COMISSÃO TÉCNICA NACIONAL
DE BIOSSEGURANÇA
[National Technical Biosafety Committee]

NORMATIVE RESOLUTION No. 5, of March 12, 2008

The *Comissão Técnica Nacional de Biossegurança – CTNBio* [National Technical Biosafety Committee], pursuant to its legal and regulatory duties, in compliance with the provisions of subsection II, article 14 of Law No. 11105, dated March 24, 2005, hereby resolves:

CHAPTER I

PRELIMINARY AND GENERAL PROVISIONS

Article 1. The commercial release of Genetically Modified Organisms - GMO and its derivates shall comply with the rules set forth in this Normative Resolution, as well as the authorization in written issued by the CTNBio, in compliance with all conditions imposed in the aforementioned authorization.

Sole Paragraph. The CTNBio authorization does not exempt the applicant from complying with other legal obligations in the country applicable to the subject matter of the application.

Article 2. That derivative which GMO has been approved by the CTNBio shall not be submitted to assessment and issuance of technical opinion by this latter.

Article 3. The GMO with the same genetic construction as that used in GMO of the same specie with technical opinion favorable to the commercial release in Brazil, shall be submitted to simplified analysis, aiming at its release, at the CTNBio's discretion.

Article 4. At the CTNBio's discretion, subject to consultation, the assessment and issuance of a new technical opinion may be dismissed for GMOs that comprise more than one event, combined by means of classic genetic breeding and which have already been previously approved for commercial release by CTNBio.

Article 5. It shall not be included in the category of GMO derivate the pure substance, chemically defined, obtained by means of biologic process and which do not contain GMO, heterologous protein or recombinant DNA.

Sole Paragraph. The pure protein, chemically defined, shall not be considered heterologous protein, even if produced from GMOs.

Article 6. For the purpose of this Normative Resolution it shall be considered:

I - risk assessment: combination of procedures or methods, by means of which it is assessed, case by case, the potential effects of the commercial release of the GMO and its derivates on the environment and the human and animal health.

II - organism: every biologic entity able to reproduce or transfer genetic material, including virus and other classes that may be known;

III - Genetically Modified Organism - GMO: the organism whose which genetic material - DNA/RNA has been modified by any genetic engineering technique;

IV - GMO derivate: product obtained from a GMO and which has no autonomous capacity of replication or which does not have a viable form of GMO;

V - applicant: Any legal entity with a Biosafety Quality Certificate - CQB that proposes to carry out commercial release, in compliance with this Normative Resolution;

VI - legally responsible person: an individual responsible for the development of the commercial release, pursuant to CTNBio's rules.

VII - post-commercial release monitoring: a set of processes to monitor the effects of the commercial release of the GMO and its derivates on the environment and on human and animal health;

VIII - risk: probability of occurrence of adverse effect.

Article 7. The authorization for commercial release of a GMO or derivate maybe suspended or revoked by the CTNBio, at any time, in case adverse effects on the environment or on human and animal health are detected, provenly arising from the results of the post-commercial release monitoring or before proof of new scientific knowledge.

Article 8. The legally responsible person of the applicant entity and the CIBio shall be in charge of ensuring the full compliance with of this Normative Resolution.

Article 9. Whenever a commercial release of a GMO and its derivates is authorized, the applicant’s legally responsible person must communicate any non-compliance with the conditions established in the CTNBio's technical decision.

CHAPTER II

THE PROPOSAL

Article 10. The applicant shall, after CIBio's approval, submit the proposal to the CTNBio, along with:

I – application for commercial release dated and signed by the legally responsible person;

II – copy of CIBio's technical opinion on the proposal;

III – statement on the accuracy of the information provided signed by the legally responsible person;

IV – executive summary, including the abstract of the proposal;

V – information related to the GMO, pursuant to the Annex II of this Normative Resolution;

VI – risk assessment to human and animal health, in compliance with the Annex III of this Normative Resolution;

VII – risk assessment to the environment, in compliance with the Annex IV of this Normative Resolution;

VIII – monitoring plan in compliance with the Annex I of this Normative Resolution.

Sole Paragraph. The proposal shall be submitted in Portuguese, together with twenty printed copies and one digital copy.

Article 11. After the receipt of the proposal for commercial release, the CTNBio Executive Office shall inform the applicant if the documentation is complete within a thirty-day term maximum.

Article 12. The commercial release proposal filed at the CTNBio Executive Office shall have its previous abstract published in the Federal Official Gazette after registered and duly documented.

Article 13. The CTNBio shall carry out the public consultation of the proposal for commercial release, for 30 days from the publication of the previous abstract in the Federal Official Gazette. In this sense, the relevant information shall be available in the SIB, in the CTNBio portal and at its Executive Office.

Article 14. The CTNBio may carry out a public hearing required by one of its members of by a party provenly interested in the subject matter of the decision and approved by absolute majority, assuring the participation of the civil society.

§1 CTNBio shall publish in the Federal Official Gazette, in the SIB and in its electronic webpage, no less than thirty (30) days in advance, the call notice for the public hearing, including in such notice the subject matter, date, and time and venue where the public hearing will be held.

§2 The public hearing shall be coordinated by the President of CTNBio who, after exposure of the subject matter of the hearing, will open the discussions with those interested present.

§3 After the conclusion of the public hearing, the manifests, opinions, suggestion and documents shall be available to those interested at the CTNBio Executive Office.

§4 For the purposes of this article, an interested party shall be the applicant of the process or legal entity, which corporate purpose is related to the areas set forth in the main clause and in subsections III, VII and VIII of article 3 of the CTNBio internal proceedings.

§5 After holding the public hearing, CTNBio shall include the relevant biosafety subject matter in its meeting agenda, with the objective of discussing and considering the remarks and questions received.

Article 15. The proposal shall be assessed by all the CTNBio Permanent Sectorial Sub-commissions, which may request technical opinions from *ad hoc* consultants, whenever needed.

Sole Paragraph. It shall be simultaneously guaranteed, a ninety-(90)-day term to each one of the sub-commissions for analysis and preparation of the reports, and such term may be extended, for an equal period, maximum, as per CTNBio plenary decision.

Article 16. CTNBio may require supplementary information and if it become necessary to submit new documents, the applicant shall respond within a ninety-(90)-day term maximum, as of the date of receipt of the mail send to it, subject to filing of the process.

Sole Paragraph. The counting of the term set forth in the article 14 hereof shall be adjourned during the compliance with the diligences.

Article 17. The reporters of the technical opinions of the sub-commissions and of the plenary shall consider, besides the applicants' reports, the existing scientific literature, as well as studies and other documents filed in public hearings or in the CTNBio, on prior to fifteen days after the public hearing is held, including the occasional opposing vote, pursuant to article 34 of CTNBio By-laws.

Article 18. After the publication of the favorable technical decision on the biosafety of the proposal for commercial release of GMO and its derivates, CTNBio shall send copy of the process, within ten (10) business days, to the registration and inspection agencies and entities, for the accomplishment of their duties.

CHAPTER III

RISK ASSESSMENT

Article 19. The risk assessment, as defined in article 4, subsection I, hereof, shall identify and assess the potential adverse effects of the GMO and its derivates on human and animal health, on the environment and on vegetables, keeping the transparency, the scientific method and the precautionary principle.

Article 20. It shall be included in the respective commercial release proposals, the information required in Annexes I, II, III and IV of this Normative Resolution, duly supported by scientific reports of the results achieved during the planned environmental releases or from other studies, without prejudice to other pieces of information deemed relevant by the CTNBio.

§ 1 Having any doubt about the answer provided to one of the questions stated in the annexes of this Normative Resolution, the nature of the doubt shall be clarified.

§ 2 The existence of risk related to commercial release shall be declared, making explicit the prevention and mitigation measures.

Article 21. Those cases not considered for in this Normative Resolution shall be settled by the CTNBio.

Article 22. Companies that have filed their commercial release requests with CTNBio before this Normative Resolution came into force shall submit, within sixty (60) days from its publication, supplementary information or new data it deems necessary, so as to adapt its request to the conditions set forth in this Normative Resolution, and a new filing request shall not be deemed necessary.

Sole paragraph. If the sixty (60)-day term is not enough for occasional supplementation of such information, the applicant shall request additional deadline to CTNBio with its due justifications.

Article 23. CTNBio's Normative Instruction No. 20, of December 20, 2001, is revoked.

Article 24. This Normative Resolution shall come into force as of the date of its publication.

WALTER COLLI
President of CTNBio

ANNEX I

POST-COMMERCIAL RELEASE MONITORING

1. The applicant shall submit to CTNBio, for evaluation and approval, a post-commercial release monitoring plan which shall be analyzed case by case.

2. The applicant shall submit the monitoring plan along with the commercial release request and shall have a period of thirty (30) days to adjust its monitoring plan proposal for CTNBio's appraisal and approval after the publication of favorable technical decision for commercial use.

3. The monitoring shall be carried out by the applicant aiming at following the effects deriving from the commercial release of the GMO and derivates onto the environment and human and animal health.

4. The monitoring shall be carried out in strict compliance with the precautionary principle, transparence and scientific independence.

5. The monitoring shall have as guideline the use of international acknowledged scientific methodology and the use of experimental designs appropriate to the inferences to be made.

6. The monitoring plan, once approved, shall be sent by CTNBio to the registration and monitoring agencies and entities for acknowledgement and follow-up.

7. The applicant shall submit an annual report for a period of at least five (5) years on the post-commercial release monitoring and a final report after the end of the monitoring, which shall be forwarded to the inspection agencies.

ANNEX II

GMO-RELATED INFORMATION

Inform:

1. Identification of the genetic transformation event, objective and use of GMO and its derivates;

2. Taxonomic classification, from the family to the most detailed level of the organism to be released, including, when appropriate, subspecies, cultivar, pathovar, lineage and serotype;

3. Introduced genes, organisms of origin and their specific functions;

4. Vector used and its spectrum of hosts;

5. Genetic map used in the transformation process (transgene/vector), indicating the regions that specify function - promoters, cis regulatory elements, selection marker genes and origin of replication;

6. Summary of the constructions used to obtain the GMO;

7. Risk classification of the Genetically Modified Organism in compliance with Normative Resolution No. 2, of November 27, 2006;

8. Methods used to obtain the genetic modification;

9. Molecular characterization of the insert into the receptor organism, providing information related to: (1) number of copies inserted; (2) localization of the insert into the genome, when applicable; (3) gene flanking sequences; (4) nucleotide sequence of transgene insert in the GMO, indicating the regulatory elements - promoters, cis regulatory elements, poliadenilation sites, introns and exons and region where transcription ends;

10. The expression product from the inserted gene in the receptor organism, described in details;

11. General and specific GMO detection techniques, presenting corresponding methodology;

12. Inserted genes' genetic inheritance profile

13. Description of pleiotropic and epistatic effects of the inserted genes, when noticed;

14. Degree of genotypic stability, specifying the methodology used and number of assessed generations;

15. Existence of interactions with adverse effects, when two or more genes are inserted in the same GMO by DNA recombining techniques and their possible consequences;

16. Genetic modifications into the GMO that may alter its reproduction, survival, dissemination or capacity of transference of inserted genes to other organisms;

ANNEX III

HUMAN AND ANIMAL HEALTH RISK ASSESSMENT

(A) Organisms consumed as food

Inform:

1. The background of the use in food, in Brazil and in other countries of the parental or donor organism, indicating the consumption level, the processing previous to consumption and animal species feeding from these organisms;

2. Possible effects on human and animal food chain by ingesting the GMO and their derivatives;

3. Difference in the chemical and nutritional composition between food derived from genetically modified vegetables and non-modified vegetables, in natura, or after processing, and the occurrence of substantial equivalence between the GMO and its parental organism;

4. Changes on animal performance, when fed with genetically modified organisms or any of its parts, in natura, or after processing, even providing the results of the nutritional assessment on experimental animals for two generations, indicating the species used in the tests, length of experiments, physiologic and morphologic variations observed in relation to the control-groups and nutritional quality alterations, if applicable;

5. Stability to digestion and to industrial processing of the protein specified by the transgene based on physic-chemical properties;

6. The possible deleterious effects of the GMO in pregnant animals and their teratogenetic potential;

7. The conclusions of the immunologic and histological analyses of relevant tissues, especially from the digestive tract;

8. The Ability of the GMO to produce toxins or metabolites that cause adverse conditions to consumers, either animal or human ones, reporting experimental evidences;

9. Toxicological and pharmacological assessment carried out in experimental animals, describing results;

10. Similarity of the GMO expression products with know allergens, reporting on possible allergic reactions identified after GMO ingestion in the assessment carried out in experimental animals, describing the results.

(B) Microorganisms used as vaccine

Inform:

1. Disease to be controlled with the use of vaccine and host species, indicating organs colonized by the vaccine, if alive, and the parental organism host species, from which the vaccine was created;

2. Immunity level and length produced in the host species after vaccination with the GMO, informing how long one can detect the GMO in vaccinated animals or in their excrements, providing experimental evidence;

3. Possible dissemination of vaccinal organism of vaccinated animals to other unvaccinated ones or to other species, including human beings, informing the mechanisms and frequency of such event with experimental data;

4. Details, if applicable, of host susceptibility to the vaccinal organism affected by the general state (for instance, immunosuppression or concomitance of other disease) or by medicative treatment or others;

5. Experimental evidence that the vaccinal organism genetic material was entirely or partially integrated to the genome of the vaccinated host cells;

6. Possibility of a viral vaccine to return to its wild condition by recombination or complementation with other intracellular viruses, providing experimental results if such phenomenon takes place;

7. Possible deleterious effects of vaccines in pregnant animals and their teratogenetic potential, describing the efficiency and innocuousness tests carried out;

8. Possible interferences of the vaccinal organism in the efficiency of other vaccination or in subsequent immunizations against other diseases.

ANNEX IV

ENVIRONMENT RISK ASSESSMENT

(A) PLANTS

Inform:

1. Area of natural occurrence of the GMO parental organism, its ancestors and wild relatives – origin and genetic diversity centers – and ancestral or wild relative species, existing in some Brazilian ecosystem of the same genera of the non-modified parental species.

2. Cultivation and use of parental organism background in terms of safety to the environment, for human and animal consumption, informing the possibility of introgressive hybridization with sexually compatible species and possible selective advantage of the transgene;

3. Possible effects on relevant indicator organisms (symbionts, predators, pollinators, parasites or competitors to the GMO) in ecosystems where one intends to carry out its cultivation, in comparison to the GMO parental organism in a conventional production system;

4. Dispersion ability of the GMO propagation and reproduction structures besides the cultivation areas and the mechanisms of its dispersion in the air, water and soil, providing information on the pollen viability and indicating potential pollination agents and their geographic distribution in Brazil;

5. Possibility of forming long term reproduction structures in the parental organism;

6. Frequency in which the crossing of the GMO parental organism occurs, within the same species and with sexually compatible species, listing the assessed species, the techniques used and the resulting effects;

7. Resulting effects of horizontal transference to soil microbiota, if applicable;

8. Negative and positive effects impacts to target and non-target organisms that may occur with the release of GMOs, listing the assessed species, the reasons for the choice and the techniques used to demonstrate the impacts;

9. Modifications in the plant ability to add substances or remove them from the soil, due to the introduction of new traits, describing possible physical and chemical alterations in the soil and contamination of adjacent water bodies resulting from interactions with the GMO, comparatively to the conventional systems.

10. Possible modification of the GM plant biodegradability, in comparison to the parental genotype;

11. Possible resistance to chemical agents caused by the introduced traits;

12. Historic of the use of the GMO and countries in which its commercialization and planting has been authorized or denied, presenting, in such case, commercial post-release monitoring or study data, if available;

13. Changes in the GMO capacity to survive on environments different form those in which the parental organism is found, caused by new introduced traits.

(B) MICROORGANISMS

Inform:

1. The possibility of such GMO to produce spores and be resistant to desiccation.

2. Sterilizing and antimicrobial agents that act against GMOs and their mutagenic capacity to the GMO;

3. The possible effects of GMOs on water, air and soil quality;

4. Survival and dispersion of the GMO in water, air and soil;

(C) MICROORGANISMS ASSOCIATED TO ANIMALS

These issues refer to microorganisms associated to animals. The aspects referred to herein shall also take into account the ecological interactions and the host animal behavior, which could cause environmental impact.

Inform:

1. Host animal species and historic of the use of the parental organism;

2. GMO capacity to colonize other animals at any level, including feral populations and the possible effects in plants, non-host animals and the environment;

3. Traits granted by the GMO to the host species, reporting the secondary effects that may arise from the new trait granted to the host;

4. Possible alterations in the host's competitive advantage or reproductive adaptability;

5. Secondary effects of GMO release in the host and if the transgene can be transferred. In case of horizontal transference to another microorganism or to the host's cells, report the results resulting from the transference;

6. How long the GMO can last in the environment and factors that affect its survival after excreted by host animal.

(D)MICROORGANISMS ASSOCIATED TO PLANTS

These issues are related to microorganisms associated to plants and microorganisms that can be applied to modify the environment.

Inform:

1. Plant species to which GMO is associated.

Describe the interaction specificity and indicate the spectrum of other host species with which the GMO may interact;

2. Use of parental organism in agriculture, if applicable;

3. The GMO effect on the associated vegetal species, including possible secondary effects, including monitoring ways of such effects;

4. The GMO effect on the distribution and abundance of associated plant species and on other species with which the GMO may interact;

5. Interactions and effects caused by the GMO to organisms in soil benefic to plants and found in cultivation areas, reporting how often such events occur;

6. Possible effects resulting from the exchange, if applicable, of GMO genetic material with phytopathogens.

(E) ORGANISMS USED FOR BIOLOGIC CONTROL

Inform:

1. The target species of biologic control and the GMO direct effects over it compared to the effects over the parental organism;

2. Spectrum of organisms susceptible to the GMO and the susceptibility of non-target organisms to the GMO, describing the criteria employed in the choice of the assessed organisms;

3. Ways in which GMOs disperse from one individual to another one and factors that affect such dispersion;

4. Secondary effects that may occur in predators, preys, competitors, and parasites of the target species;

5. Metabolites produced by the GMO that may cause direct or indirect deleterious effects to other species by means of concentration in the food chain;

6. Resulting effects of horizontal transference to another organism, if applicable;

7. Possible genetic modifications that may occur in target organism populations as a result of the GMO use.

(F) ORGANISMS FOR BIOREMEDIATION

Inform:

1. Bioremediation target substratum and GMO effect on such substratum, when compared to the effect in the parental organism, as well as necessary additional measures to the process efficiency;

2. Substances that may be metabolized by the GMO and may not be metabolized by the parental organism;

3. Possible deleterious effects of the GMO or of its metabolites directly over other organisms or indirectly by means of the food chain concentration;

4. Mechanisms involved in the GMO dispersion and possible consequences to the environment, describing the measures used to mitigate occasional undesired dispersions.

(G) VERTEBRATES (EXCLUDING FISH)

Inform:

1. Environmental effects or about the well-being of animals deriving from the GMO release and the probabilities for such intercurrence;

2. Changes in other species characteristics caused by genetic modifications, providing details about them, if applicable;

3. Possible effects of the modified characteristics expression on the behavior, physiology and reproduction of the animal, providing details deriving from sample-animals data;

4. Existence of feral populations of the experimental species in Brazil and environmental, agricultural or sanitary damage cause by such existence;

5. Experimental data related to the crossing between the GMO and feral animals kept in captivity;

6. The effect of the new genetic material introduction on the distribution and abundance of feral populations or on their ability to cause agricultural and environmental problems, as well as to contribute to the dissemination of infectious diseases;

7. The effect of the new genetic material introduction on the gene set of feral species, including changes in the distribution of such feral populations or on their ability to cause agricultural or environmental problems, as well as to disseminate infectious diseases;

8. Management procedures and environmental factors requested for the best expression of the new trait, providing data to support the response;

9. Possibility of the GMO to cross with native species in Brazil;

10. Possibility of the new trait to increase the species ability to establish feral populations.

(H) FISH AND OTHER WATER LIVING ORGANISMS

Inform:

1. New metabolites or toxins produced by the GMO that may have a damaging effect on parasites or predators;

2. Possible adverse effects, different from those expected that may result from the GMO release, including its interaction with the ecosystem in the place where the release occurs;

3. Effects on other traits of such organism resulting from the genetic modification;

4. Possible transference of modified genetic material to other species, by means of non-conventional reproductive mechanisms, and, if applicable, provide details and describe such effects;

5. About the existence of natural population of the parental organism in the country – including rivers, lakes, dams, or costal waters, describing possible problems caused by such populations to other organisms, providing details about them;

6. Possible contribution of such modified trait to the ability of such species to colonize water habitats in the country, in case there are no natural populations of such parental organism in Brazil;

7. Occasional experimental studies on the phenotypical expression of the modified genetic material in natural occurrence organisms (for example, the crossing of the GMO with wild animals, or animals raised in captivity);

8. Possibility of the new genetic material to integrate the natural population gene set;

9. Mechanisms adopted to prevent the dispersion of GMOs to other ecosystems.

(I) INVERTEBRATES

Inform:

1. GMO effect on food chain;

2. Possible production of new toxins or metabolites by the GMO that is able to cause deleterious effects in their parasites or predators;

3. Possible adverse effects of such release in the local ecosystem;

4. Register of natural populations of the parental organism in Brazil, and, if applicable, inform their effects, either positive or negative, to agriculture, the environment and to public health;

5. Possibility of the transgene to be transmitted to other species, by means of non-conventional reproductive mechanisms, and, if applicable, provide details on the transfer mechanisms by listing the species;

6. Eventual experimental study on the phenotypical expression of the transgene in crossings of modified families with wild organisms. If so, detail the results;

7. Distribution and abundance of natural population changes by the possible integration of the transgene to the gene set of such populations, informing the possible effect of such change;

8. Mechanisms to be adopted to prevent the dispersion of GMOs to other environments.