA, and will be published in the Federal Official Gazette to make them known to the public.

The aims of the list referred to in this article are the following:

I. Indicate the legal situation a determined GMO is in, and

II. Determine the cases in which licensed GMOs to be commercially released or imported for this end may be released and imported freely in the geographical areas determined in accordance with an analysis made case by case.

In such a list, the corresponding Secretaries may indicate the cases in which the importation, use, handling or release of determined organisms may be carried out unconditionally and, in which cases these must comply with specific conditions.

ARTICLE 105.- A list of GMOs having an authorization will be elaborated and issued by the SSA, considering the outcomes of the evaluation made, case by case, of the possible risks such organisms may have for human health, and will be issued in the Federal Official Gazette to make them known to the public. Their aims will be to indicate the legal situation these GMO are in, and to determine the cases in which authorized GMOs may be commercialized and imported according to this Law.

ARTICLE 106.- The list of GMOs to be used in a confined way for teaching or scientific and technological research will be issued jointly by the Secretaries, and will be published in the Federal Official Gazette to make them known to the public.

ARTICLE 107.- The formulation, issuing and modification of GMO informative lists will be undertaken in accordance with the regulatory dispositions derived from the present ordinance, and taking into consideration the following guidelines:

They will be formulated considering:

I. The nature of the genetically modified organism;

II. The presence in the country or region of interest of species sexually compatible with the genetically modified organism;

III. The type of sexual reproduction of the genetically modified organism, as well as that of the native sexually compatible species;

IV. The nature of the receptor or parental organism;

V. The characteristics of the vector and of the insert of genetic material used in the procedure;

VI. The capacity and the form of propagation of the genetically modified organisms;

VII. The existence of related wild species in some area or region of the national territory that is their center of origin;

VIII. The scale or handling volume, and

IX. The possible effects or risks the different activities with such organisms may cause to the environment and biological diversity, or to the health of humans, animals, plants or aquatic organisms.

EIGHTH TITLE
On the Information on Biosafety

CHAPTER I
On the National System of Information on Biosafety

ARTICLE 108.- CIBIOGEM, through its Executive Secretary, will develop the National System of Information on Biosafety with the aim of organizing, actualizing and disseminating the information on biosafety. In this System, CIBIOGEM must integrate, among other aspects, the corresponding information to the Registry.

CIBIOGEM will collect relevant reports and documents stemming from scientific and academic activities, technical studies or any other field in the matter

of biosafety, including GMO innocuousness, carried out by physical or moral persons, national or international, that will be transferred to and organized by the National System of Information on Biosafety. In addition, it will elaborate and publish an annual report showing in detail the prevailing general situation in the country in the subject of biotechnology and biosafety, matter of this Law.

Besides, CIBIOGEM will undertake studies and socioeconomic considerations consequence of the GMO effects released to the environment in the national territory, and will establish mechanisms to carry out consultations and the participation in the towns and indigenous communities settled in the zones where the release of GMOs is to take place, taking into consideration the importance of biological diversity.

Likewise, the Executive Secretary of CIBIOGEM will act in the capacity of National Focal Center before the Secretariat of the Cartagena Protocol on Biotechnology Security in the Treatise on Biological Diversity, being responsible of the link with such Secretariat and see the fulfillment of what is established in Article 19 of such International Treaty. The Executive Secretary of CIBIOGEM will also be responsible for providing the Center for Information Exchange of Security on Biotechnology established in the aforementioned Protocol with any information related to:

I. Laws, regulations and existent national guidelines for the application of the Protocol, as well as the required information and documentation, in the terms of this Law, for the administrative procedure to obtain GMO importation licenses to be released experimentally, within a pilot program or commercially;

II. Agreements and bilateral, regional and multilateral settlements;

III. Summaries of GMO risk evaluations, as well as the pertinent information concerning products derived from GMOs;

IV. The definitive resolutions related to the importation or release to the environment of GMOs, as well as the modifications of resolutions derived from the appeal resource carried out in accordance with this Law;

V. GMO socioeconomic effects, especially those in indigenous and local communities, and

VI. The reports dealing with the fulfillment of the obligations established in the Protocol, including those relative to the application of GMO importation procedure to be released to the environment in experimental form, within a pilot program or commercially.

The competent Secretaries may provide directly to the Center for Information Exchange of Security on Biotechnology, the information referred to in the previous fractions, as well as informing simultaneously the Executive Secretary of CIBIOGEM.

CHAPTER II
On the National Registry on Biosafety of GMOs

ARTICLE 109.- The Registry, which will be a responsibility of the Executive Secretary of CIBIOGEM, will have a public character and its aim is the inscription of the information relative to GMO activities, as well as of the organisms themselves. Its functioning and the objects of inscription will be determined by the regulatory dispositions derived from this Law. SEMARNAT, SAGARPA and SSA will contribute to the organization and operation of the Registry.

NINTH TITLE
On the Mexican Official Norms in the Matter of Biosafety

ARTICLE 110.- To guarantee the biosafety in GMO activities, the Secretaries, jointly and having the participation of other dependencies of the Federal Public Administration, will issue the Mexican official norms to establish guidelines, criteria, technical specifications and procedures in accordance with the dispositions in this Law.

ARTICLE 111.- In the formulation of the Mexican official norms in the matter of biosafety it must be taken into account that the fulfillment of its preventive measures must be carried out in accordance with the characteristics of each activity or productive process with GMOs.

ARTICLE 112.- The application of the Mexican official norms in the matter of biosafety, as well as inspection and surveillance measures will correspond exclusively to the competent Secretaries in the terms of this Law. The fulfillment of such norms may be evaluated by certification organisms, verifying units or test laboratories approved by such Secretaries in conformity with the regulatory dispositions derived from the present ordinance and with the Federal Law on Metrology and Normalization.

TENTH TITLE
Inspection and Surveillance and Security or of Urgent Application Measures

CHAPTER I
Inspection and Surveillance

ARTICLE 113.- To verify and demonstrate the fulfillment of this Law, its regulations and the Mexican official norms derived from it, the competent Secretaries may, through authorized personnel, carry out the necessary inspections and surveillance, by means of the Administrative Units legally authorized for this function, in accordance to this Law.

ARTICLE 114.- With respect to the requirements and formalities to be fulfilled in the visits of inspection and surveillance, the dispositions in the Eleventh Chapter of the Third Title of the Federal Law of Administrative Procedure are applicable in a suppletory manner. In the matter of restoration or damage compensation to the environment or to biological diversity, the dispositions, laid on the second

paragraph of Article 168 of the General Law for the Ecological Balance and the Protection of the Environment, are applicable.

CHAPTER II
Security or of Urgent Application Measures

ARTICLE 115.- The Secretaries, in their field of competence according to this Law, will order one or some of the measures established in this article, in the case that when these GMO activities are undertaken they are accompanied by the following:

I. Risks not previously foreseen appear that may harm or have adverse and significant effects to human health or to biological diversity or to the health of animals, plants or aquatic living organisms, or

II. Harm or adverse and significant effects are caused to human health or to biological diversity or to the health of animals plants or aquatic living organisms, or

III. GMOs, not licensed and/or authorized, are accidentally released to the environment.

In these cases, the measures adopted will be the following:

A. Temporal, partial or total closure of the places or facilities where these GMOs are handled or stored, or where the development of activities originating the suppositions giving rise to the implementation of the measure takes place.

B. The cautionary securing of GMOS, as well as the assets, vehicles, tools and instruments directly related to the action or omission giving rise to the measure;

C. The temporal, total or partial suspension of the activity motivating the implementation of the measure;

D. The repatriation of GMOs to their country of origin;

E. The undertaking of actions or necessary measures to avoid the continuation of the suppositions motivating the implementation of the measure, and

F. The extermination of the determined GMO, at the expense of the interested person, and for this matter the following will be minded:

a) The action will take place only in the case that the risks or damage are severe or beyond reparation, and when the implementation of this measure be the only possibility to avoid, attenuate or mitigate the risks or damage caused.

b) To determine the implementation of this measure, the competent Secretary will issue a dictate, based on scientific and technological evidence, providing the justification to proceed with the extermination of a determined GMO, informing the interested person, so that he/she, in the term of the next five days, explains what in his own right is convenient, and in his/her case provides the pertinent proofs he/she has available, and

c) In the meantime the competent Secretary dictates a resolution; it may order previously the cautionary securing of the GMOs. This can be done by the proper Secretary or through the interested person.

Similarly, the competent Secretary implementing the measures referred to in this article may promote before other competent Secretaries, the execution of one or some measures established in other ordinances.

ARTICLE 116.- When the competent Secretaries order some of the measures mentioned in the previous article, they must indicate the interested person the actions he/she must undertake to correct the irregularities motivating the implementation of the determined measures, as well as the terms necessary for their fulfillment, so once the actions are completed, the withdrawal of the implemented measures is ordered .

If the interested person refuses to adopt the measures to correct the irregularities motivating the implementation of the measure or measures, the Secretary imposing them will carry them out immediately, and the total expense will be covered by the unwilling interested person.

In the case that the interested person carries out the security measures or measures of urgent application or corrects the irregularities he/she committed, previous to the implementation of the sanction or sanctions ordered by the competent Secretary, such Secretary will take the former situation into consideration as an extenuating circumstance of the infraction committed.

ARTICLE 117.- In the case of accidental GMO releases taking place in the national territory, and that may have significant adverse effects to biological diversity or to the human health of other country, the competent Secretary will notify of the situation to the corresponding authority of the country that might be affected by such release. This notification must include the following:

I. Information related to the estimated quantities and GMO relevant characteristics and/or traits;

II. Information on the circumstances and the estimated date of the accidental release, as well as the use given to the GMO in the national territory;

III. Available information on the possible adverse effects to the biological diversity and human health;

IV. Available information on the possible measures of regulation, attention and control of the risks, and

V. A contact point to obtain additional information.

Without detriment of the aforementioned, the Secretaries, in the field of their competences in accordance to this Law, will undertake the actions and necessary measures to reduce to a minimum any risk or adverse effect that GMOs released accidentally may cause. Such actions and measures will be ordered by the Secretaries to the person or institution causing the accidental release of GMOs to the environment, these must comply with them immediately. If this were not the case, the Secretaries will proceed in accordance to what is established in the second paragraph of the previous article:

ARTICLE 118.- The dispositions laid down in the Unique Chapter of the Fifth Title of the Federal Law of Administrative Procedure are applicable in a suppletory manner to the ones in this chapter, with the exception to what is regulated in the previous article.

ELEVENTH TITLE
Infractions, Sanctions and Responsibilities

Chapter I
On Infractions

ARTICLE 119.- A person is liable to administrative infractions to the dispositions in this Law, when having plain knowledge that he/she is dealing with GMOs performs the following:

I. Activities with GMOs without the respective license or authorization;

II. Activities with GMOs without complying with the terms and conditions established in the respective license and authorization;

III. Activities of confined GMO utilization without presenting the notifications in the terms established in this Law;

IV. Activities with GMOs which are subject or exempted of a notification, but not complying with the other dispositions in this Law, its regulations and Mexican official norms derived from the first, that are applicable to the determined activity, or that are common to all the activities in the matter of biosafety;

V. Presentation to the competent Secretaries of false information and/or documentation referred to in this ordinance, including that relative to the possible risks that the activities with GMOs may cause to human health or to biological diversity;

VI. Non-compliance of the sanitary, monitoring, control and prevention measures indicated by the interested persons in the information and documentation provided to obtain the respective licenses and authorizations, as well as of the measures established by the Secretaries in the proper licenses and authorizations;

VII. Non-compliance of the control and response measures in the case of emergency indicated by the interested persons in their studies on possible risks that the activities with GMOs may entail to human health or to biological diversity or to the health of animals, plants or aquatic organisms;

VIII. Non-compliance of the obligation to inform or make known to the Secretaries, in the suppositions established in this Law;

IX. Non-compliance of the obligation to adopt or implement the requirements and additional biosafety measures determined by the Secretaries, in the cases of activities of confined use subject to notification, when it is determined in this way;

X. Non-compliance of the obligation to revise, implement or adopt new sanitary, monitoring, control and prevention measures, in the cases the competent Secretaries considered it so in accordance with the dispositions in this Law;

XI. Activities with GMOs or any other organism with the aim of building and/or utilization of biological weapons;

XII. Releases of GMOs in the centers of origin or of genetic diversity, other than the cases established in the present Law;

XIII. Activities with GMOs in protected natural areas indicated in this Law, other than the cases established in it;

XIV. Non-compliance of the obligation to inform SEMARNAT and SAGARPA, according to the field of competence in accordance with this Law, with the corresponding report, the results of the experimental releases or releases within a pilot program, having the respective license;

XV. Importation of GMOs that are forbidden in the country of origin or are classified as not permitted for their commercial release or imported for this activity in the lists referred to in this Law, when the corresponding Secretaries have not issued a positive determination stating that those prohibitions are not applicable in the national territory;

XVI. Presentation of the notifications to the corresponding Secretaries without being signed by the person appointed in accordance with this Law;

XVII. Not keeping and/or not providing the corresponding Secretary the registry notebook where the activities to be carried out in a confined manner are recorded, in the terms established in this Law and in the Mexican official norms derived from it;

XVIII. Continuation of the activities of confined utilization in the cases in which the corresponding Secretaries determine their suspension, once the notification has been presented by the interested person and, in this case, the activity needs additional requirements or biosafety measures to be allowed to continue;

XIX. Activities of confined utilization without complying with the measures of confinement, treatment, final disposal and elimination of GMO residues originated in the undertaking of the activity;

XX. Non-compliance of the dispositions relative to the generation, treatment, confinement, final disposal, destruction or elimination of GMO residues established in the Mexican official norms derived from the present ordinance;

XXI. Failure to integrate the internal biosafety commissions in the cases, forms and terms established in the regulatory dispositions derived from this Law;

XXII. Non-compliance of the obligation of undertaking the actions and security or of urgent application measures established by the competent Secretaries, in the cases and terms established in this Law;

XXIII. Non-compliance of what is laid down in this Law and in the Mexican official norms derived from it in relation to the labeling of products containing GMOs or products derived from such organisms;

XXIV. Non-compliance of the dispositions laid down in this ordinance and in the Mexican official norms regarding the identification of GMOs;

XXV. Activities of confined GMO utilization different from the ones declared in the notifications presented in the terms of this Law;

XXVI. Activities with GMOs different from the permitted, or assigns GMOs other purposes than the ones licensed or authorized;

XXVII. Intentional releases of GMOs to the environment, without the corresponding release licenses, and in its case, the corresponding authorizations in agreement with this Law, and

XXVIII. Releases to the environment GMOs imported or produced in the national territory, in the terms of this Law, to be used for direct human or animal consumption, for processing foods for human consumption, or for other purposes than the release to the environment.

CHAPTER II
On Sanctions

ARTICLE 120.- Infractions to the precepts of this Law, its rules and regulations and to the Mexican official norms derived from it, pointed out in the previous article, will be sanctioned administratively by the competent Secretaries with one or more of the following sanctions:

I. Fine consistent of five hundred to fifteen hundred days of general minimum salary in force in the Federal District to anyone committing infractions foreseen in fractions IV, V, VIII, XIV, XVI, XVII and XXI, Article 119 of this Law, and

II. Fine consistent of fifteen hundred and one to thirty thousand days of general minimum salary in force in the Federal District to anyone committing infractions foreseen in fractions I, II, III, VI, VII, IX, X, XI, XII, XIII, XV, XVIII, XIX, XX, XXII, XXIII, XXIV, XXV, XXVI, and XXVII, Article 119 of this ordinance.

In the case of repetition of an offense, the amount of the corresponding fine will de duplicated. For the effects of this fraction, an infringer is considered a second time offender when it falls more than once in behaviors implying transgressions to the same precept, within a two-year period, starting on the date that the competent Secretary determines by means of a definitive resolution, the commission of the first infraction, as long as this one was not demerit.

III. Temporal or definitive closure, partial or total, of the facilities where infractions were committed whenever:

A) The infractions cause possible risks or adverse effects to human health, or to biological diversity, or to the health of animals, plants or aquatic organisms;

B) The infringer did not comply with the terms or conditions established by the competent Secretaries, nor with the security measures or those of urgent application ordered by the Secretaries, or

C) The non-compliance of one or more of the security or of urgent application measures, implemented by the competent Secretaries, is reiterative.

IV. The confiscation of the instruments, exemplars, obtained organisms or products directly related to the committed infractions;

V. The suspension or revocation of the corresponding licenses and authorizations

VI. Administrative arrest up to 36 hours;

VII. Prohibition of the experimental release, release within a pilot program or the commercialization of GMOs and products containing them.

ARTICLE 121.- Independently of what is established in the previous article, any person, having plain knowledge that he/she is dealing with GMOs, causes damage to third persons in his/her assets or health, by the misuse or mishandling of such organisms will be held responsible and obliged to compensation in the terms of the federal civil legislation. The same obligation will assume the person damaging the environment or biological diversity, by the misuse or mishandling of GMOs, for which the dispositions laid down in Article 203 of the General Law for the Ecological Balance and the Protection of the Environment will apply.

The persons directly affected in his/her assets may ask the judge to require the competent Secretary through its respective scientific technical committee established in accordance with this ordinance, a technical dictate with the aim of demonstrating the existence of a damage, and that this be the basis used by the

judge to determine, in its case, the form of compensation. The technical dictate issued will be free of cost to the solicitants.

In the case of damage to the environment or to biological diversity, the SEMARNAT, through the Federal Proctorship for the Protection of the Environment will exert the responsibility action in any of the following forms:

I. Of office, and based on the file relative to the acts of inspection and surveillance that must have been definitely concluded, the commission of infractions to this Law has been determined and this determination has not been demerit by any means of impugnation, or

II. By denunciation, presented by the members of the affected community, of acts that may violate what is established in this Law and in other dispositions emanating from it. The accusation must be accompanied of supporting scientific and technical information, with the participation of the Scientific Advisory Council of the CIBIOGEM, with the previous opinion of the National Commission for the Understanding and Utilization of Biodiversity.

In the cases referred to in the previous fractions, the Federal Proctorship for the Protection of the Environment will exert the responsibility action based on the technical dictate that was elaborated for this effect by the scientific and technical committee of the SEMARNAT. To formulate the dictate, the scientific and technical committee will evaluate the information and the elements provided by the Federal Proctorship for The Protection of the Environment, these may be in the administrative file or may be rendered by the accusers, respectively, and will determine, in its case, the existence of damage. The district tribunals in civil matters will be competent to acknowledge the responsibility actions for damages to the environment or to biological diversity in the terms of this Article, in accordance with the territorial competence established in the respective dispositions.

Administrative sanctions, established in the previous Article, will be implemented without detriment, in its case, of the punishments corresponding to acts or omissions constitutive of infractions to this Law, when these are as well constitutive of punishment in accordance with the applicable dispositions in the Federal Penal Code.

ARTICLE 122.- The dispositions of the Unique Chapter of the Fourth Title of the Federal Law of Administrative Procedures are applicable in a suppletory manner to this chapter in relation to administrative responsibilities, with the exception of article 70-A of that ordinance.

TWELFTH TITLE
Appeal Resource

ARTICLE 123.- The definitive resolutions, dictated in the administrative procedures in the application of this Law, its regulations and the norms derived from it, may be impugned by the affected persons by a appeal resource, within fifteen days following the notification date, or before the competent jurisdictional instances.

The appeal resource will be interposed directly before the Secretary issuing the impugned resolution, which in its case, will grant its admission and will consent

or deny the suspension of the appealed act by means of this resource, sending it to its hierarchical superior in the same Secretary for its definitive resolution.

ARTICLE 124.- With reference to the other procedures related to the substantiation of the appeal resource referred to in the previous article, will be subject to the dispositions in the Sixth Title of the Federal Law of Administrative Procedures.

TRANSITORIES

FIRST ARTICLE.- This Law will be in force thirty lawful days posterior to its publication in the Federal Official Gazette.

SECOND ARTICLE.- The competent Secretaries must issue and publish in the Federal Official Gazette the notification formats referred to in this ordinance, within twenty days following their approval by the Federal Commission of Regulatory Improvement.

THIRD ARTICLE.- Once the formats, referred to in the previous transitory article, have been issued and published, the interested persons that in conformity with this Law have the obligation of presenting notifications, must do so within ninety days starting on the day such formats were published in the Federal Official Gazette.

FOURTH ARTICLE.- The holders of authorizations granted before this Law was issued will not be affected by the enforcement of this ordinance in the rights and obligations consigned in them.

FIFTH ARTICLE.- The application for authorizations whose administrative procedure started previous to the issuing of this Law, and are pending of resolution, must be resolved in accordance to the legal and administrative dispositions in force at the moment the applications were admitted.

SIXTH ARTICLE.- The SHCP will carry out the necessary acts to transfer the necessary resources for the functioning of the Executive Secretary and the Scientific Advisory Committee of CIBIOGEM, and will approve the positions necessary for the functioning of the Executive Secretary of the CIBIOGEM, with the resources approved by this Commission, as well as with those resources that the dependencies and the entities have designated for these purposes, in the terms of the applicable dispositions.

The actions derived from the implementation of this Law and other dispositions derived from it will be taken care of with the budget approved for this effect by the dependencies and entities of the Federal Public Administration constituting the CIBIOGEM.

The Presidential Agreement by which the CIBIOGEM was created will be in force in the matters not contravening this Law, until the corresponding regulatory dispositions of this ordinance are issued.

SEVENTH ARTICLE.- The regulatory dispositions related to the dispositions in Chapter IV, First Title of the present Law, as well as those corresponding to Chapters I and II of the Eighth Title of this same ordinance must be issued in a six-month term starting on the entrance into force of the present ordinance. The

CIBIOGEM will issue the operation rules within sixty days following the in force of the regulatory dispositions laid down in this article.

EIGHTH ARTICLE.- The convocation to integrate the Advisory Council will be issued within the thirty days following the entrance into force of this Law, and will be integrated in the following three months to the publication of this convocation.

NINTH ARTICLE.- CONACyT will carry the necessary steps to modify the trust established for the handling of the financial resources of the Inter-secretarial Commission created by the Presidential Agreement published in the Federal Official Gazette on November 5th , 1999 to comply with this Law, so that it operates hereafter as the Fund for the Promotion and Support to Scientific and Technological Research on Biosafety and Biotechnology established in the present ordinance.

TENTH ARTICLE.- The program for the development of biosafety and biotechnology referred to in Article 29 of this Law will be formulated and issued in a term no longer than one year starting on the entering in force of this Law.

ELEVENTH ARTICLE.- The preliminary projects of the Mexican official norms referred to in Articles 42, fraction VII; 50, fraction V; 55, fraction VII; 74; 101, and 102 of this Law must be presented to the corresponding National Advisory Committees of Normalization within a term no longer than six months starting on the entering in force of the present ordinance, in conformity and to the effects established in the Federal Law on Metrology and Normalization.

The preliminary projects of the other Mexican official norms referred to in this Law will be presented within the term of one year starting on the entering in force of the present ordinance, for the effects laid down in the previous paragraph.

In the meantime the Mexican official norms referred to in articles 42, fraction VII; 50, fraction V, and 55, fraction VII of this Law are issued, SEMARNAT and SAGARPA, in their respective fields of competence, may determine the information considered necessary, with the corresponding participation of the Federal Commission of Regulatory Improvement, and in the term no longer than a year after the coming in force of the present ordinance, to issue the corresponding licenses.

TWELFTH ARTICLE.- All legal dispositions contrary to this Law are revoked.