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This is to certify that I, Marco Antônio Rochadel, Official Public Translator, designated and installed in Office according to The Official Gazette of June 23, 1982, page 5428, have received and translated, to the best of my knowledge and belief, a document with the following contents:

Ministério da Ciência e Tecnologia

GOVERNO FEDERAL BRASIL PAÍS RICO É PAÍS SEM POBREZA

Ministry of Science, Technology and Innovation – MCTI

National Biosafety Technical Commission – CTNBio

comissão técnica nacional CTNBio de biossegurança

Office of the Executive Secretary

SPO, Área 05, Quadra 03, Bloco B, Térreo, Salas 08 a 10

70610-200 Brasília, Distrito Federal, ☎ +55 61 3411 5516 • +55 61 3317 7475

Technical Opinion no. 3021/2011

Proceedings:	01200.001798/2010-01
Applicant:	Du Pont do Brasil S.A. – Divisão Pioneer Sementes.
CNPJ:	61.064.929/0043-28
Address:	SGAS 902, Lt 74, Conjunto B, Bloco A, salas 221 a 224, Ed. Athenas, Asa Sul, 70390-020 Brasília, Distrito Federal
Matter:	Commercial Release of GMO
Previous Extract:	2379/2010, published on 05.28.2010
Meeting:	144th Regular Meeting held on 08.11.2011
Decision:	**GRANTED**.

CTNBio, following examination of an application for a Technical Opinion on commercial release of TC1507 x MON810 genetically modified corn, featuring resistance to insects and tolerance

to ammonium glufosinate herbicide, as well as all progenies therefrom, reached a FAVORABLE conclusion, on the terms of this technical opinion.

Du Pont do Brasil S.A. – Divisão Pioneer Sementes, holder of *Certificado de Qualidade em Biossegurança – CQB* (Biosafety Quality Certificate) no. 013/97, requested CTNBio an opinion on biosafety of TC1507 x MON810 corn resulting from crossbreeding, by classical genetic improvement, of genetically modified corn events for resistance to insects attack and tolerance to ammonium glufosinate, TC1507 x MON810 r the purposes of cultivation, human and animal consumption, manipulation, transportation, disposing, import and export, as well as any other activities related to such corn and progenies therefrom. Insect resistant and tolerant to ammonium glufosinate herbicide, TC1507 x MON810 was produced by conventional improvement technique, crossing Herculex I, event TC1507 (TC1507 – DAS – 01507-1), with MON810 (MON00810-6). Event TC1507 includes genes *cry1F*, granting protection against lepidopteran insects, and *pat*, which grants tolerance to ammonium glufosinate herbicide. Protein Cry1F controls important lepidopterans that are pests to corn plants and damage the tillage. Protein PAT gives the plant tolerance to herbicides formulated with ammonium glufosinate. MON810 corn produces protein Cry1Ab, which also controls lepidopterans that represent corn pests. Events MON810 and TC1507 were already approved by CTNBio for commercial release according to technical opinions 1100/2007, on 09.04.2007 and 1679/2008, on 12.15.2008, respectively. The combination of both events aims at controlling pests of the same entomology order in order to aggregate the action of two proteins coming from *Bacillus thuringiensis* as well as operating as one further tool in the management of pests that are resistant to the individual proteins. Field and laboratory tests showed that there is no interaction between Cry1F and Cry1Ab, being its effect held as additive in pest control, that is

to say, that the events are independent in their respective contribution to insect control. Besides, no changes in composition or expression of the proteins were detected when compared with individual events. Thus, in order to prove that the stacked event TC1507 x MON810 exhibits the same safety to human/animal health and the environment than the commercial conventional lineages, and further, than their genetically modified parental corns already passed by CTNBio in Brazil and in several other countries, the applicant submits results of essays conducted under restraint and in the same environment, using scientific methodologies with the purpose of showing absence of interaction or synergic effect between genes introduced in the stacked event and between the expressed proteins, which would cause emergence of any new characteristics in the modified plant. Each parental of genetically modified corn TC1507 and MON810 used in the construction of the stacked event were previously examined by CTNBio, both separately and in combinations and all were held as safe to human and animal health and to the environment. The levels of Cry1F, Cry1Ab and PAT proteins were determined in samples of pollen, leaves, forage, whole plant and grains cultivated in planned releases conducted in four regions of Brazil and no statistically significant differences were recorded between the average concentrations of protein Cry1F, Cry1Ab and PAT in samples of leaves, plants, forage and grains derived from TC1507 and TC1507 x MON810. The natural crossbreeding process failed to alter the integrity and stability of inserts in the stacked event; in field conditions, the levels of expression of inserted proteins are similar to those of individual events. Centesimal composition data fail to show significant differences between genetically modified varieties and conventional ones, suggesting that nutritional equivalence between them and agronomic and phenotypic characteristics of the stacked event are maintained in field assessments, making possible to infer about inexistence of detectable

interactions between and genes or proteins expressed in the combined event, as well as enabling the expression of any other characteristics different regarding resistance to lepidopteran insects and tolerance to the ammonium glufosinate herbicide. For the foregoing, the conclusion is that cultivation and consumption of TC1507 x MON810 corn is not a potential cause of significant degradation of the environment, or risks to human and animal health. Therefore, there is no restrictions to the use of this corn and its derivatives. CTNBio determines that the post-commercial release monitoring shall be conducted in commercial tillage and not in experimental ones. Areas selected for monitoring shall not be isolated from remainder areas, nor have borders or any other situation that may be extraneous to the commercial standard. Monitoring shall be conducted in a compared model between the conventional cultivation system and the GMO cultivation system and data shall be collected by sampling. Monitoring shall be performed in representative biomes of the main GMO cultivation areas and, whenever possible, contemplate the different types of farmers. Monitoring shall continue for a period of five years. Monitoring reports shall contain detailed information on all activities performed in pre-sowing and sowing, on its conduction, reporting on activities conducted in the monitoring areas during the culture cycle, harvesting activities and climatic conditions. Any harm to human and animal health shall be followed through official systems of adverse effect communication, such as SINEPS – *Sistema de Notificação de Eventos Adversos relacionados a Produtos de Saúde*, the *Health Product Adverse Effects Notification System*, regulated by ANVISA. Analytical results and related interpretations shall be developed under the principles of independence and transparence, observing commercial confidentiality aspects previously justified and defined as such. As far as the *pat* gene is concerned, granting resistance to herbicides, the following shall be reported: nutritional and sanity status of genetically

modified plants; chemical and physical characteristics of the soil related to fertility and other basic pedological characteristics; soil microbial diversity; soil diaspore bank; invading plants community; development of resistance to herbicide in invading plants; herbicide residues in the soil, grain, aerial part and gene flow of the two inserted genes. Regarding genes *cry1Ab* and *cry1F*, which grant resistance to insects, the following shall be monitored: impact on target insects and non-target insects; impact on non-Insecta soil indicator invertebrates; results of proteins inserted on organic matter in decomposition, both in the soil and in watercourses near the monitoring area; development of resistance among target insects and the gene flow of the two inserted genes.

CTNBio TECHNICAL OPINION

I. GMO Identification

GMO Designation:	TC1507 x MON810 Corn
Applicant:	Du Pont do Brasil S.A. – Divisão Pioneer Sementes
Species:	*Zea mayz L.*
Inserted Characteristics:	Resistance to insects and tolerance to ammonium glufosinate herbicide
Characteristics Introduction Method:	Characteristics introduced through the technique of conventional improvement using Herculex I corn event TC1507 and MON810 corn

Purposed use: Cultivation, animal and human consumption, manipulation, transportation, disposal, import and export, as well as any other activities related to this corn and progenies derived therefrom.

II. General Information

Zea mays L. corn is a species of the Gramineae family, Maydae tribe, Panicoidae subfamily, separated within the subgenus *Zea*, featuring chromosome number 2n = 20,21,22,24. The sylvan species closest to corn is teosinte, found in Mexico and some parts of Central America, where it may crossbreed with corn cultivated in production fields.

Corn has a history of over eighth thousand years in the Americas where it is cultivated since pre-Columbian times. It is one of the best scientifically characterized higher plants and is the cultivated species that reached the topmost degree of domestication to a point that its survival in nature depends on being cultivated by man. There are currently about 300 identified corn races and, within each race, thousands of cultivars.

One of the most important food sources of the world, corn is the raw material for production of a range of foods, rations and industrial products. Brazil is one of the largest world producers of corn, with corn farms in practically the whole domestic territory.

Occurrence of insects in Earth is higher in the tropics as against temperate regions, where the damages caused by these animals are heavier. Among the most important corn pests there is the armyworm, *Spodoptera frugiperda*. Cruz and colleagues (1999) estimated that losses in Brazil caused by *S. frugiperda* reached 400 million American Dollars per annum. Other lepidopteran important corn pests are *Helocoverpa Zea*, the corn earworm; and *Diatrea Saccharalis*, the sugarcane borer.

The main insect controlling measure in corn tillage is the use of insecticides. In some areas of the Brazilian Center-West, for instance, dozens of insecticide sprayings are necessary in a single cycle of cultivation. Another pest-controlling measure is the use of resistant cultivars.

The use of cultivars containing stacked events is increasing all over the world. This represents a trend that aims at meeting the demand of farmers by combining two characteristics of agronomic importance in a same hybrid. Several corn hybrids containing events stacked through classical genetic improvement have been approved in different countries.

Combination of two events targeted to control pests of the same entomologic order aim at adding the action range of two proteins originated in *Bacillus thuringiensis*, as well as serving as a further tool to manage the resistance of pests to the individual proteins.

III. Description of GMO and Expressed Proteins

Insect resistant and ammonium glufosinate tolerant TC1507 x MON810 corn was produced using conventional improvement technique by crossing Herculex I corn event TC1507 (TC507-DAS-01517-1) and MON810 (MON 00810-6). Event TC1507 includes gene *cry1F*, granting protection against lepidopteran insects and *pat,* which grants tolerance to ammonium glufosinate herbicide. Protein Cry1F controls important lepidopteran corn pest insects and damage the tillage. The PAT protein makes the plant to be tolerant to herbicides formulated with ammonium glufosinate. MON810 corn produces protein Cry1Ab, which also controls lepidopteran insects that are corn pests.

TC1507 corn was developed by embryo transformation, through the biolistic method, using plasmid PHP8999 containing gene *cry1F* and gene *pat*. The insecticide protein present in TC1507 corn is a truncated Cry1F protein derived from strain PS811 of *Bacillus thuringiensis*

var. Aizawai. *Bacillus thuringiensis* (Bt) is a gram positive soil bacterium that produces crystal protein inclusions containing hundreds of proteins named endotoxins, proteins with insecticide action both before and after the sporulation phase of its life cycle. There are currently many collections in the world that contain thousands of isolated *Bacillus thuringiensis*, being the different races classified according to their action gamut, crystal toxins and genetic similarities.

The Cry1F protein is an endotoxin that displays specific activity on the digestive system of some insect families. The action mechanism of such Cry toxins has been extensively studied in lepidopteran insects and results show that in the alkaline pH of the insect intestine the ingested protein crystals are dissolved and the pro-toxins are activated by the insect digestive proteinases. The active form of the protein links to specific receptors that are present in the target insects, and in the case of the Cry1F protein, the action takes place in lepidopteran insects. The Cry protein action takes place by permeabilization of the intestine epithelium and enabling the bacteria of the intestine to contaminate the hemolymph, leading to sepsis and death of the caterpillar.

Besides resistance to insects, TC1507 corn contains the *pat* gene, derived from *Streptomyces viridochromogenes strain Tu494*, a soil gram-positive bacterium, non-pathogenic to plants, humans and animals. Gene *pat* codes for phosphinothricin-N-acetyltransferase (PAT), responsible for acetylation of phosphinothricin, a substance also known as ammonium glufosinate. Ammonium glufosinate is the active principle of several herbicides, as it inhibits the glutamine synthetase and reduces the levels of glutamine in the plant tissues, besides causing an increased concentration of water, which ruptures the cell membrane and blocks photosynthesis, with the consequent death of the plant. The glufosinate inactivation by the PAT protein enables the selective use of herbicides that contain this compound as active

principle.

The original sequence of genes *cry1F* and *pat* were changed to maximize expression of proteins introduced in the plants, through preferential codons. Transcription of *cry1F* gene is directed by the promoter and the non-translated region 5' of corn ubiquitin (ubi) includes the first and intron. The sequence 3' of termination/polyadenylation is derived from ORF25 PolyA of *Agrobacterium tumefaciens*. Transcription regulation of gene *pat* takes place through sequences of the promoter and terminator derived from transcript 35S of Cauliflower Mosaic Virus (CaMV).

MON810 corn lineage was obtained through genetic transformation of embryos by the biolistic method, using plasmid PV-ZMBK07 containing the *cry1Ab* of *Bacillus thuringiensis*.

Similarly to protein Cry1F described above, protein Cry1Ab is an endotoxin featuring specific activity on the digestive system of some lepidopteran insects, and has no toxic effects on dipterans or coleopterans.

Gene *cry1Ab* present in vector PV-ZMBK07 is expressed under the control of transcriptional promoter E35S. An intron of 0,8kb was additionally inserted, originated from corn gene *hsp70*, between the promoter and gene *cry1Ab*. The insertion was conducted with the purpose of increasing the transgene expression levels. Sequence 3'UTR of nopaline synthase was used as terminator, containing the polyadenylation signal.

Field and laboratory tests showed that there is no interaction between proteins Cry1F (inherited from parental TC1507) and Cry1Ab (inherited from parental MON810), being their effects held as additive in controlling pests, that is to say that there is independence between the events in their contributions to insect control. There were also no changes in composition

and expression of the same proteins when compared with the individual events.

Genetically modified parentals TC1507 and MON810 that originated the stacked event were previously assessed by CTNBio and released for commercialization after being held as safe to human and animal health and the environment as the conventional corn (Technical Opinions no. 1679/2008 and 1100/2207, respectively). Besides Brazil, the events have been individually authorized in several countries. Existence of adverse effects resulting from consumption of TC1507 and MON810 corn has not been recorded up to now.

IV. Aspects related to Human and Animal Health

Event TC1507 grants corn plants protection against lepidopteran insects, such as armyworm (*Spodoptera Frugiperda*) and sugarcane borer (*Diatraea Saccharalis*). Besides, the TC1507 corn lineage features additionally tolerance to herbicide formulations containing ammonium glufosinate as active ingredient: the TC1507 corn lineage expresses also protein Cry1F originated from *Bacillus thuringiensis* var. *aizawai*. *Bacillus thuringiensis*, which produces δ-endotoxins under the form of pro-toxins that will be transformed in toxic peptides inside the intestines of insects through action of alkaline pH and proteases. The active toxin causes lysis of epithelial cells and death of larvae.

Event 1507 also contains gene *pat*, a synthetic version of the gene Pat natural of bacterium *Streptomyces viridochromogenes*, which codes for enzyme PAT, the phosphinothricin acetyltransferase. The optimized synthetic gene *pat* conditions the adequate expression. of protein PAT in corn plants, granting them tolerance to herbicide glam in controlling pests.

Absence of toxicity and allergenic potential of Cry1F and PAT was already demonstrated. There are innumerable scientific references and studies verifying their safety to humans and animals.

Safety for human/animal food of proteins Cry was confirmed by several authors, including Xu *et al.* (2009), who obtained results similar to other studies. Protein Cry1Ab/Ac was deemed to be rapidly degraded in gastric and intestinal fluids and failed to show adverse effects in mice submitted to an acute dose above 5 g (Cry1Ab/Ac protein)/kg of corporal weight. Again, the protein was recorded as having no sequence homology with known allergenic or toxins, and sites of N-glycosylation, verifying that no damage will result from inclusion of Cry1Ab/Ac in human food or animal ration.

Another recent 28 days study conducted by Onose *et al.* (2008) showed that no adverse effect may be attributed to food containing Cry1Ab, since administration of a diet containing protein Cry1Ab failed to cause any significant effect on any physiological or biochemical parameter, except for a lower level of Aspartate transaminase (AST) in serum of animals that received corn, when compared to the control.

However, no change in organ weight or histopathological changes were recorded in organs such as heart, liver and kidney. In addition, it is normally noticed that the levels of AST serum become elevated with injury to the tissue, but interpretation of relatively small changes in AST in toxicological studies must be made with caution, since the change amplitude of the parameter may be large in healthy animals. Reduction of Aspartate transaminase (AST) in his experiment cannot therefore be taken as toxicologically significant. Additionally, Paul *et al.* (2009) studied the degrading of protein Cry1Ab in genetically modified corn in the total protein in the digestion of milk cows. Results indicated that protein Cry1Ab is growingly degraded during digestion in these animals in small fragments of 41 kDa, 34 kDa and 17 kDa.

A study conducted by Heouet and colleagues (2005) showed that protein PAT is highly specific and fails to display characteristics associated to food toxins or allergens, has a sequence

homology below 35% and no continuous sequence of eight amino acids as known allergens, as determined by *in silico* assessments and do not possess N-glycosilation sites. The authors also showed that protein PAT is rapidly degraded in simulated gastric and intestinal fluids with pancreatin and pepsin. Besides, there was no mortality or toxicity when 1 or 10 mg of protein PAT/kg of corporal weight was administered by intravenous injection in mice, confirming that the PAT protein fails to display acute toxicity (safety factor > 1000); and do not cause adverse effects in mice after intravenous administration of high doses for a period in excess of two weeks. The conclusion is that no harmful effect may be expected from inclusion of protein PAT in human and animal food. Regarding event MON810, expressing protein Cry1Ab that also controls lepidopteran insects, passed by CTNBio and published in the Federal Official Gazette of September 04, 2007, one may say that information gathered along years of commercial use of this variety indicate that it is “as safe to the environment and human and animal health as the conventional hybrid corn varieties”.

The stacked corn synthesis TC1507 x MON810 was made through conventional improvement method, crossbreeding a L1 lineage TC1507 with a L2 lineage MON810, generating a hybrid L1 x L2 – TC1507 x MON810. Stability of inserts in crossbreeding containing these two events was confirmed by Southern blot. Tests showed that there was no change in the expression parameters of recombinant proteins, control of target insects or grain composition as against the individual events. The amount of proteins Cry1F, PAT and Cry1Ab are not significantly different between the individual variety and the hybrid.

A study showed that the effects of parameters present in each events regarding control of target insects are additive, with no evidence of synergy or antagonism, an important feature in managing the resistance to insects and assessing the effects in non-target insects. The results

evidenced independence of proteins Cry1F and Cry1Ab present in the combination. It must be emphasized that independence of the two proteins will probably delay the development of pests resistance to each of them, since insects that may survive to exposure to one protein remain susceptible to the other.

V. Environmental Aspects

To verify that stacked event TC1507 x MON810 has the same safety for human/animal health and environment than the conventional commercial lineages, and even their genetically modified parents already passed by CTNBio in Brazil and several other countries, the applicant submits results of essays conducted under contention and in the environment following scientific methodologies with the purpose of showing the absence of interaction or synergic effect between the genes introduced in the stacked corn or between the expressed proteins, which may cause the appearance of a new characteristic in the modified plant. Such studies include:

(i) Molecular characterization

The purpose of the study was to confirm that stability and equivalence of the inserted DNA through the crossing of stacked events TC1507 x MON810 with their respective individual lineages TC1507 and MON810 using the Southern blot technique of molecular analysis. The hybridization standard of corn events TC1507 x MON810 was compared with the individual standards of hybridization of corn event TC1507 and corn event MON810, using special probes. Hybridization standards foreseen for probes used in detection of genes *cry 1F* and *Pat* (expressed in event TC1507) and for probe E35S/Cry1Ab (specific for detection of event MON810) were recorded in the Southern blot results for each sample tested, confirming both insertions, the insertion

of corn event TC1507 and of corn event MON810, kept stable regarding the number of copies and sequence integrity, in lineage of the stacked corn TC1507 x MON810.

(ii) **Analysis of protein expression**

The aim of this phase in the study was assessing the concentration of protein in samples of corn tissues events TC1507, MON810, TC1507 x MON810 and a conventional control lineage. Samples were collected and analyzed to determine concentration of proteins Cry1F, PAT and Cry1Ab through the ELISA technique, using specific antibodies to detect the related proteins.

The levels of proteins Cry1F, Cry1Ab and PAT were determined in samples of pollen, leaves, forage, whole plant and cultivated grains, in planned releases conducted in four regions of Brazil.

No significant statistical differences were recorded between average concentrations of protein Cry1F in samples of leaves, plants, forage and grains derived from corns TC1507 and TC1507 x MON810. One statistically significant difference was recorded in the global assessment, including all locations, when average concentrations of protein Cry1F were compared in the pollen samples derived from event TC1507 with stacked corn TC1507 x MON810. This difference, however, was not recorded when each location was compared individually.

Similarly, no statistically significant differences were recorded between the average concentrations of protein PAT in samples of leaves, plants and forage derived from corns TC1507 and TC1507 x MON810. For all pollen samples and for 80% of grains analyzed, the results of quantification showed results below the MQL (Minimum

Quantification Limit) and therefore no statistical analyses were conducted in this case.

Finally, no relevant statistical differences were recorded between average concentration of protein Cry1Ab in samples of leaves, plants, forage and grains derived from corns event MON810 and TC1507 x MON810. For all pollen samples, the quantification results showed results below MQL.

The quantification for proteins Cry1F, Cry1Ab and PAT resulted below MQL in all samples of leaves, pollen, whole plant and grains studied in the conventional lineage control.

(iii) **Compositional analysis**

The study intended to compare the nutritional composition of grains derived from stacked corn TC1507 x MON810 with grains derived from corns event TC1507 and event MON810 using a genetically similar conventional corn lineage as control The field phase was conducted in planned releases in four seeding locations in Brazil during the 2009-2010 crop. Grain samples collected were analyzed for basic nutritional components, including the main nutrients, fibers, fat acids, amino acids, vitamins, minerals, secondary metabolites and antinutrients. The conclusion reached in the report is that the results of nutritional composition showed that corn event TC1507 x MON810 is comparable to its individual events TC1507 and MON810, as well as to the control lineage. For comparison purposes, reference values found in the literature were used, including those mentioned by the ILSI Crop Composition Database and OECD – Organization for Economic Cooperation and Development, as well as results of other experiments conducted by applicant, obtained with non-modified corn lineages collected in different locations and conditions of farming in the

United States of America, whose centesimal composition data were assessed and compiled. The values found in this study remained within the intervals of reference for corn, notwithstanding the farm location.

(iv) **Agronomic and phenotypic assessments**

The study had the purpose of comparing the stacked event TC1507 x MON810 with individual events TC1507 and MON810 and a conventional lineage used as control. This characteristics assesses were performance (kg/ha) damage caused by *Spodoptera frugiperda* through Inverted Davis scale (1= highly damaged plants, 9= undamaged plants), humidity (%), plant height (cm), cob insertion height (cm), days to female flowering and days to male flowering. The experiments took place in planned releases implemented in four different regions of Brazil.

No statistically significant differences were detected when the parameters of performance, humidity, plant height, cob insertion height, days to female flowering and days to male flowering when comparing the stacked event TC1507 x MON810 and individual events TC1507 and MON810. Regarding the damage levels caused by *Spodoptera frugiperda*, statistically significant differences were found between the genetically modified events. All genetically modified genotypes recorded less damage than conventional genotypes, with stacked event TC1507 x MON810 featuring the best results.

Assessment of individual events TC1507 and MON810 biosafety performance conducted by CTNBio at the commercial release of these events took into consideration environmental aspects and found that they are not a potential cause of significant degradation of the environment, keeping with the biota a relation identical

to that of the conventional corn.

Finally, corn is an exotic species, with no sexually compatible sylvan kin in Brazil. Corn has a high level of domestication and there are no scientific reasons to expect the survival of genetically modified and non-genetically modified plants outside the farm environment.

VI. Restrictions to the Use of the GMO and its Derivatives

Pursuant to Article 1 of Law nº 11460, of March 21, 2007 “research and cultivation of genetically modified organisms are not permitted in indigenous lands and in areas of conservation units, except Environment Protection Areas”.

The evidence produced in the process and bibliographic references verify the risk level of the transgenic variety as equivalent to that of non-transgenic regarding soil microbiota, as well as other plants and human and animal health. Therefore, cultivation and consumption of corn TC1507 x MON810 are not a potential cause of significant environment degradation and do not risk human and animal health. For the foregoing, there are not restrictions to the use of this corn or its derivatives, except for places mentioned by Law nº 11460, of March 21, 2007.

VII. Considerations on Particulars of Different Regions in the Country (Subsidies to Monitoring Bodies)

As established by Law nº 11460, of March 21, 2007, “research and cultivation of genetically modified organisms are not permitted in indigenous lands and areas of conservation units.”.

VIII. Conclusion

Considering that corn variety (*Zea* mays) TC1507 x MON810 belongs to a well-characterized species, with a solid history of safety for human consumption and that genes *CryAb, Cry1F* and *pat* introduced in the variety code for proteins ubiquitous in nature, present in plants, fungi and microorganisms that are part of the alimentary diet of humans and animals;

Considering that the construct of this genotype used classical genetic improvement and that resulted in the heritage of a stable and functional copy of genes *cry1Ab, cry1F* and *pat*, which grant insect resistance and tolerance to the herbicide ammonium glufosinate;

Considering that CTNBio assessed the events separately and granted a favorable opinions to their commercial release;

Considering the internationally criteria accepted in the process of risk analysis of genetically modified raw-materials regarding stacked events; and

Whereas

1. Southern blot analyses verified maintenance of integrity of genic constructs inherited from parental corns TC1507 and MON810 during the process of classical genetic improvement;
2. Expression of proteins Cry1Ab, Cry1F and PAT on TC1507 x MON810 is not significantly different from the expression observed separately in parental events;
3. No unexpected effects from unforeseen interactions were recorded relatively to the combination, by conventional crossing, of the three events TC1507 and MON810;
4. There is no indication that the expressed proteins may cause allergy or intoxication in humans and animals
5. Levels of proteins Cry1F,. Cry1Ab and PAT were determined in pollen, leaves, forage, whole plant and grain cultivated in planned releases conducted in four Brazilian regions and no statistically significant differences were recorded between average concentrations of proteins Cry1F, Cry1Ab and PAT in leaves, plants, forage and grains derived from corns TC1507 and TC1507 x MON810;

6. The process of natural crossing failed to change integrity and stability of insects in the stacked event;
7. In field conditions, the levels of expression of the inserted proteins are similar to the individual events;
8. Centesimal composition data do not display significant differences between genetically modified varieties and conventional ones, suggesting nutritional equivalence between them and that agronomic and phenotypic characteristics of the stacked event are maintained in field assessments, one may infer inexistence of detectable interactions between the genes or the proteins expressed in the combined event, as well as expression of any other characteristics different from resistance to lepidopteran insects and tolerance to ammonium glufosinate herbicide;
9. Regarding insect control, combined event TC1507 x MON810 failed to differ from isolated events TC1507 and MON810, though behaving differently from the conventional control.

For the foregoing, the CTNBio plenary reached a conclusion that TC1507 x MON810 corn is as safe as its conventional equivalent. Therefore, within the scope of the competences mentioned by Article 4 of Law no. 11105/05, CTNBio finds that the request complies with applicable rules and legislation in effect to secure environment, agriculture, human and animal health biosafety, reaching the conclusion that TC1507 x MON810 corn is substantially equivalent to conventional corn, and that its consumption means no harm to human and animal health. As far as the environment is concerned, CTNBio finds that TC1507 x MON810 corn is not a potential cause of significant degradation of the environment, keeping with the biota a relation that is identical to that of the conventional corn. Based on technical and scientific reasons, CTNBio reserves the right to revise this Technical Opinion at any moment at its discretion.

CTNBio finds that this activity is not a potential cause of significant degradation to the environment or of harm to human and animal health. Restrictions to the use of the GMO in screen and its derivatives are conditioned to the provisions of Law no. 11460, of March 21, 2007.

In preparing the within Technical Opinion, CTNBio analyzed documents supplied by applicant and independent technical literature.

Regarding post-commercial release monitoring plan, CTNBio determines the instructions below to be followed and performed the technical monitoring actions as follows:

I) Instructions:

a) Monitoring shall be applied to commercial tillage and not to experimental ones. Areas selected for monitoring shall not be isolated from the remaining areas, have borders or exhibit any other situation away from the commercial standard.

b) Monitoring shall be performed in a model comparing the conventional corn cultivation and the GMO cultivation system, and data collection shall be conducted by sampling.

c) Monitoring shall be conducted in biomes that represent the main areas of GMO culture and, whenever possible, include different types of producers.

d) Monitoring shall continue for a period of at least five years.

e) In all monitored areas, the applicant shall give details of information on all activities conducted in pre-sowing and sowing, on their respective execution, reporting activities conducted in the monitored areas during the culture cycle, on harvesting activities and climate conditions.

f) Monitoring of any harm caused to human and animal health shall be conducted through adverse effects official notification systems, such as SENEPS – *Sistema de Notificação de Eventos Adversos relacionados a*

Produtos de Saúde), the Adverse Effects Notification System related to Health Products, regulated by ANVISA.

g) Analytical methods, results achieved and interpretations thereof shall be developed in conformity with principles of independence and transparency, except for aspects of commercial secrecy previously justified and defined as such.

h) Based on technical and scientific reasons, CTNBio reserves the right to revise this Technical opinion at any time.

(1) - Regarding gene *pat*, which grants resistance to herbicide, the following shall be monitored:

a) Nutritional status and sanity of GMO plants.

b) Chemical and physical attributes of the soil related to fertility and other basic pedological characteristics.

c) Soil microbial diversity.

d) Soil diaspore bank.

e) Community of invading plants.

f) Development of herbicide resistance in invading plants.

g) Residues of herbicide in soil, grains and aerial parts.

h) Genic flow.

(2) - As far as *cry1Ab* and *cry1F* genes, which grant resistance to insects, the following shall be monitored:

a) Impact on target and non-target insects.

b) Impact on non-Insecta Class soil indicator invertebrates.

c) Residues of insecticide proteins in organic matter in decomposition, both in the soil and watercourses near the monitored area.

d) Developed of resistance by target insects.

e) Gene flow of the two inserted genes.

IX. Bibliographic References

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Edilson Paiva

CTNBio President

Advisor: Liana Vasconcelos Braga

Dissenting Vote:

CTNBio members, Dr. José Maria Gusman C. Ferraz, Dr. Leonardo Melgarejo, Dr. Solange Teles da Silva, of the Environmental Area Permanent Sectoral Subcommission, and Dr. Graziela Almeida da Siva, Dr. Pedro Canísio Binsfeld and Dr. Rodrigo Roubach of the Human and Animal Areas Permanent Sectoral Subcommissions voted against the commercial release of TC1507 x MON810 corn.

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The rapporteur of this Technical Opinion, Dr. Paulo Kageyama issued an opinion contrary to approval of this product considering that:

- Risk assessment was not completed under CTNBio Ruling Resolution no. 05 and the principles contained in Annex III of the Cartagena Protocol of Biosafety, including studies of environment impact on Brazilian ecosystems and studies of corn farming in Brazil to assess the possibility of co-existence without contamination;
- questions contained in Mr. Kateyama opinion with attention to the opinion demands were not answered; according to the opinion it is not possible to reach a clear decision in absence of a full risk assessment.
- the Commission shall demand an answer to complementary questions and data in order to make a risk analysis.

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In Witness Whereof, I have hereunto set my hand and seal in this City of Brasília, Federal District, Brazil, this Wednesday, April 22, 2015.

Fees according to

Official Gazette of 04/15/2011

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Marco Antônio Rochadel

Public Translator