

## Technical Opinion no. 2236/2009

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Applicant: BASF S.A.

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Applicant: Embrapa Soja.

CNPJ: 000.348.003/0042-99

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Previous summary: 1711/2009.

Meeting: 129th CTNBio Regular Meeting, held on 12.10.2009.

Decision: GRANTED.

CTNBio, following examination of an application for commercial release of genetically modified soybean, decided for the GRANTING the request under the terms of this technical opinion.

BASF S.A., holder of the Biosafety Quality Certificate nº 031-97 and Embrapa Soja, Biosafety Quality Certificate nº 002/06, requested CTNBio an opinion on biosafety of genetically modified soybean, tolerant to herbicides of chemical class imidazolinones, Soybean CV127, Event BPS-CV127-9, for the purpose of its release into the environment, marketing, consumption and any other activity related to this GMO and derived progenies. The event has gene *csr1-2* that codes for enzyme acetohydroxyacid-synthase (AHAS), which acts in the first phase of branched chain amino acid (valine, leucine and isoleucine) synthesis in plants and microorganisms. Inhibition of AHAS enzyme activity by imidazolinone binding causes cell death by the inability of cells to produce these amino acids, fundamental to synthesis of proteins and other derived amino acids that are fundamental for other metabolic routes. The gene codes for a single transit peptide that directs the translation product to plastids, where synthesis of such amino acids takes place. Soybean CV127 was the result of a transformation by means of biobalistics. The following biochemical characteristics related to protein AHAS were assayed:

- (i) molecular mass;
  - (ii) immunoreactivity;
  - (iii) enzymatic activity and its inhibition through feedback by product amino acids;
  - (iv) glycosilation;
  - (v) determination of peptide amino acids sequences derived from the purified protein.
- Preparations of the recombinant protein were obtained from young leaves of Soybean CV127 cultivated under field conditions. All results indicated full equivalence of the recombinant protein derived from Soybean CV127 to the same protein produced by a heterolog system.

Environmental safety of Soybean CV127 was comparatively analyzed with its non-GM isoline and two other conventional varieties of soybean in essays held in different places that represent soybean farming in Brazil. The following phenotypic, agronomic and ecologic characteristics were assayed:

- (i) seed germination rate;
- (ii) seed vigor;
- (iii) comparative follow-up along time of main development phases;

- (iv) height of plants;
- (v) leaf-dropping;
- (vi) susceptibility of diseases and field pest-insects;
- (vii) grain yield;
- (viii) insect population in plants and soil (microfauna);
- (ix) populations of parasitic and free-living nematodes;
- (x) soil microbial biomass; and
- (xi) relevant factors for nitrogen fixation to soil by Bradyrhizobium symbiosis.

All data obtained in this study demonstrated that Soybean CV127 is equivalent to its non-GM equivalent and two soybean varieties used as controls. Results of the study on number, germination patterns and morphologic and microspore (pollen) characteristics, as well as germination characteristics, indicated that there were no significant differences between the transgenic variety and its non-GM isoline. Equally, there was no difference recorded in seed dormancy and likelihood of emergence of long-term reproduction structures, which are practically non-existing in soybean. Additionally, studies were submitted supporting that the GM soybean analyzed has no difference from its non-GM isoline regarding ability to extract or introduce substances into the soil, equaling, therefore, the potential impact to environment caused by conventional soybean. Biodegradability of plant soybean tissues in soil after harvest was assayed, as well as that of protein AHAS, and the result was that GM and non-GM plants behave equally. Regarding aspects of human and animal feeding safety assessment and harmful effects to the environment, data submitted lead to an understanding that there were no pleiotropic and epistatic effects caused by inserted genes in the course of at least seventeen generations of soybean containing the transgenic construct. Besides, no allergenic potential was detected in the protein introduced, and studies demonstrated its digestibility in simulated gastric fluid and in guinea-pigs. Results submitted confirm the transgenic variety risk level as equivalent to that of non-transgenic ones regarding soil microbiota, non-target vertebrate and invertebrate animals and other plants. In conclusion, alimentary safety of Soybean CV127 is rooted in the transgene nature and remaining exogenous DNA sequences introduced in the plant, its behavior, and the plant proliferation environment that is restricted to tillage of small, middle and large extensions. CTNBio analyzed the reports submitted by applicants in addition to independent scientific literature.

#### TECHNICAL OPINION

##### I GMO identification:

GMO Designation: Soybean CV127

Applicant: BASF S.A. and Embrapa Soja

Species: Glycine max (L.) Merr

Inserted Characteristics: Tolerance to herbicide of the imidazolinone chemical class

Insertion Method: Soybean CV127, classified as Risk Class I, was obtained by transformation through biobalistics of a commercial variety of Conquista soybean, using a plasmid Pac321 DNA fragment of about 6.2 kb, containing the expression cassette of Arabidopsis thaliana gene csr1-2 (granting tolerance to herbicides of the imidazolinone chemical class) and the complete sequence of protein AsSEC61y gamma subunit.

Prospective Use: Free registration, use, essays, tests, sowing, transport, storage, marketing, consumption, release and discarding and any other activities related to this GMO.

##### II. General Information

Applicants developed a soybean variety tolerant to herbicides of imidazolinone chemical class, an event styled BPS-CV127-9, "Soybean CV127" hereinafter. This

soybean derives from a single transformation event obtained by biobalistic introduction of *Arabidopsis thaliana* genes *csr1-2* with its native promoter and untranslated native region (UTR) 3'. Gene *csr1-2* codes a major subunit of acetohydroxyacid synthase that grants tolerance to imidazolinone chemical class herbicides. A fragment of plasmid pAC321 DNA, containing the expression cassette, was used to modify the original apical meristheme tissue embryo axis of a soybean seed belonging to Conquista, a Brazilian variety most used by soybean farmers, widely adaptable to Brazilian regions. The resulting phenotype is a soybean that enables farmers to use imidazolinone group herbicide while causing no harm to the plant. Gene *csr1-2* codes for a single polypeptide, formed by 670 amino acids including protein AtAHASL (or AHAS), the *Arabidopsis thaliana* cytoplasmic transit peptide (CTP), responsible for directing the protein to chloroplasts (where branched chain amino acids biosynthesis takes place). During the transport phase of protein AtAHASL to the chloroplast, the transit peptide is removed to produce active enzyme AHAS. The enzyme grants tolerance to imidazolinone group herbicide given by a punctual mutation that results in substituting one asparagine for the serine amino acid in position 653. Enzyme AHAS catalytic subunit has a property to link with herbicides while keeping the normal plant biosynthetic function (Pang et al., 2002).

### III. Aspects Related to Human and Animal Health

The weed control by imidazolinones results from inhibition of acetohydroxyacid synthase enzyme in plants, which acts in the valine, leucine and isoleucine amino acid synthesis route. They act in both mono- and dicotyledoneae (Shaner and Mallipudi, 1991). The initial transformer came from buds of meristheme tissues with plant regeneration while exposed to the herbicide. Reselection occurred up to the F4 generation. Molecular follow-up monitoring the inserted gene single copy stability and agronomic performance. Development followed with retrocrossing between T4 and Conquista soybean that gave way to the new line (603) conducted up to F8, once more under agronomic and molecular monitoring, followed by a new crossing with the Conquista variety to obtain the 127 line (generation F7), the origin of Soybean CV127. Genetic maps detailing the plasmid and insert were submitted by applicants. The *Arabidopsis thaliana* DNA sequences were presented, together with the protein amino acid sequence. Southern blots demonstrated existence of a single insertion event and pointed out to the location of several diagnostic probes evidencing an absence of elements from the vector used (such as the ampicillin antibiotic resistance gene). The analysis also evidenced absence of 501 pb open reading frame (ORF) expression generated by duplicating 376 base pairs of a sequence part that is the coder for gene *csr1-2*, directly before the 3' integration point.

Inserted gene *csr1-2* codifies for a 670 amino acid protein that has a transit peptide to the chloroplast, which is removed after translocation. The gene, besides the mutation granting resistance to the herbicide, carries mutation R272K, with no recognized phenotype. The *Arabidopsis thaliana* gene still not recorded, AtSEC61-gamma, appears as part of its promoter upstream gene *csr1-2*. It codes for an endoplasmic reticulum transport short protein (69 amino acids), ubiquitous in plants and other eucaryotes. Its expression was assessed in soybean and its transcription was found in very low levels in leaf tissue, while remaining the protein undetectable in leaves and kernels within the detection levels of the Western blot method (5 and 15 ppb, respectively). Self-specific PCR tests were developed for identification and verification of Soybean CV127.

Besides, Soybean CV127 and controls kernels collected in four locations within Brazil were processed to produce the most used soybean fractions in human and animal food: refined oil, soybean meal and protein fraction. Protein AHAS expression level was

assayed in each of the processed fractions. Results confirmed that protein AHAS is present in very low levels, though effective in granting resistance to the herbicide. Genetic inheritance pattern was tested and showed to be typically Mendelian. No pleiotropic or epistatic effects resulting from insertion in Soybean CV127 were detected.

Protein AHAS is expressed in soybean in small amounts. The assay was conducted with Brazilian samples, coming from seven field essays on the 2006 and 2007 crops, and from six essays on the 2007 late summer crop. ELISA tests revealed quantities lower than one part per million (dry tissue). The figures range from about 500 ng per gram (leaves) to about 15 ng per gram (kernels) considering dry weight (DW). In kernel processed fractions (oil, flour and isolated protein) detection of the protein was not possible. Applicants submitted additional information related to materials and methods for determining concentration of proteins AHAS and SEC61(gamma) in Soybean CV127 tissues, complying with a CTNBio request. The document describes in detail the procedures employed, using two biologic replicas for experiment, each one generating three technical replicas for the ELISA tests. A total of thirteen charts display the quantitative data of analyses conducted with the different samples that were collected. Protein AHAS was analyzed at the applicant laboratory in Brazil and tests for quantification of SEC61(gamma) protein were conducted in Germany.

Allergenicity was tested *in silico* by comparison with a FARRP v. 8.0 database (containing 1,313 proteins) using two different methods of screening. The results failed to reveal any allergenic potential. High digestibility and instability to heat (60°C) exhibited by both the optimized and feral protein are characteristics of non-allergenic proteins. Soybean has 33 known natural allergenic proteins and the patterns of such proteins in Soybean CV127 and Conquista were similar. Besides, the proteins were verified to be non-glycosylated, a positive fact since proteins with a potential to cause allergies are in general glycosylated.

The BLASTP tool compared the *csr1-2* protein sequence with the remaining ones deposited with GenBank and there was no significant homology with any toxic protein of a reference database. Acute toxicity tests in mice used a 2.62g/kg of body weight dose. There was no clinical sign of toxicity or effect on weight of animals treated. The weight of organs examined fourteen days after gavage (brain, spleen, kidney, liver and heart) was similar to the ones measured in control groups. Innocuity of the dose represents a safety factor above  $5 \times 10^8$  regarding the human daily average consumption in Brazil, assuming that the protein is present in all soybeans consumed. A recent revision by the EFSA (Alink et al., 2008) on animal tests to assess safety of foods derived from genetically modified plants concluded that there is no biologically relevant difference, within the parameters of the test, in animals used to demonstrate food safety when fed with genetically modified plants.

Digestibility of protein AHAS in gastric and intestinal fluids was fast (30 seconds). About seventy components were examined to assay centesimal composition, proteins, lipids, ashes, carbohydrates, calories, alimentary fibers, humidity, post-treatment fibers, amino acids, fat acids, minerals, vitamins, isoflavones, phospholipids, and antinutrients. Herbicide-treated Soybean CV127 was compared to assess any important alteration on the above parameters. Analyses included kernels, fodder and processed fraction of soybean (oil, soybean meal and concentrated protein). The data indicated equivalence in composition among Soybean CV127, Conquista soybean and two other non-transgenic commercial varieties currently marketed. This equivalence was also confirmed in feeding animals with broiler chickens (576 individuals) fed on a balanced diet (42 days) in treatments containing meals of two commercial soybeans and isolate. Results were

equivalent in body weight gain, ration consumption, clinical signs, mortality, behavior, microscopic pathology, hematological and biochemical parameters, demonstrating nutritional equivalence. There was no evidence of adverse effects on animals fed on Soybean CV127. The studies conducted with rats failed to record any clinical sign of toxicity and there was no significant difference in body weight and average absolute weight on different organs selected (brain, spleen, kidneys, liver and heart) when compared with the control group. Besides no adverse effect or lesion related to the treatment was recorded in the study, ratifying the atoxic nature of protein AHAS in mammals.

Although the request for this particular soybean is the first in the world, varieties of imidazolinones chemical class herbicide resistant plants, expressing enzyme AHASL were obtained by induced or spontaneous mutagenesis, with the same substitution for amino acid S653N in corn, canola, rice, lentil and sunflower. The varieties are commercial known as Clearfield and are already farmed in several countries, including Brazil, for over fifteen years.

For the foregoing, there are no experimental evidences that Soybean CV127 presents any toxicological or nutritional risk for humans or animals, when compared with conventional soybean varieties. Taking into account internationally accepted criteria in the process of analyzing risk in genetically modified raw materials, based on the concept of substantial equivalence, the modification introduced by genetic manipulation, inserting a gene of a non-toxic or invasive model plant, such as *Arabidopsis thaliana*, simply granted the soybean resistance to imidazolinone class herbicides.

#### IV. Environmental Aspects

Varieties of herbicide resistant plants have been obtained by induced or spontaneous mutagenesis in corn, canola, lentil and sunflower. Specifically for the imidazolinone chemical class herbicides, this approach was already used in cultivated varieties in different countries with a technology named Clearfield. For the sake of alimentary and agronomic safety strategy, existence of herbicide resistant varieties with different action mechanisms is desirable so that a farmer may have tools for managing resistant invading plants whenever they appear as a result of the applied pressure (Fedoroff and Brown, 2004). Herbicide tolerant varieties have contributed in widening direct sowing cultivars, a highly beneficial practice to the environment. Attempts to obtain the imidazolinone resistance in soybeans through chemically induced mutation resulted in partial resistance only, which was useless in the fields. The mutagenesis process results in global alterations of gene expression that are higher than those obtained by genetic engineering, as shown in rice by Batista et al. (2008). The fact is an additional assurance of safety provided by directed genetic manipulation. The interested companies submitted a well grounded application with a complete molecular and chemical characterization of the insert and its products.

Results of studies on number, germination pattern and morphological characterization of microspores (pollen), as well as germination characteristics indicate absence of significant differences between the plant transgenic and non-transgenic isolines. Equally, there was no recorded difference regarding seed dormancy or likelihood of establishment of long term reproduction structures that, on soybean, are practically nihil.

Documents submitted by applicants discuss aspects of a possible horizontal transfer and consequences of the event. The conclusions, supported by competent bibliographic references, concur to the fact that, besides being unlikely, no relevant consequence will take place with horizontal transfer of the transgene to the microbiota inhabitants.

A number of studies were submitted in this analysis that support the assertion that the GM soybean analyzed is no different from its non-GM isoline regarding ability to extract or introduce substances in soil, equaling, therefore, the potential impact to the environment under this viewpoint. Biodegradability of soybean plant tissues in soil was assessed after harvest, as well as that of the AHAS protein, providing equal results for modified and conventional plants.

Quantitative and qualitative results of Soybean CV127 agronomic behavior were equivalent to conventional soybean plants either in the presence or absence of imidazolinone class herbicides during two harvest periods in different places of the country. The aspects assessed were: seed size and germination, vigor of plants, initial and final stand, green stem, plant height, dehiscence, leaf-dropping, days to flourish and maturing, grain yield and seed quality. The conclusion was that Soybean CV127 plants and derivatives showed agronomic properties compatible with those of conventional plants of the farmed soybean in Brazil.

All studies related to assessments of human and animal safety and adverse effects to the environment clearly lead to the understanding that there was not and are not pleiotropic and epistatic effects of the inserted genes along at least seventeen generations of soybean containing the genetic construct. Bibliographic data and results submitted confirmed the transgenic variety risk level as being equivalent to that of non-transgenic ones regarding soil microflora, non-target vertebrate and invertebrate animals, as well as other plants.

Tests were additionally conducted to assess incidence of soybean foliar diseases, based on statistic studies of foliar area damage. In no place and for no disease any significant difference between Soybean CV127 and the isoline was recorded, demonstrating that insertion of gene *csr1-2* failed to affect susceptibility to diseases. Studies were also conducted in seven places during the 2006-2007 harvest and in six places during the 2007 late summer harvest to assess Soybean CV127 effects to nematodes, with a number of treatments, in both presence and absence of some herbicides. Data enabled a conclusion that, independently from the herbicide, the soybean fails to cause impact in free-living nematode populations and to contribute for an increased number of parasite nematodes in the plant.

Studies aimed at assessing incidence of predators, number of insects of orders Coleoptera, Lepidoptera and Hemiptera detected in Soybean CV127 failed to record statistically significant differences in plants of the isoline or of the conventional soybeans in the four moments of the sampling. Besides, the damage caused by insect feeding among treatments and among essay locations was minimal, no differences recorded among treatments. Resistance to insect damage and effect of Soybean CV127 in pest insect populations in the fields were no different from the ones found in the isoline and varieties of conventional soybean.

Assessment of symbiotic organisms was conducted in seven essays during the 2006-2007 harvest and six during the 2007 late summer harvest. There were no significant differences in populations, and figures were compatible to the ones commonly found in experiments with bradyrhizobium-inoculated soybean. A good nodulation was recorded in all places and treatments. Regarding the remaining microorganisms, especially those of the microbial carbon biomass (MCB) there was no statistically significant differences recorded among treatments in any place and for different phases of plant development. Analysis of variance was conducted for all places and no significant differences were recorded among treatments. Equally, for the microbial nitrogen biomass, no statistically significant difference was found among treatments.

The technique of rDNA profiles, also used in 2006-2007 harvest and 2007 late summer

harvest samples, was used to qualitative assessment of the soil microbial community. The results showed that there were no effects caused by the different treatments or by application of different herbicides in the soil microbial community qualitative characteristics.

Regarding soil microfauna, population and diversity were assayed in seven places during the 2006-2007 harvest and in six places during the late summer 2007 harvest. Results of the impact assessment in cultivation of herbicide-treated genetically modified soybean showed an absence of changes in populations and community diversity of soil macro-organisms when compared to the isoline and to commercial varieties used as standards.

Regarding assessment of soybean dispersion mechanisms in the air, water and soil, insertion of the *csr1-2* gene failed to change any botanical trait of the plant. Soybean has no natural dispersion mechanisms for its propagation and reproduction structures in air, water and soil; however it may be disseminated by insects, agricultural tools and man. Soybean is predominantly self-fertile. In case of pollen dissemination by insects, it may take place by hymenopters, though in significantly low rates (Beard and Knoles, 1971; Erickson et al., 1978). Thus, Soybean CV127 is botanically comparable to its isoline. Regarding horizontal gene transfer from plants to bacterium, followed by functional expression, it involves an extremely complex process that demands successive phases with very low probability of occurrence. As the first phase, the gene must be available intact in the environment, but this is extremely improbable in view of the endonuclease action of the plant itself. Besides, the quantity of the insert is significantly smaller when compared to the plant genomic DNA. Once made available in intact form, the gene must be captured by an able microorganism, yet not all microorganisms may be transformed in a laboratory facility that uses optimized conditions not found in nature. Studies concluded that after different transformation essays, the quantity of bacterium in the soil and rhizosphere that are naturally transformable is extremely low (Richter and Smalla, 2007). After the events have taken place, besides containing the complete gene coding sequence, the DNA fragment must contain, in addition, sequences that are homologue to the genome of the receiving organism to facilitate a stable integration to the fragment by homologue recombination. Finally, the gene must contain its appropriate sequences for expression; however in this case and in most transformation events, cassettes are constructed with promoters that do not act as transition promoters in bacteria and fungi, even facing the possibility of stable integration to the host genome. Thus, transference of gene *csr1-2* features a very poor likelihood, under the demonstrated conditions, as shown in other studies (Miki and McHugh, 2004; Van de Eede et al., 2004).

#### V. Restrictions to the use of the GMO and its derivatives

As established by Article 1 of Law n° 11,460, of March 21, 2007 “research and cultivation of genetically modified organisms may not be conducted in indigenous lands and areas of conservation units.”

Studies submitted by applicants demonstrated lack of significant difference between genetically modified soybean and its conventional isoline regarding agronomic characteristics, reproduction mode, dissemination and survival ability. All evidence submitted in the proceeding and bibliographic references confirm the risk level or the transgenic variety as being equivalent to that of the non-transgenic varieties regarding soil microbiota, as well as other plants and human and animal health. Thus, cultivation and consumption of Soybean CV127 are not a potential cause of significant degradation to the environment or risks to human and animal health. For these reasons, there are no restrictions to the use of such soybean and its derivatives, except in places mentioned in

Law nº 11,460, of March 21, 2007.

Soybean is an exotic species to Brazil and there are no feral kindred able to cross and originate descendants. Gene flow between soybean plants is already studied in tropical conditions. Soybean is an autogamous species, with full flowers, and crossed pollination rates of 0.5% to 1% have been recorded according to the type and place of the cultivar, being eight meters the maximum distance to enable gene flow.

After ten years of use in different countries, no problem has been recorded to human and animal health or to the environment that could be traced to transgenic soybeans.

It shall be emphasized that lack of negative effects in transgenic plant farming is not a guaranty that such effects may not occur. Zero risk and absolute safety do not exist in the biologic world, although there is a mass of reliable scientific information of use of transgenic varieties in agriculture. Therefore, applicant shall conduct post-commercial release monitoring under CTNBio Ruling Resolution nº 3 and according to this Technical Opinion.

The monitoring plan includes assessment of GM and non-GM plants in regions that are representative in soybean farming, such as the States of Rio Grande do Sul, Paraná, Minas Gerais, Mato Grosso e Bahia, for five consecutive years and in areas not below three hectares in each location. The following indicators shall be assessed:

- (i) Change in composition of species in the infesting community (diasporas bank and invading plants);
- (ii) effects coming from herbicide resistance development in invading plants;
- (iii) study of nutritional status and phytosanitary;
- (iv) changes in soil physical and chemical characteristics;
- (v) herbicide degraders; and
- (vi) studies of impacts to human and animal health.

Each such assessment was adequately described in the proceeding.

VI. Considerations on particulars of different regions of the country (background information to monitoring agencies).

As established by Article 1 of Law nº 11,460, of March 21, 2007 “research and cultivation of genetically modified organisms may not be conducted in indigenous lands and areas of conservation units.”

#### VII. Conclusion

Considering that soybean is a well characterized plant with a solid history of safety for human consumption and the genes introduced into this variety code for proteins that are ubiquitous in nature.

Considering that centesimal composition data fail to point out significant differences between genetically modified conventional varieties, suggesting their nutritional equivalence.

Whereas:

1. AHAS protein is present in plants and microorganisms and in several natural mutants presenting tolerance to the imidazolinones class herbicides. Therefore, humans and animals have a long history of use of this protein in food;
2. Several imidazolinone tolerant that produce AHAS enzyme with the same substitution at position 653 (substitution of asparagine for serine), present in Soybean CV127, have been marketed under the brand name Clearfield® and farmed for several years without adversely affecting human and animal health and the environment;
3. Molecular analysis of Soybean CV127 evidenced that integrity and stability of the insert was maintained;
4. Segregation analysis and genetic inheritance pattern are stable along successive generations; and



5. Agronomic and efficacy assessments of Soybean CV127 indicated that the insertion failed to lead to expression of any other characteristic but the expected one, tolerance to herbicides of the imidazolinones chemical class.

For the foregoing and considering internationally accepted criteria in the process of risk analysis of genetically modified raw materials one may conclude that Soybean CV127 is as safe as its conventional equivalents. In the context of the competences attributed to CTNBio under Article 14 of Law nº 11,105/05, CTNBio considered that the request complies with the rules and laws in effect aimed at securing biosafety of the environment, agriculture, human and animal health, and reached a conclusion that Soybean CV127 is substantially equivalent to conventional soybean and its consumption is equally safe for human and animal consumption. Regarding the environment, CTNBio concluded that Soybean CV127 is not a potential cause of significant degradation to the environment, maintaining with the biota a relation identical to conventional soybean.

CTNBio holds this activity is not a potential cause of significant degradation to the environment and of harm to human and animal health. Restrictions to the use of the GMO studied and its derivatives are conditioned to the provisions of Law nº 11,460, of March 21, 2007.

CTNBio analysis considered the opinions issued by the Commission Members; ad hoc consultants; documents submitted by applicant to CTNBio Office of the Executive Secretary; results of planned releases into the environment; lectures, texts. Independent scientific studies and publications submitted by applicant and conducted by third parties were also taken into account.

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**Walter Colli**  
**President of CTNBio**

#### Dissenting Votes:

Doctor Leonardo Melgarejo voted against approval of Soybean CV127, following an opinion by Doctor Paulo Brack, who recommended rejection of the request for commercial release by allegations:

- (i) Presence of a protein with possible allergenic effects should be more clearly identified;
- (ii) Quantity of essays conducted to assess alimentary safety and environmental safety was insufficient, that is to say, analysis should have been conducted with products derived from a larger number of field experimentations, for longer periods of time, in

addition to derivatives from the 2006-2007 and 2007 harvests;

(iii) Disagreement with the assertion by applicants that reducing the quantity of active ingredients in the herbicide by hectare would benefit the environment, since the available information are not complete in what relates to the ecology of complex Brazilian ecosystems and their conversion and simplification with conventional farming purposes, more recently with the increase of genetically modified plants;

(iv) The high number of the used herbicide target-species sounds odd considering that the study holds to be “weed” species that occur in Brazil for millions of years and that are popularly used, including in medicinal applications;

(v) Considers number and contents of arguments submitted by applicants stressing the GMO benefits and absence of risks to health and environment. The author of the opinion understands that more comprehensive studies are needed to consolidate the data and reduce any possible subjective interpretation often linked to alleged advantages of the product in advertising;

(vi) Studies with the event in analysis are still short lived, being questionable the guaranties of results consolidated by long term scientific studies ;

(vii) Absence of secure supply of non-transgenic seeds to producers, especially at the south of Brazil;

(viii) The GM soybean, with events for other types of herbicides, displayed lower productivity when compared to conventional soybean;

(ix) Brazil, despite a massive advent of GMOs, became the bigger consumer of agrochemicals, especially herbicides;

(x) Events related to herbicide tolerant GM plants should be more closely monitored to verify whether plant species not always considered as weed, including those near tillage areas, are not being eliminated, which could bring important loss of biodiversity;

(xi) The principle of seed (living organisms) protection follows an industrial logic, which is not compatible with bioethics;

(xii) Absence of studies demonstrating sustainability and viability of events that maintain very high agricultural scale based on the paradigm of monospecific uniformity;

(xiii) Scarcity or absence of better studies treating the Brazilian vocation, made by the differential of a country very rich in alternative use of thousands of esculent native plants, which strengthens a vicious circle of high environmental impact monocultures such as, in this case, soybean.

#### X. Abstentions

Doctor Paulo Barroso, Doctor Solange Teles, Doctor Paulo Kageyama, Doctor Graziela Almeida da Silva and Doctor José Maria Ferraz abstained from voting in Soybean CV127.