

REGULATIONS to the Genetically Modified Organisms Biosafety Law

In the margin, a stamped seal with the Mexican coat of arms reading: United Mexican States, Presidency of the Republic.

FELIPE DE JESÚS CALDERÓN HINOJOSA, President of the United Mexican States, hereby acting by virtue of the faculty vested upon me by Article 89, section I of the Political Constitution of the United Mexican States, and based on the provisions set forth by Article 13, Article 32 bis, Article 34, Article 35, Article 38, and Article 39 of the Organic Law of the Federal Public Administration, and on the Genetically Modified Organisms Biosafety Law, I have seen fit to issue the following

REGULATIONS TO THE GENETICALLY MODIFIED ORGANISMS BIOSAFETY LAW

TITLE ONE

General provisions

Sole Chapter

Article 1. This ordinance is aimed at regulating the Genetically Modified Organisms Biosafety Law in order to provide for the precise compliance therewith.

Article 2. For purposes hereof those definitions set forth in Article 3 of the Genetically Modified Organisms Biosafety Law as well as the provisions stipulated hereinbelow shall be observed.

- I. Law: the Genetically Modified Organisms Biosafety Law;
- II. Mexico: United Mexican States;
- III. NOM: Mexican Official Standard;
- IV. GMO intended for public health: Such organisms the genetic modification of which is aimed at producing prevention mechanisms or those to control human being diseases; with the exception of those mechanisms referred to in Article 5, section III of the Law;
- V. Cartagena Protocol: The Cartagena Protocol on the Biotechnology Safety of the Convention on Biological Diversity;
- VI. HEALTH: Secretariat for Health;
- VII. Competent secretariat: SEMARNAT and SAGARPA within the scope of their respective responsibilities in accordance herewith;
- VIII. Executive Secretariat: CIBIOGEM's Executive Secretariat;
- IX. Completed application: Attached information and documents provided for in Article 5 of these Regulations, and
- X. UTM: UTM [*Universal Transverse Mercator*] projection, system used to convert spherical geographic coordinates into flat Cartesian coordinates.

Article 3. In absence of an explicit provision in this ordinance, the provisions set forth in the Federal Law of Administrative Procedures shall be complied with.

Article 4. Each time that a proceeding is submitted with the competent Secretariat or with the Secretariat of HEALTH, as applicable, a copy of the receipt reflecting the payment of fees shall be attached thereto whenever it is so provided by the relevant Law.

TITLE TWO

Permits for Activities with GMOs

Chapter I

On the application for permits

Article 5. Those who intend to perform any of the activities provided for in Article 32 of the Law shall submit with the competent Secretariat a written application in the form issued for such purpose by the competent Secretariats, attaching thereto such information set out in Article 16, Article 17, and Article 19 of these Regulations. A single application for each GMO shall be submitted, the original and one copy thereof. The information to be included in such application shall be as follows:

- I. Name, corporate or firm name of the applicant, and if applicable, the legal representative's name;
- II. Domicile to listen and receive notices, as well as the name of the person(s) authorized for the reception thereof;
- III. E-mail address to receive notices in case that the applicant desires to be notified through these means;
- IV. Mode of the release being requested and the reasons for such application;
- V. Indication on the body of the competent Secretariat to which the application is addressed;
- VI. Date and place, and
- VII. Signature of the interested party or legal representative, or if applicable, fingerprint.

The applicant shall attach to such application those documents evidencing the legal capacity thereof.

In the event of having the registry identification number for authorized individuals, it may state such number in the written application and shall not be necessary to entry the information set forth in sections I, II and VII of this Article, and neither those documents needed to prove its legal capacity, except for the information provided for in sections III, IV, V and VI hereof.

The applicant shall not be obliged to provide any additional information nor to deliver additional sets of documents previously delivered to the competent Secretariat; provided that it states the identification data of the written document where such information was stated or the written document to which such information was attached, and that the new procedure is performed thereby before such Agency.

In addition to the abovementioned requirements, the information and additional documents including information and requirements stipulated in Article 42, Article 43, Article 50, Article 51, Article 55 and Article 56 of the Law, and Articles 16, 17, and 19 of these Regulations shall be submitted according to the relevant mode of release.

Application shall be submitted with two data mass storage devices including the electronic version of the application filed in writing, as well as all the additional information and documents including the information and requirements provided for by the Law, these Regulations, and the NOMs.

Such electronic version shall be submitted in the format determined by means of such resolution jointly issued by the SEMARNAT and SAGARPA; resolution which shall be published in Official Gazette of the Federation.

Article 6. The completed application shall be submitted in Spanish. In the event it is drafted in another language, the versions in both languages shall be attached; and in case of dispute as regards the contents, the statements made in the language of origin shall prevail.

Article 7. The interested party may clearly identify in the information provided, such data regarded as confidential, according to Article 70 and Article 71 of the Law.

Article 8. The competent Secretariat shall revise the completed application within ten business days following the date of reception; and in case that such application fails to comply with the relevant information or requirements, it shall notify the interested parties in writing and for one sole time in order for them to remedy such omission within a term not greater than twenty business days as from the day following that on which the notification was made.

Once the relevant term is elapsed and there is no remedy for the notification made, the procedure shall be rejected.

For purposes of the provisions set forth in Article 44 of the Law, it is understood that the completed application was received and the information complete in the cases where once the application is submitted, there is no warning or if the notification is made, the same is taken into account by the applicant, without prejudice to the competent Secretariat regarding the powers vested thereupon by Article 34, section II of the Law.

Article 9. - In case that the competent Secretariat fails to provide the notice in terms stipulated under the above Article, such Secretariat may not reject the procedure by arguing that the same fails to be complete.

Article 10. The competent Secretariat may only require additional information within the twenty days following the admission of the complete application in the events provided for in Article 63 of the Law.

Article 11. The applicant shall have a twenty business-day term as from the day following that on which the notification becomes effective to meet the requirement referred to in Article 10 hereof.

Once such term is elapsed and the applicant fails to submit the required information, the competent Secretariat may reject the permit in accordance with the provisions set forth in section II of Article 34 of the Law.

Over such twenty-day term and the term that may be provided for to deal with the warning mentioned in Article 8 or this ordinance, the terms to resolve on the application for permit or the terms to issue the authorized or expert opinion shall be suspended, and they shall be resumed on the business day following that on which the applicant complies with the requirement.

Article 12. Within two business days following that on which the completed application is admitted, the competent Secretariat shall deliver to the Registry a copy thereof for its relevant registration and promotion in terms of Article 33 of the Law.

Article 13. For purposes of issuing the authorized or expert opinion referred to in Article 34 of the Law, it shall be proceeded as follows:

- I. Within three business days following that on which the complete application for permit was admitted, the competent Secretariat shall deliver a copy thereof to the Secretariat with obligation to issue the authorized or expert opinion;
- II. Whenever additional information is required, in the events provided for in Article 63 of the Law, the Secretariat with obligation to issue the authorized or expert opinion, and for purposes of issuing such authorized or expert opinion, it shall communicate such fact in writing and for one sole time to the competent Secretariat, and for which purposes the provisions set forth in Articles 10 and 11 of these Regulations shall be complied with.

The term to carry out such revision and communicate in writing the result to the competent Secretariat, shall be ten business days as from the day following that on which the copy of such application for permit is received, and

III. In the event that the Secretariat with obligation to issue the authorized or expert opinion fails to request the additional information, the same shall issue its authorized or expert opinion with the information included in the copy of the completed application referred to in section I hereof, and the such Secretariat may not argue the failure to provide such information in order to issue a negative authorized or expert opinion.

Article 14. The Secretariat with obligation to issue the authorized or expert opinion regarding the permits to release, including the permits for importation referred to in Article 32 of the Law, shall have the following terms to deliver them to the competent Secretariat:

- I. For the case of experimental release into the environment, up to eighty business days;
- II. For the case of release into the environment in pilot program, up to forty business days; and
- III. For the case of commercial release into the environment, up to fifty business days.

The terms referred to herein shall count as from the day following that on which the Secretariat with obligation to issue the authorized or expert opinion, receives the copy of the completed application by the competent Secretariat.

In the event that the Secretariat with obligation to issue the authorized or expert opinion fails to provide the same within the terms stipulated hereunder, it shall be understood that no objection is found to the applicant's intentions.

Article 15. The authorized or expert opinion referred to in the above Article shall include:

- I. The Statement by the Secretariat issuing the authorized or expert opinion, whether positive or negative with respect to the completed application for permit;

II. In the event the same is positive, the following shall be stated:

- a)** Opinion regarding the proposal for such permits terms, and if needed, the monitoring measures and procedures and any biosafety measure additional to those submitted by the applicant;
- b)** The reasons based on which it is decided to include any such additional measures and procedures, and
- c)** The legal provisions to ground such additions cited in section a) hereof, and the scientific reasons to set out any such additional measures and procedures.

III. In the event such opinion is negative, the following shall be stated:

- a)** If applicable, the reasons based on which it is considered that the applicant failed to observe the issues stated in the requirement provided for in Article 10 of the Regulations;
- b)** The scientific or technical reasons based on which it is considered that the risks of the relevant GMOs may negatively affect the biological diversity, environment, the animal, vegetal or aquatic health, and that may cause them serious or irreversible damages.
- c)** The reasons based on which the release being requested is in contravention with the Law, these Regulations and other applicable provisions, and
- d)** Every other resolution by the authority in exercise of the precautionary approach provided for by the Law.

Pursuant to the last paragraph in Article 15 of the Law, the biosafety authorized opinion referred to in section I of such Article shall be binding for the SAGARPA as to the resolution on the applications for permits which may fall under its responsibility according to the law.

Chapter II

On the requirements for permits to release into the environment

Article 16. The information that shall be attached to the application for permits to release GMOs into the environment pursuant to Article 5, Article 6, and Article 7 of these regulations, shall be the following:

I. GMO characterization;

a) Sole identifier of the transformation event by international organizations of which Mexico may be part of, if applicable;

b) Species related to the GMO and their distribution in Mexico;

c) Specification on the existence of sexually-compatible species;

d) Description of habitats where such GMO may subsist or grow within the environment of the release;

e) Taxonomic description of recipient and donor organism of the genetic construction;

f) Country and location where such GMO was gathered developed or produced;

g) Documentary reference on the origin and diversification of recipient organism;

h) Detailed genetic sequence of the transformation event, including size of inserted fragment, insertion site of genetic construction, including oligonucleotide sequences allowing for amplification of insertion site;

i) Description of flanking sequences, number of inserted copies and results of experiments confirming the above data, as well as expression of desired product in the genetic transformation event, including demonstration of results;

- j)** Genetic construction map, type of inheritance of product characters in the inserted genes, protein expression and their localization;
- k)** Description of transformation method;
- l)** Description, number of copies, insertions sites and expression of non-relevant sequences for the expression in the genetic modification, and as applicable, identification of unexpected effects;
- m)** Amino acid sequence and that of innovative proteins expressed by the GMO, size of gene product, expression of multiple copies;
- n)** Metabolic routes involved in the transgene expression and their changes;
- o)** Degrading products of coded protein for the transgene in the by-products;
- p)** Nucleotidic sequence of regulating sequences including promoters, terminators and others and their description, amount of inserted copies, ownership of such sequences to the recipient species, inclusion of regulating sequences equivalent to the recipient species;
- q)** Pathogenicity or virulence of donor and recipient organisms;
- r)** Selection genes used during development of GMO and phenotype given by these selection genes, including their action mechanism;
- s)** Amount of generations that proved stability in the transgene inheritance, and
- t)** Bibliographic reference on the submitted information.

II. Identification of the zone(s) where the GMO release is intended:

- a)** Total surface of the polygon(s) where such release will be carried out;
- b)** Location, in UTM coordinates of the polygon(s) where such release will be carried out; and
- c)** Description of polygons where release shall be carried out and that of bordering zones according to the relevant GMO disseminating features:

1. List of sexually-compatible species and of species interacting in the area of release and bordering areas;
2. Geographic description, and
3. Location layout indicating main communication routes.

III. Survey on the potential risks that such GMOs release may cause to the environment and biological diversity referred to in Article 42, section III of the Law. In addition to the provisions under Article 62 of the Law, it shall include the following information:

- a) Stability of the GMO genetic modification;
- b) Expression of inserted gene, including protein expression levels of interest in different tissues, as well as evidencing results;
- c) GMO phenotype characteristics;
- d) Identification of any new physical and phenotypic feature relating to the GMO and which may have adverse effects on the biological diversity and recipient environment of the GMO;
- e) Comparison of GMO phenotypic expression as compared to the recipient organism, and which shall include at least biological cycle and changes in basic morphology.
- f) Statement regarding the existence of any effect on the biological diversity and environment that may be caused by the GMO release;
- g) Description of one or more specific event identification methods of the GMO, including sensibility and reproducibility levels, with express statement by the applicant regarding that the identification methods are acknowledged by the GMO developer in order to detect such GMO;
- h) Potential existence of genetic flow of such GMO to related species;
- i) Recent bibliographic reference to the submitted information, and

j) Every other provided for by the NOM as a result from the Law.

IV. Biosafety monitoring measures and procedures of the activity to be carried out:

a) Monitoring measures and procedures of the activity:

1. Detailed monitoring plan;
2. Monitoring strategies after the GMO release aimed at detecting any interaction between such GMO and species present in the zone(s) where such release is intended, as applicable, and
3. GMO detecting strategies and later presence in the zone(s) where such release is intended and bordering areas, once such release is concluded.

b) Biosafety measures and procedures:

1. Measures and procedures to prevent the GMO release and dissemination outside the zone(s) where such release is intended;
2. Measures and procedures to reduce access of dispersion vector organisms or people not authorized to enter into the area of such zone(s);
3. Measures to completely remove such GMO from zone(s) other than those authorized;
4. Measures to isolate the zone where the GMO is experimentally intended to be released;
5. Measures to protect the human health and the environment, in case of an undesired release event, and
6. Cleaning methods or final disposal of release waste matter.

The applicant shall clearly differentiate the measures and procedures to be performed during such release from those to be carried out thereafter.

V. Background regarding the GMO release in other countries, where such release has been performed and the relevant information within reach of the applicant:

- a)** Description of the zone where such release was carried out;
- b)** Effects of such release on the flora and fauna;
- c)** Assessment on the potential risks of GMOs release submitted in the country of origin, where it has been required by the authority from another country and access thereto is available. Description of biosafety monitoring measures and procedures set forth shall be included in such assessment.
- d)** In case it is regarded suitable by the applicant, other assessments or considerations where both the contribution of such GMO to the solution of environmental, social, production or other type of problems are analyzed, as well as any socioeconomic considerations as to the environmental release of GMOs. These analyses should be supported by scientific and technical evidence, history of use, production and consumption and the competent Secretariats may take them into account as additional elements to resolve on the experimental release into the environment and ensuing releases into the environment of the GMO in question under any pilot and commercial program, respectively, and
- e)** In the event of importation, legalized copy or apostille of the copy of authorizations or official documents evidencing such GMO is permitted according to the laws in the country of origin, at least for its experimental release and its translation into Spanish. The competent Secretariat, if deemed needed thereby, may request a simple copy of the applicable legislation in force in the exporting country translated into Spanish.

VI. Considerations about the risks of technological options in place in order to fight the problem for which the GMO was produced, in case such options exist.

VII. Authorization number issued by the Secretariat of HEALTH, in the event such GMO is intended for public health or bioremediation. In the event that there is no authorization in place upon filing the application for permit, the applicant may submit the same at a later time attached to a free format written document stating the authorization number.

VIII. The proposal for the term of such permit and elements used for determination thereof, and

IX. The information determined by the NOMs for each specific case.

Article 17. The information to be attached to the application for permit to release GMOs into in a pilot program according to Article 5, Article 6, and Article 7 of these Regulations shall be the following:

I. Identification data of the experimental release permit or simple copy of the afore-cited permit;

II. References and considerations on the results report of the experimental releases carried out in relation with the potential risks for the environment and biological diversity, and also to the animal, vegetal and aquatic health;

III. Amount of GMO to be released;

IV. The handling conditions to be given for such GMO;

V. Identification of the zone(s) where the GMO release is intended:

a) Total surface of the property(ies) where such release will be carried out;

b) Location, in UTM coordinates of the polygon(s) where such release will be carried out; and

c) Description of polygons where release shall be carried out and that of bordering zones according to the relevant GMO disseminating features:

1. List of sexually compatible species and of such species interacting at the release area and at bordering zones within the radius set out in this section;

2. Geographic description, and
3. Location layout indicating main communication routes.

VI. Biosafety and monitoring measures to carry out:

a) Monitoring measures:

1. Detailed monitoring plan;
2. Monitoring strategies after the GMO release aimed at detecting any interaction between such GMO and species present in the zone(s) where such release is intended, as applicable, and
3. GMO detecting strategies and later presence in the zone(s) where such release is intended and bordering areas, once such release is concluded.

b) Biosafety measures:

1. Measures to completely remove such GMO from zone(s) other than those authorized; and
2. Measures to protect the human health and the environment, in case of an undesired release event.

The applicant shall clearly differentiate the measures and procedures to be performed during such release from those to be carried out thereafter.

VII. Authorization number issued by the Secretariat of HEALTH when the GMO is intended for human use or consumption, or when intended for food processing for human consumption, or when it is intended for public health purposes or destined for bioremediation. In the event that there is no authorization in place upon filing the permit application, the applicant may submit the same at a later time attached to a free format written document stating the authorization number;

VIII. In the event of GMO importation, legalized copy or apostille of the copy of authorizations or official documents evidencing such GMO is permitted

according to the laws in the country of origin, at least for its experimental release and its translation into Spanish. The competent Secretariat, if deemed needed thereby, may request a simple copy of the applicable legislation in force in the exporting country translated into Spanish;

IX. The proposal for the term of such permit and elements used for determination thereof, and

X. The information determined by the NOMs for each specific case.

Article 18. In accordance with the provisions set forth in Articles 46 and 53 of the Law, the holders of the experimental release permits and to release in a pilot program shall inform by submitting a report, the Secretariat issuing such permit, on the results of any release carried out when it is so provided for in the relevant permits. The report shall include the following:

I. Guidelines of the proposed protocol for the experimental or pilot program release;

II. Phenotypic changes of the GMO as regards its acclimatization to the release area;

III. Effects of selection genes and potential effects on biodiversity;

IV. Biochemical and metabolic characterization of every product in the new gene with respect to its activity, degrading products or by-products, secondary products and metabolic paths;

V. Changes in the GMO competitive capability as compared to its unchanged counterpart, including survival and reproduction, production of reproductive structures, latency periods and length of life cycle;

VI. Potential effects on the environment and biological diversity due to the GMO release, including the protocol used to set out such potential effects;

VII. Effects of exploitation and usage practices, and

VIII. Bibliographic reference on the submitted information, if any.

The competent Secretariat may provide for in any such permits and on a case-by-case basis, the specific requirement for the contents of the result reports. Regarding GMOs releases under the responsibility of SAGARPA such Secretariat shall take into account such stipulations set forth in the binding authorized opinion issued by the SEMARNAT according to the Law and these Regulations.

Article 19. The information that shall be attached to the application for permits to release GMOs into the environment pursuant to Article 5, Article 6, and Article 7 of these Regulations, shall be the following:

- I. Identification data of the experimental release permit and of the release permit in the pilot program, or simple copy of each of the above-cited permits;
- II. Description of the area where the release shall be performed and which shall consist in the following:
 - a) Location, in UTM coordinates of the polygon(s) where such release will be carried out;
 - b) Municipality(ies) where each of such polygon(s) are located; and
 - c) State(s) where each of such polygon(s) is located.
- III. Reference and considerations on the result reports for experimental release and pilot program release performed, in terms of the permits referred to in the above fraction.
- IV. Specific instructions or recommendations for transportation in accordance with NOMs provided for in Article 76 of the Law, as well as for storage, and as applicable, for handling;
- V. Conditions for their release and commercialization, if needed.

- VI.** Considerations about the risks of technological options in place in order to fight the problem for which the GMO was produced, in case such options exist.
- VII.** The information held by applicant, if applicable, on data or marketing results of the same GMO in other countries;
- VIII.** In the event of GMO importation, legalized copy or apostille of the copy of authorizations or official documents evidencing such GMO is permitted according to the laws in the country of origin, at least for its experimental release and its translation into Spanish.
- IX.** The competent Secretariat, if deemed needed thereby, may request a simple copy of the applicable legislation in force in the exporting country translated into Spanish, and
- X.** The information determined by the NOMs for each specific case

Chapter III

On the resolution of applications for permits and terms thereof

Article 20. The competent Secretariat shall issue a resolution to the applicant regarding its application for permit to release including issues regarding importation within the next maximum terms and shall be effective as from the business day following that on which the respective application is admitted.

- I.** For the experimental release into the environment, six months;
- II.** For the release into the environment in pilot program, three months, and
- III.** For the commercial release into the environment, four months.

It is understood that the application is admitted in the events where the application has been received and the information is complete pursuant the provisions of Article 8, last paragraph of these Regulations.

Article 21. Under the provisions set forth in Article 35 of the Law, only in the event that the authorization from the Secretariat of HEALTH is needed, and the same has failed to issue such resolution yet, the term to issue the resolution on the permit application shall be extended in such a manner that the competent Secretariat may resolve within ten business days following that on which the interested party evidences his/her obtainment of such authorization in the relevant file.

Article 22. The term for permits to carry out the experimental release and release in a pilot program shall be proposed by the applicant together with the relevant substantiation in agreement with Articles 16 section VIII, and Article 17, section IX hereof.

The competent Secretariat may limit the proposed term by reviewing the elements of the file.

Regarding the permit to carry out the commercial release, the term shall be indefinite.

Permits shall expressly include their respective terms.

Once the relevant permit is granted, the competent Secretariat may change the term thereof whenever the information provided by the interested party concludes that serious and irreversible damages shall be prevented to the biological diversity or vegetal, animal or aquatic health, and it must identify in any such resolution those damages to be prevented and shall state the scientific reasons proving such change is reasonable.

TITLE THREE
On the authorizations
Chapter I
General Provisions

Article 23. Those who intend to get an authorization for any of the GMOs referred to in Article 91 of the Law shall submit with the Secretariat of HEALTH, a written application together with the information provided for in Article 31 of these Regulations. Such application shall be submitted in original and simple copy for acknowledgment of receipt purposes.

Article 24. A single application shall be submitted for each GMO and shall include the following information:

- I.** Name, corporate or firm name of the applicant, and if applicable, the legal representative's name;
- II.** Domicile to listen and receive notices, as well as the name of the person(s) authorized for the reception thereof;
- III.** E-mail address to receive notices in case that the applicant desires to be notified through these means;
- IV.** Type of GMO pursuant to the sections of Article 91 of the Law and the reasons for such request;
- V.** State the body of the Secretariat of Health to which the application is addressed;
- VI.** Date and place, and
- VII.** Signature of the interested party or legal representative, or if applicable, fingerprint.

The applicant shall attach to such application those documents evidencing the legal capacity thereof.

In the event of having the registry identification number for authorized individuals, it may state such number in the written application without the need to entry such information set forth in sections I, II and VII of this Article, and neither those documents needed to prove its legal capacity, except for the information provided for in sections III, IV, V and VI hereof.

The applicant shall not be obliged to provide any additional information nor to deliver additional sets of documents previously delivered to the Secretariat of HEALTH; provided that it states the identification data of the written document where such information was stated or the written document to which such information was attached, and that the new procedure is performed thereby before such Agency.

Application shall be submitted with two data mass storage devices including the electronic version of the application filed in writing, as well as all the additional information and documents including the information and requirements provided for by the Law, these Regulations, and the NOMs.

Such electronic version shall be submitted in the electronic format resolved by the SECRETARIAT OF HEALTH by means of a resolution published in the Official Gazette of the Federation.

Article 25. Documents and information referred to in Articles 23 and 24 of these Regulations shall be submitted in Spanish. In the event it is drafted in a different language, the versions in both languages shall be attached; and in case of dispute as regards the contents, the statements made in the language of origin shall prevail.

The interested party may clearly identify in the information provided, such data regarded as confidential, according to Article 70 and 71 of the Law.

Article 26. The applications for authorization shall be submitted with the Secretariat of HEALTH together with their relevant attachments. The reception date and hour shall be entered in the original document of the application and in its acknowledgement of receipt.

Article 27. The term provided for in Article 95 of the Law to issue the authorization shall start to elapse as from the business day following that on which the application is admitted.

Article 28. Once such application is admitted, the SECRETARIAT OF HEALTH shall assess the data and documents submitted with the application in order to resolve whether they comply with the information and requirements stipulated in the Law, these Regulations, and other applicable provisions. If needed, such Secretariat shall notify the applicant in writing and for one sole time in order to remedy such omission.

The term to carry out the assessment and require from the applicant such information or requirements failing to comply with the provisions of the Law, the Regulations, and other applicable provisions shall be thirty business days as from the business day following that on which the application was admitted for procedure.

Article 29. The applicant shall have a twenty business-day term as from the day following that on which the notification becomes effective to meet the requirement referred to in the above Article. Throughout this term the terms to resolve on the application for authorization shall be suspended and resumed the business day following that on which the applicant complies with such requirement.

Once the relevant term is elapsed and the applicant provides no remedy for the notification made, the Secretariat of Health shall reject such procedure.

Article 30. Once the notification referred to in Article 28 hereof has been provided or else, in the event that the notification fails to be provided to the applicant or if notified out of term or in terms other than those provided for in such Article, the authority may not reject the procedure by arguing the incompleteness thereof.

For purposes of the provisions set forth in Article 95 of the Law, it is understood that the application was received and the information complete in the cases where once the application is submitted, no notification is provided or if the notification is made, the same is taken into account by the applicant, without prejudice to the authority regarding the powers vested thereupon by Article 96, section II of the Law.

Chapter II

On the requirements for and the resolution on applications for authorizations

Article 31. The information to be attached to the application for authorization of GMOs in accordance with Article 23 and Article 24 of these Regulations shall be the following:

I. Study of potential risks that the human use or consumption of the GMO in question may represent to human health, which shall include scientific and technological information about its safety, and shall include the following:

a) Recipient organism, whether vegetal, animal or microorganism:

1. Identification;

2. Most recent taxonomic designation;

3. Origin, history of safe use in foods, previous experience in use or consumption;

4. Pathogenicity associated to genders and species, any suitable evidence of the production potential of toxic compounds or anti-nutrients; and

5. Indication on the presence of plasmids, transposons and integrons containing antimicrobial-resistant genes.

b) In relation with each gene donor organism:

1. Most recent taxonomic classification;

2. History of use;

3. Origin, and

4. Indication on the presence of plasmids, transposons and integrons containing antimicrobial-resistant genes.

c) For the case of genetically modified microorganisms, whether they are donors or recipients:

1. Gender, species, subspecies, strain and common name of recipient;

2. Genetic stability, potential immunogenic impact and potential impact on human health, capability to form spores or other survival structures, and

3. Infectivity, virulence factors and range of recipients potentially susceptible to being infected.

d) About the introduction of genetic material:

1. Function of introduced DNA;

2. Location and arrangement of genetic material;

3. For every DNA that is introduced, the following shall be described: DNA sequence or restriction map, characterization of each genetic component including marking genes, regulating elements, promoters, terminators and others having an effect on DNA function;

4. Detailed description of transformation method and amount of codifier sequences;
 5. Regulation of gene expression, identification of any reading frame opened within the inserted DNA or created by changes on the adjacent DNA in the chromosome;
 6. Stability of such modification, and
 7. Intermediary host organisms.
- e) Whenever a marker gene is used as an element for organism selection:
1. Reasons for selecting such marker, and
 2. In case it is a gene conferring antimicrobial resistance, its use must be substantiated and foundations laid as to the fact for not selecting a different marker gene.
- f) As regards the GMO:
1. Organization of the inserted genetic material and methods used for its characterization;
 2. In case that truncated portions have been inserted, their size, action mechanism of the expression product for inserted genes shall be established;
 3. Genetic products or transcription analysis or analysis of expressed products to identify any new substance that may be present in the relevant food; or in the case of organisms intended for bioremediation in the environment or public health, any side effect in GMO's biochemistry, physiology and metabolism;
 4. Stability of genetic construction under different processing conditions and expression of new materials or change in native materials, and
 5. Characterization, sensibility and specificity of designated action on the expression products of inserted transgenes.

g) Whenever genetic modifications change the expression of natural constituents or metabolites, information shall be provided as to the potential side effects on the related metabolic paths;

h) On the expression of transgenes:

1. Gene expression kinetics in the modified organism;
2. In the case of vegetables, expression level at different plant structures;
3. Demonstration whether or not the effects sought with such modification have been accomplished, and if every expressed characteristic is inherited with stability in the dissemination amount needed for their use in food production, bioremediation or public health and if they are in agreement with inheritance laws;
4. State if there is information suggesting that one or more genes in the recipient organisms has been affected by such changes or by the genetic exchange procedure, and
5. Size and number of copies of all detectable insertions, both those complete and truncated insertions.

i) Detection and identification methods of the GMO, including infrastructure required for their identification, adjuvants required for extraction, purification and material detection methods, primers sequences and specific event probes to detect transgenic DNA, at least 300 pb aside the insertion site, specific antibodies for exogenous protein, and reliability level for each method. Attach samples of positive and negative controls used. In the case of genetically modified microorganisms, a detailed description shall be provided as to the identification method that allows their clear detection, by grounding their selection in their sensibility, specificity, and reproducibility;

j) Whenever the GMO is used as a foodstuff or intended for food processing:

1. Product description;
 2. Proposed use by stating in detail its processing information;
 3. Any change introduced into the GMO that may change the way it interacts with alimentary matrix, and as applicable, in the intestinal lumen and with the microorganisms coexisting the intestinal lumen;
 4. Development of transgene expression during the life cycle of the plant and sections where the insertion is expressed, and
 5. Substantial equivalence studies applied to use and consumption conditions in Mexico which shall include:
 - i. Content of true protein, nonproteic nitrogen, amino acids profile;
 - ii. In case that a new protein is introduced: presence and level at different sections of the plant and in the proposed food, consumption evidences in other foods, processing effects, biological function, digestibility;
 - iii. Qualitative and quantitative composition of total lipids;
 - iv. Composition of carbohydrates fraction;
 - v. Qualitative and quantitative composition of vitamins;
 - vi. Presence of antinutritional constituents;
 - vii. Stability during storage, in particular degrading of nutrients and nutriments bioavailability, and
 - viii. For each case, the impact of changes on nutritional constituents that might affect the global profile of nutrients shall be determined.
- k)** In the event of genetically modified microorganisms, procedure by means of which raw materials are transformed into the final product, step by step and making special emphasis in the most significant parameters to characterize the final product as regards safety and nutritional features.

l) Complete toxicity studies:

1. Severe toxicity;
2. Subchronic toxicity;
3. Chronic toxicity in the events where the subchronic toxicity study assumes or proves any long-term risk for the health of every expression product of transgenes, depending whether they are intended for human use or consumption, bioremediation or public health;
4. In the event they are intended for food or food processing, studies on the food constituents or specific constituents that may be changed as a result of the genetic modification, and
5. Whenever transgenic protein obtained from bacterial cultures is used for bioassay purposes, prove shall be established that the protein expressed in the GMO has the same molecular weight and immunoreactivity as that of the microbial protein.

m) Complete allergenicity studies. Suitable criteria used shall include aspects with respect to:

1. Origin of the transferred genetic material;
2. Homology of amino acid sequences between the new protein and known allergens;
3. pH effect or effect of enzymatic digestion;
4. Stability against temperature or elaboration;
5. Post-transduction modifications, and
6. Whenever, and notwithstanding that there is no homology between the transgenic protein and known allergens, but the quoted tests as to enzymatic digestion, pH and temperature or elaboration stability prove their allergenic

potential, information shall be provided as to the cross IgE reactivity analysis between a new expression protein and a known allergen;

n) In case of events with combinations of genes, parental events involved in the production of such event shall be previously authorized. The information that must be submitted in this specific type of GMOs includes:

1. Specification of the following categories:

i. Category 1. Parentals with non-related phenotypic characteristics;

ii. Category 2. Parentals with related characteristics but the action of which is derived from different pathways or are included into different ways of action, and

iii. Category 3. Parentals with characteristics related to the same metabolic or biosynthetic pathway.

2. Procedure applied to obtain the event with combination of genes, including genotypic and phenotypic characteristics of its parental lines:

i. Metabolic pathways where each codified transgenic protein act in such event together with genes combination.

ii. Studies on stability of inserted genes, and

iii. Substantial equivalence studies, and

II. In the event of applications to authorize the importation of a GMO for the purposes referred to in Article 91 of the Law, the information and documents evidencing that the GMO is authorized according to the laws in the country of origin, or failing which, the statement by the interested party about the nonexistence of such condition and the submittal of evidencing elements supporting that the SECRETARIAT OF HEALTH may resolve the application for authorization, and

III. Every other requirement determined by the SECRETARIAT OF HEALTH and the NOMs derived from the Law.

Article 32. The SECRETARIAT OF HEALTH shall resolve on the application for authorization within a term not greater than six months as from the business day following that on which the application is admitted.

It is understood that the application is admitted in the events where the application has been received and the information is complete pursuant the provisions of Article 30, paragraph two of these Regulations.

TITLE FOUR

On the reassessment of negative resolutions and review of permits and authorizations

Chapter I

On the reassessment of negative resolutions

Article 33. For the assumptions stipulated by Article 67 and Article 98 of the Law, the application for reassessment of a negative resolution about a permit or regarding an authorization shall be submitted with the issuing authority and shall include such elements based on which the intention of the applicant is supported in the same written document for reassessment.

In the reassessment written document, the applicant shall state:

- I. The identification data of the resolution and date of issuance, and
- II. The arguments and elements proving that its application complies with the assumptions provided for in Article 67 of the Law.

Article 34. In the events where the permit to release a GMO into the environment is rejected in view of the fact that the SECRETARIAT OF HEALTH failed to grant the relevant authorization, the applicant shall concurrently submit with the competent Secretariat and the SECRETARIAT OF HEALTH, such application for reassessment. However, in order that the competent Secretariat rejecting such permit may resolve on the application for reassessment, the application submitted with the SECRETARIAT OF HEALTH must have been resolved.

Within three business days following that on which the relevant reassessment is resolved, the SECRETARIAT OF HEALTH shall deliver a copy of its resolution to the competent Secretariat that negatively resolved the application for permit or application for authorization, in order that the latter may resolve on any such reassessment within the following five business days.

Article 35. In the event that the application for permit may have been rejected based on the resolution by the SEMARNAT or in the opinion by the SAGARPA, the competent Secretariat that resolved on the application for permit shall deliver the application for reassessment to the Secretariat responsible for issuing an authorize or expert opinion within a term not greater than three business days as from that on which the applicant has filed its application for reassessment.

Likewise, the application for reassessment shall be delivered to the Secretariat with obligation to issue any such authorized or expert opinion, whenever from the new information stated in the reassessment issues are derived that the Secretariat issuing such authorized or expert opinion should be aware of.

The Secretariat with the responsibility for issuing the authorized or expert opinion shall have a term not greater than one month as from the day following that on which the application for reassessment was delivered thereto, in order

to issue its authorized or expert opinion to the competent Secretariat that resolved on the application for permit.

Article 36. The Secretariat negatively resolving on the application for permit or for authorization shall resolve on the application for reassessment in a term not greater than two months as from the business day following that on which the applicant delivers the relevant application for reassessment.

Chapter II

On the review of permits and authorizations

Article 37. The competent Secretariats and the SECRETARIAT OF HEALTH may review the permits and authorizations granted within the scope of their respective responsibilities in the event of any of the assumptions provided for in Article 69 and Article 98 of the Law.

The review of permits and authorizations granted by such Secretariats shall be performed in accordance with the following procedure:

- I.** The reviewing Secretariat shall notify the holder of the permit or authorization on the commencement of the reviewing proceeding and shall provide the grounds and reasons to start any such proceeding;
- II.** The holder of the permit or authorization shall have fifteen business days to state whatever may be in its best interest according to the law and submit any convincing element and that may be regarded as evidence;
- III.** Once any such statements and evidence are received from the holder of permit or authorization, or without any of them, the reviewing Secretariat shall commence the assessment proceeding and shall confront any such information in order to issue the relevant resolution;

IV. The resolution that may devolve upon the review of the permit or authorization may:

- a)** Keep such permit in same terms as it was granted;
- b)** Change the conditions under which it was granted;
- c)** Suspend any effects thereof, or
- d)** Revoke such permit, and

V. The reviewing Secretariat shall have thirty business days to issue the relevant resolution, it shall be made known to the other Secretariats, and to the holder of the permit or authorization subject matter of such review; save for the case of paragraph a), section IV of this Article, in which case only the holder of such permit or authorization shall be notified.

Article 38. Whenever the permit is granted by the SAGARPA and the SEMARNAT holds new scientific or technical information that may allow the setting out of potential risks to the environment or biological diversity, this agency shall made such fact known to the SAGARPA in order to start the reviewing proceeding referred to in the above Article.

Article 39. - Throughout the assessment proceeding referred to in section III, Article 37 of these Regulations, the SEMARNAT shall review its authorized opinion based on the new scientific or technical information and, if needed, it shall change its authorized opinion. The authorized opinion issued by the SEMARNAT shall be binding for the resolution on the review proceeding carried out by the SAGARPA.

Article 40. The review of permits and authorizations conducted by competent Secretariats and the SECRETARIAT OF HEALTH under their respective scope of responsibilities and under the terms of the Law and these Regulations shall be carried out regardless of the safety and urgent application measures that

may determine such Secretariats themselves in accordance with Article 115 of the Law.

TITLE FIVE

On the importation and exportation of GMOS intended for release into the environment

Sole Chapter

Article 41. Prior to the importation of GMOs intended to release into the environment, the permit corresponding to the relevant release shall be secured; this permit shall become effective as importation permit as provided by the Law.

Article 42. The notice referred to in Article 72 of the Law shall be made in writing and comply with the requirements provided for by international treaties and agreements of which Mexico is a part, as well as those requested by the authorities in the GMOs country of destination.

TITLE SIX

On the biosafety internal commissions

Sole Chapter

Article 43. Biosafety internal commissions referred to in Article 74, section III of the Law shall be constituted by at least three individuals with experience and knowledge as to the activities for contained use of GMOs.

Article 44. - Biosafety internal commissions shall be permanent and their members may be replaced according to the internal rules they may issue to

operate and shall be approved by the enabled authority of those who perform activities for the contained use of GMOs.

Article 45. Biosafety internal commissions shall:

I. Issue biosafety rules that must include, among other aspects, issues relating to prevention of accidental releases and surveillance in the compliance with the rules and good practices;

II. Define good scientific research practices that must be complied with;

III. Provide scientific and technical expert advice to the persons in charge of the activities for contained use of the GMO, in their material scope of responsibilities;

IV. Issue a technical opinion regarding the biosafety training aspects and proposed research, with the prior review of the facilities and materials to be used for the secure handling of the GMO and involved methods;

V. Guarantee the security of facilities where the activities for contained use will be conducted, as well as the safety handle the GMO, and

VI. Guarantee the physical and biological integrity of the exposed personnel and of the individuals performing the contained use.

TITLE SEVEN

On the scientific and technical committees

Sole Chapter

Article 46. The scientific technical committees may provide support to the Secretariats as to the applications for permits and for authorizations, as well as regarding notices to be provided; they shall be formed by individuals with

scientific or technological knowledge with experience in issues of GMO assessment, control and risk management, whether for the human health, environment and biological diversity or animal, vegetal or aquatic health; or issues concerning modern biotechnology applied to research, creation and development of this type of organisms.

The appointment of such member falls under the responsibility of the Head of the Secretariat where support is provided or public officer upon whom such faculty is vested thereby.

Article 47. Committees referred to in the above Article shall issue their operation rules with the prior validation by relevant Secretariats.

Article 48. The scientific technical committees shall behave in strict compliance with the principles of objectivity, impartiality and legality for the issuance of expert or authorized opinions requested therefrom, by complying with provisions regarding protection of confidential information set forth by the relevant judicial ordinances.

TITLE EIGHT

On the restricted zones

Sole Chapter

On the centers of origin and genetic diversity

Article 49. The agreements through which the centers of origin and genetic diversity are established referred to in Article 86 of the Law shall include:

- I. List of species, including scientific and common name;
- II. Taxonomic classification;
- III. Polygonal of the geographic area(s) in UTM coordinates, and

IV. Measures needed to protect such species.

The agreements shall be fostered either by the SEMARNAT or the SAGARPA, and issued jointly by both Secretariats.

TITLE NINE

On the Information about Biosafety

Chapter I

About the National System of Information on Biosafety

Article 50. The National System of Information on Biosafety shall be under the responsibility of the Executive Secretariat. The information collected by such System shall be available through the CIBIOGEM's webportal and updated on a permanent basis.

Article 51. The National System of Information on Biosafety shall include:

- I.** The information of the Registry according to the provisions set forth by Article 56 of these Regulations;
- II.** National statistics on biosafety matters and GMO;
- III.** The restricted zones and municipality(ies) where it is located, by differentiating:
 - a)** Centers of origin and of genetic diversity per species; in UTM coordinates;
 - b)** Natural protected areas of Federal competence in the coordinates stipulated in their incorporation documents;
 - c)** Natural protected areas of local competence in the coordinates provided for in their incorporation documents in case that the local authorities desire such areas may be found in the National System of Information on Biosafety, and
 - d)** Zones free of GMOs, in UTM coordinates.

IV. Relevant reports and documents resulting from the scientific, academic technical or any other type of works in biosafety issues including GMOs safety performed by firms or individuals, domestic or foreign;

V. The information about formats for the notices to be provided and referred to in Article 78 of the law and the communications provided for by Article 59 hereof; the measures taken by holders of permits or by those performing activities of contained use, and the measures taken by the authority to deal with accidental releases or any change in the release and which may increase potential risks for the environment and biological diversity by conducting activities of experimental release or release in pilot program;

VI. The information regarding application for permits for purposes of provisions set forth in Article 33 of the Law, and

VII. The annual report referred to in Article 53 of the Regulations.

Article 52. The Executive Secretariat shall establish the information-technology system to receive the information referred to in the above Article, in order to include it in the National System of Information on Biosafety.

The following entities shall be responsible of incorporating such information technology system within the terms provided therefor:

I. The Secretariats, according to the provisions of Article 57 hereof, for purposes of information stipulated in section I of above Article;

II. The competent Secretariat which has fostered the Agreement to decide on a center of origin and of genetic diversity for purposes of the information provided for in section III, paragraph a) of the above Article and shall do the above within five business days following that on which the Agreements are published;

III. The SEMARNAT, for purposes of the information provided for in section III, paragraph b) of above Article, and shall do so within the five business days following that on which a Federal natural protected area has been created;

IV. The SAGARPA for purposes of the information referred to in paragraph d), section III of the above Article, within the five business days following that on which the zone free of GMOs has been created;

V. The agencies and entities of the federal public administration, national research centers and persons developing biotechnology that produce relevant documents on biotechnology,

VI. The competent Secretariat admitting an application for permit for the purposes of section VI in the above Article, and

VII. The competent Secretariat receiving a communication in terms of Article 59 hereof within five business days following that on which there is a decision about the measures to be adopted by the competent Secretariat.

For purposes of section II of the above Article, the Executive Secretary shall request from the Secretariats and from the consultancy and opinion bodies at the CIBIOGEM, such information that may be needed to embody the statistics.

The Secretariats, consultancy and opinion bodies of the CIBIOGEM shall respond to such applications by entering into the information technology system referred to herein, such information and documents required by the Executive Secretariat.

Chapter II

On the follow up on the information about biosafety

Article 53. The CIBIOGEM shall prepare and publish in its Website the annual report of the general condition in the country as to biosafety issues, by taking into account at least such statistics resulting from the information included in the Registry regarding applications, permits, authorizations and notices, as well as the information about actions taken in compliance with the Cartagena Protocol.

Article 54. The inquiry and participation and indigenous people and communities settled in the zones where the GMOs release is intended shall be carried out in accordance with the methods decided by the CIBIOGEM for such effects.

Chapter III

On the Registry

Article 55. The Registry is part of the National System of Information on Biosafety, shall be public and responsible for the Executive Secretary. It shall have as purpose the registration of information regarding activities with GMOs, as well as the bodies themselves that are subjected to the provisions of the Law and these Regulations.

Article 56. The following shall be entered into the Registry:

- I. Applications for permits and authorizations;
- II. Resolutions on permits and authorizations by marking as different what GMOs are being imported, as well as the resolutions referred to in Article 37, section IV of these Regulations;
- III. Suspensions and revocations;
- IV. Contained use Notices;
- V. Additional requirements and measures for the notices provided for in Article 84 of the Law;
- VI. Communications referred to in Article 50 of these Regulations, and
- VII. Every other notice that may be stipulated by applicable provisions.

TITLE TEN
On the GMOs Lists
Sole Chapter

Article 57. The lists of GMOs referred to in Article 103 and Article 104 of the Law shall be issued by the competent Secretariats and the SECRETARIAT OF HEALTH by means of a notice to be published in the Official Gazette of the Federation. Such lists referred to in sections I and II, Article 103 of the Law, shall be published jointly among SEMARNAT, the SECRETARIAT OF HEALTH and the SAGARPA.

The lists referred to in this Article shall be published within the ten first business days of February, each year and in the Official Gazette of the Federation.

Once the lists are published, they may only be amended due to any of the reasons provided for in Article 58 hereof, by means of a notice to be published in the Official Gazette of the Federation within ten business days following the verification of the relevant cause for such modification.

A systematic approach shall be followed in the publications of the annual lists and include each GMO included in previous lists, in terms of the provisions of Article 103 and Article 104 of the Law.

Article 58. The following are motives to change the lists referred to in the above Article:

- I. The resolution for an authorization or permit;
- II. Change on the legal condition of the GMOs and referred to in sections I and II, Article 103 of the Law, and

III. Changes on the events referred to in Article 104, section II and last paragraph of the Law.

TITLE ELEVEN

On the inspection, surveillance, safety measures or urgent application measures and on the infringements and penalties

Sole Chapter

Article 59. In case of an accidental release the holder of permits or those performing activities of contained used shall communicate such fact to the Secretariat issuing the permit or to which the notice was submitted within twenty-four hours after such fact becomes known. The competent Secretariats shall set out in the permit the means through which the holder of permit shall perform such communication, as well as the formats for the notices referred to in Article 72 of the Law.

Immediately after being cognizant of the accidental release, the Secretariat issuing the permit or which received the notice shall inform the other Secretariats about the accident, and the risks or effects that may be caused or that may have been caused to the human health, the environment, biological diversity or animal, vegetal or aquatic health. Such agencies may, within the scope of their respective responsibilities, impose the safety measures or urgent application measures they deem necessary to fight against such condition.

In addition to the communication provided for in the first paragraph hereof, within three business days after the condition described in the above paragraph becomes known, the holder of permit or the person performing activities of contained use shall submit a written notice with the Secretariat issuing the permit or that received the permit, and it shall include:

I. Identification data of the permit or notice;

- II. Polygon where accidental release occurred, located in UTM coordinates;
- III. Circumstances and estimated date of the accidental release;
- IV. Estimated amounts of GMO accidentally released;
- V. Information in possession of the holder of permit or the person performing activities of contained use on the potential adverse effects for the biological diversity and human health;
- VI. Measures to deal with and to control such risk applied by or to be applied by the holder of permit or the person performing activities of contained use; and
- VII. Name and telephone of the person who shall act as contact.

Article 60. The Secretariats may, within the scope of their respective responsibilities, establish any or some of the safety measures or urgent application measures provided for in Article 115 of the Law. Once the inspection certificate is received by the authority ordering the inspection and surveillance actions shall, by means of a personal notice or through certified mail acknowledge receipt requested, require the interested party to carry out on its sole account and cost, such safety measure or urgent application measures that may be applicable, also stating the terms for the compliance therewith.

Article 61. Whenever repatriation is imposed as safety measure, the interested party shall cover the cost thereof and it may charge the costs incurred by it against the one accountable for the infringement.

Article 62. If as a result of an inspection or surveillance visit, there is an order to impose safety measures or urgent application measures, the party subject to such inspection shall notify the competent Secretariat in compliance with each of those measures within a five business-day term as from the date of expiration of the term granted to execute each of them.

Article 63. Whenever the competent Secretariat summons the presumptive infringer and it appears by means of a written document accepting the failures included in the inspection certificate, the Secretariat shall proceed, within the next twenty business days, to issue the respective resolution.

Article 64. The administrative resolution issued shall provide for, in addition to the infringements and penalties, the measures to be carried out to correct failures or deficiencies observed during the inspections conducted and the term granted for the compliance therewith in term of the Law.

TITLE TWELVE

On the Maize special protection regime

Sole Chapter

Article 65. The maize special protection regime shall be made up by the legal provisions in relation with biosafety set out by the authority.

TRANSITORY ARTICLES

ONE. These Regulations shall become effective as from the day following its publication in the Official Gazette of the Federation.

TWO. The persons currently performing activities of contained use of GMOs intended for training and scientific and technological research shall assemble their respective internal biosafety commissions within thirty days after these Regulations become effective.

THREE: The Holders in charge of the SECRETARIAT OF HEALTH, the SEMARNAT and the SAGARPA shall publish in the Official Gazette of the Federation the relevant resolutions by means of which the general public is informed that the application for permits and for authorization, as well as the

notices in biosafety issues shall be received through the WebPages enabled for such effect. Such publication shall be made within a term not greater than twelve months as from these Regulations becoming effective.

FOUR. In order to fully comply with the provisions of Article 51, section III, paragraph b), and Article 52, section III of these Regulations, the SEMARNAT shall include in the information technology system determined by the Executive Secretary the information regarding natural protected areas created up to such date on which these Regulations become effective. For such effect it shall have a three-month term as from the day following on which these Regulations enter into force.

FIVE. Without prejudice to the provisions of transitory Article eight of these Regulations, the application for permits submitted before they become effective, and those submitted until the resolutions provided for by Article 86 of the Law are issued, shall be resolved by the competent Secretariat prior consultation with the institutions provided for in the afore-cited Article.

SIX. While the Resolutions referred to in Article 78 of the Law are issued, the official formats shall include the following:

- I. Name, corporate or firm name of the applicant, and document evidencing its legal capacity. In the event there are more than one individual in charge of the biosafety internal commission, the names of every person in charge shall be included;
- II. Name of legal representative, if applicable;
- III. Domicile to listen and receive notices;
- IV. E-mail address to receive notices in case that the applicant desires to be notified through these means;
- V. Place where the contained use shall be performed, in UTM coordinates, as well as the description of confinement facilities and biosafety measures;

VI. Purpose and objective of contained use;

VII. GMO information including scientific, common and commercial name, and

VIII. The means through which the communication referred to in Article 59 of these Regulations shall be carried out.

IX. The registration number of authorized person, if it holds any. In this case, the information referred to in sections I to IV shall not be submitted.

The notice shall be submitted in the events provided for in Article 79 and Article 80 of the Law.

SEVEN. Those actions derived herefrom shall be executed with charge to the budget approved by the Agencies and Entities in charge of their application.

EIGHT. Within sixty days after these Regulations become effective, the SEMARNAT and the SAGARPA shall issue the legal provisions relating to the biosafety which shall constitute the special protection system referred to in Article 2, section XI of the Law and that may be needed to resolve on the applications for permitting the release of maize.

The SEMARNAT and SAGARPA may request the opinion from the CIBIOGEM as regards the drafting of the legal provisions set forth in the above paragraph.

The applications for permitting the release of maize shall be resolved by the competent secretariats according to the stipulations of the first paragraph in this Article.

NINE. Members of CIBIOGEM shall, within a year after these Regulations become effective, provide for the public policies for protection, use, development and sustainable usage of species of which Mexico is the center of origin and genetic diversity.

TEN. Every provision opposing these Regulations is hereby invalidated.

Provided for in the Presidency of the Federal Executive Branch, in Mexico City, Federal District, as of the fourteenth day of March, year two thousand and eight.- **Felipe de Jesús Calderón Hinojosa**.- Signature.- The Secretary of Environment and Natural Resources, **Juan Rafael Elvira Quesada**.- Signature.- The Secretary of Economy, **Eduardo Sojo Garza Aldape**.- Signature.- The Secretary of Agriculture, Livestock-raising, Rural Development, Fishery and Food, **Alberto Cárdenas Jiménez**.- Signature.- The Secretary of Public Education, **Josefina Eugenia Vázquez Mota**.- Signature.- The Secretary of Health, **José Ángel Córdova Villalobos**.- Signature.