Technical Opinion nº 2273/2010

Proceedings: 01200.003881/2008-92
Applicant: Bayer S.A.
CNPJ: 18.459.628/0001-15
Address: Rua Domingos Jorge, 1100, Prédio 9504, 3º andar, 04779-900 São Paulo, SP.
Matter: Commercial release of genetically modified soybean.
Previous summary: 1647/2008, published on 10.31.2008.
Meeting: 130th Regular Meeting held on 02.11.2010.
Decision: GRANTED.

CTNBio, following examination of an application for commercial release of genetically modified gluphosinate ammonium tolerant soybean, as well as all progenies coming from transformation event A5547-127 and its derivatives through crossing of non-transgenic soybean lineages and populations with lineages carrying event A5547-127, decided favorably to its GRANTING under the terms of this technical opinion.
Bayer S.A. requested CTNBio a Technical Opinion related to biosafety of genetically modified gluphosinate ammonium tolerant soybean (Glycine max), styled Liberty Link Soybean (LL Soybean), with the purpose of free registration, using, conducting essays, testing, sowing, transporting, storing, marketing, consuming, importing, releasing into the environment and disposing of gluphosinate ammonium soybean (Glycine max) event A5547-127. LL Soybean was developed through a specific genetic modification by inserting in the plant the pat gene responsible for synthesizing enzyme phosphinothricin N-acetyltransferase (PAT), which catalyzes conversion of L-phosphinothricin (gluphosinate ammonium) into non-toxic products, inactivating the active ingredient and this way granting the plant the attribute of tolerance to the herbicide. Gene pat used was a modified version of a gene isolated from a soil-natural bacterium, Streptomyces viridochromogenes, and was inserted in the plant cells through a transformation process via biobalistics. The modification introduced in the pat gene was one of reducing, via site-directed mutagenesis, the content of G:C bases (frequent in bacteria genomes, yet atypical in plant genomes). The modifications conducted failed to modify the original sequence of PAT protein amino acids. The genetic elements present in the insert were the pat gene, the promoter 35S derived from Cauliflower Mosaic Virus (CaMV), and the *f*Ò-Lactamase selection marker gene (*f*Òla) coming from Escherichia coli, which grants resistance to the antibiotic ampicilin. Plasmid vector used to replicate the insert was pB2/35SAcK derived from plasmid pUC19. The plasmid vector was linearized prior to the transformation process in order to deactivate gene *f*Òla coding sequence. Southern blot analyses showed that the LL Soybean genome contains one single copy of gene pat, which is flanked by fragments of gene *f*Òla. The PAT protein was the only exogenous protein to be expressed in the transgenic event. Amounts of PAT protein produced in different tissues of LL Soybean were assayed using the immunologic test ELISA and the results were 0.017% in leaves and 0.003% in hay and grain, against total protein in related tissues. Thus, the PAT protein was detected in low level in plant tissues assayed and, as expected, no amount was detected in refined oil. Besides, the protein is rapidly degraded in gastric and intestinal fluids, with great susceptibility to digestion and denaturation. The safe history of LL Soybean cultivation in the United States (since 1998), Canada (2000) and Japan (2006) grants the product a strong evidence of environment safety. To these results one shall

aggregate assessments conducted by international organizations, as well as data supplied by applicant showing that the event fails to present any harmful effect to the environment and non-target organisms and fails to possess any characteristic that may grant adaptive advantages. Available information indicates that there is substantial equivalence, that is to say, transgenic plants of LL Soybean are not fundamentally different from the non-transformed soybean genotypes, except for the gluphosinate ammonium tolerance. Regarding horizontal gene flow, it is practically impossible, since there are no feral kindred of soybean in the Brazilian territory. Besides, soybean is an autogamous plant, which makes the vertical gene flow very difficult. Although the issue is beyond the scope of CTNBio, it is worth stressing that gluphosinate ammonium is a non-systemic and non-selective herbicide, used mainly in the control of invading plants in post-emergence, both of large leave and narrow leave invaders, and is registered, approved and free to be marketed in Brazil by the Ministry of Agriculture and Supply (MAPA), IBAMA and the Ministry of Health, used in Brazil and several other countries to control pest plants, either with or without farming of transgenic plants resistant to the herbicide. The herbicide wide use worldwide is due to its biodegradability, low residual activity and low toxicity to humans, animals and other organisms of the food chain. For the foregoing, the conclusion is that farming and consumption of Liberty Link Soybean (LL Soybean event A5547-127) is neither a potential cause of significant degradation of the environment nor of risks to human and animal health. For the reasons above, there are no restrictions to the use of this soybean and its derivatives. Applicant shall conduct the post-commercial release monitoring pursuant to CTNBio Ruling Resolution nº 5. As established in Article 1 of Law nº 11,460, of March 21, 2007, "research and cultivation of genetically modified organisms are forbidden in indigenous and conservation unit areas". CTNBio analyzed the reports submitted by applicant as well as the independent scientific literature.

Under Article 14 of Law nº 11,105/05, CTNBio held that the request complies with applicable rules and legislation in effect aimed at securing biosafety of the environment, agriculture, human and animal health and concludes that Liberty Link Soybean is substantially equivalent to conventional soybean, being therefore its consumption safe for human and animal health. Regarding the environment, CTNBio concluded that farming of Liberty Link Soybean is not potentially a cause of significant degradation of the environment, keeping with the biota a relation identical to that of conventional soybean.

CTNBio TECHNICAL OPINION

I. Identification of GMO

Name of GMO: Genetically modified soybean tolerant to gluphosinate ammonium – Liberty Link Soybean, Event A5547-127.

Applicant: Bayer S.A.

Species: Glycine Max

Inserted Characteristics: Tolerance to gluphosinate ammonium.

Method of insertion: Particle acceleration method (Biobalistics)

Proposed use: Farming, production of grain, human and animal consumption of the product and its derivatives.

II. General Information

Soybean is a predominantly autogamous plant, whose crossed pollination rate is as low as 1.0%. Soybean cross pollination rate in an environment such as the Brazilian cerrado (Abud et al., 2003) is about 0.45% at a distance of 0.5 m; 0.14% at 1.0 m and detectable absence at a distance of 6.5 m. Soybean is an exotic species with no feral

kindred sexually compatible in Brazil. Therefore, crossed pollination with feral species in the natural environment may not occur in the national territory.
Soybean is a domesticated species that depends highly on the human species for its survival. Therefore, there are no scientific reasons to foresee survival of plants derived from lineage A5547-127 outside farm environments. Besides, in absence of selective pressure (use of herbicide), expression of the inserted gene fails to grant any adaptive advantage.
Around the world, the area farmed with herbicide tolerant soybean in 2008 was about 65.9 million hectares. Since 1998, genetically modified soybean tolerant to glyphosate herbicide (Roundup Ready – Monsanto) is extensively cultivated in Brazil. About 65% of the soybean produced in Brazil during 2008 was RR® transgenic, representing 21.9 million hectares (ISI, 2008). Until now no report of harmful effect of this GMP to the environment due to gene flow has come to light.
However, the massive use of the same type of herbicide crop after crop, as in the case of glyphosate, accelerates appearance of invading plants naturally resistant to such herbicide (Owen, 2008). In this case, the possibility of using varieties of genetically modified soybean that are tolerant to another herbicide, such as the gluphosinate ammonium, may be an important tool to help manage invaders, making possible to increase longevity of such technologies.
Soybean plants of event A5547-127 are sensitive to other herbicides, such as glyphosate, indicating the substrate specificity of protein PAT and showing that the plants of this event may be managed by the techniques usually employed in the field to eradicate undesirable plants.
Herbicide gluphosinate ammonium is rapidly degraded in the soil by action of microorganisms using this molecule as a source of nitrogen, releasing CO2 and phosphorus. Soils maintained in laboratory conditions demonstrated that at a temperature of 20 ºC gluphosinate has a half-life of 10 days (Smith, 1988; OECD, 2002). According to Hoerlein (1994), this synthetic phosphinothricin (gluphosinate ammonium) is not toxic to fungi, nematodes and insects.
III. Description of the GMO and Proteins Expressed
Event A5547-127, styled LibertyLink Soybean, presents gene pat derived from Streptomyces viridochromogenes that grants tolerance to herbicide gluphosinate ammonium. This exogenous gene codes for enzyme phosphinothricin N-acetyltransferase (PAT protein) that promotes inactivation of the herbicide.
Gene pat was replicated using plasmid pB2/35Sack and the nucleotide sequence was inserted in the soybean genome by particle acceleration technique. The plasmid displayed gene pat, promoter and terminator 35S (derived from Cauliflower Mosaic Virus (CaMV) and marker gene *f*Òla (resistance to antibiotic ampicilin).
Gene *f*Òla (*f*Ò-lactamase derived from Escherichia coli) that is present in the plasmid vector, was fragmented by restriction enzyme prior to the event insertion.
Hybridizations of Southern blots and amplifications by chain reaction of DNA-polymerase were presented to demonstrate integration of the exogenous DNA fragment to the plant genome, the number of gene copies, presence or absence of other DNA elements and location of transgene parts. The results submitted indicate that event A5547-127 has a single copy of gene pat in orientation 5',,_3'.
The event has a gene *f*Òla fragment copy of the 3'end and a copy of the 5'end. However, *f*Òla fragments are unable to reconstitute the gene for they are invertedly oriented, making its expression impossible. The construct inserted in the soybean genome fails to present sequences associated to mobility in the genome.
The characteristic of resistance to the gluphosinate ammonium herbicide followed the

Mendelian way in the event, regarding generations assayed by applicant, indicating genetic stability of the insert.
Enzyme PAT is the only protein expressed by the transgene; it has 183 amino acids and molecular weight of 22 kDa. Event A5547-127 plants display PAT protein in concentrations of 26.22 *f*Ýg/g in leaves, 13.85 *f*Ýg/g in stalks, 3.6 *f*Ýg/g in roots (Annex 11) and 9.0 *f*Ýg/g in seeds (Annex 32) (AgBios, 2009).
During the event A5547-127 transformation, three new junctions, originating eight ORFs (open reading frames), were created. Based on bioinformatics analyses, the likelihood that a new protein expression created because of DNA insertion in event A5547-127 is very low for ORF-1, ORF-2, ORF-3, 0RF-4, ORF-6, ORF-7 and ORF-8. However, ORF-5 has all the regulating elements needed to initiate transcription and translation, though in non-optimal form and spacing, and one may not exclude the fact that it may lead to expression of a freshly created protein (Annex 35).
Northern blot analyses were conducted for A5547-127 soybean to demonstrate expression of gene pat introduced and to assay absence of a putative cryptic gene expression coming from different junction regions. The study characterized the presence of gene pat mRNA in all tissues tested. Downstream cryptic expression on junctions II and III were noticed in transgenic samples only, though no cryptic expression has been found in non-transgenic samples. However it is not likely that a fresh protein, in addition to PAT, is translated in such transcriptions (Annex 36).
Comparisons of event A5547-127 with its non-transgenic isoline A5547-127 showed that there are no differences regarding allergenic potential. In this assay, slight differences were found in some nutritional components. However, the variations were within the range normally found in conventional soybean lineages (FSANZ – Food Standards Australia and New Zealand, 2003), and resulted in no risks.
Gluphosinate ammonium (synthetic phosphinotricin) acts through controlling invading plants by inhibiting enzyme glutamine synthetase. The enzyme is responsible for incorporating ammonia to glutamic acid, forming glutamine. Inhibition of glutamine synthase promotes both a reduction in the levels of glutamine and collection of ammonium in plant tissues, leading the plant to death.
Glutamine synthetase is a protein produced by the cell nucleus that catalyzes formation of L-glutamine in the cytoplasm and predominantly in chloroplasts. The reaction is the main route of ammonium assimilation in plants. Gluphosinate ammonium is racemic, where the L-isomer has the function of inhibiting glutamine synthetase. The L-isomer has a structure similar to that of L-glutamate, leading to inhibition of glutamine synthetase by competition. However, ammonium collection is not directly responsible for the gluphosinate toxic effect. Gluphosinate indirectly inhibits the photochemical phase of photosynthesis, blocking the electron transportation chain, leading to disorganization of thylakoid membranes (Tan et al., 2006).
Protein PAT is able to inactivate gluphosinate through acetylation, by converting gluphosinate into N-acetyl-L-gluphosinate, which is atoxic. The rapid activity of PAT enzyme either eliminates or reduces the odds of gluphosinate to inhibit glutamine synthetase. Up to now, no occurrence of this protein has been identified in any plant. However, experiments have shown that some plants display reduced ability to naturally detoxify gluphosinate through deamination reactions, as it is the case for soybean, wheat, maize, tobacco, alfafa and carrot (Dropege-Laser et al., 1994), resulting an atoxic composite (4-methylphosphinic-2-oxo-butanoic acid, PPO). This natural inactivation route is quite slow, leading the plant to death prior to complete gluphosinate detoxification. Presence of exogenous PAT protein inactivates gluphosinate in a fast way, leading to increased tolerance to the herbicide (OECD, 2002). Up to now, there is

no record of invading plants naturally tolerant to gluphosinate.

IV. Aspects Related to Human and Animal Health

World production of soybean is about 200 million tons, and the grain is used as edible oil, animal ration, foodstuff component to humans, besides being input for meal, soap, cosmetics, resins, paint, solvents and biodiesel. Due to presence of anti-nutrients, such as stachyose, rafinose, trypsin and lectin inhibitors, soybean shall be submitted to a thermal process before being used for consumption.

PAT protein is degraded by animal gastric fluid and by artificial gastric fluid similar to that of humans, weakening its physic-chemical characteristics after oral exposure. Therefore it is not expected that the protein may be wholly absorbed, being thereby impossible for it to cause adverse or toxic effects.

Innocuity of transformation by gene pat is warranted by works developed by different research groups. A detailed study on PAT protein innocuity was conducted focusing structural assay, search for glycosylation sites, thermal stability and in vitro digestibility. Protein expressed by pat gene was analyzed and the conclusion was that it is safe for use in plant modification regarding all aspects investigated (Hérouet et al., 2004). Results of such study enable inferring that protein PAT fails to display any characteristics of allergenicity to sensitized individuals, either by direct action or by cross-reaction with other allergenic molecules.

Allergens originated in foodstuffs are generally resistant to heat, acid and proteases, may be glycosylated and are present in high concentration. The protein analyzed is readily digested by gastric juices, is not glycosylated and exposure to heat leads to protein bioactivity loss.

In order to ensure safety of LibertyLink® soybean in animal food, Bayer and other research institutions demonstrated that the genetically modified soybean by introduction of the pat gene:

1. Has a bromatological composition similar to its unmodified parental;
2. Fails to present any adverse effect to mammals, even when intravenously administered in high doses;
3. Protein PAT has no homology with allergenic or toxic proteins;
4. Protein PAT fails to present any glycosylation site;
5. Protein PAT is not structurally unstable in acid environments;
6. Protein PAT has substrate-specific activity.

The search for PAT protein glycosylation sites, thermal stability, in vitro digestibility and allergenicity is fully described in studies conducted by applicant and other laboratories, upon applicant's request, and is available in the Annexes of the proceedings.

Composition analyses were comparatively conducted in genetically modified plants and its respective conventional analogues (control lineages), which had been developed in similar environmental conditions to avoid possible variations in composition that are unrelated to genetic modifications. Thus, different parameters were assayed for Event A5547-127 and for the unmodified conventional lineage. Chart 3 of the topic "Assessment of Risk to Human and Animal Health" describes the analyzed groups and respective components, for instance: centesimal composition: humidity, gross fat, proteins, ashes, among others; minerals and vitamins: Ca, P, K, B1 vitamins, vitamin B2, vitamin E, folic acid, among others.

The similarity noticed for average values of analyzed composts indicates that the genetic modification resulting from insertion of pat gene to Event A5547-127 failed to affect any other metabolic function that might result in changed percentage of nutritional chemical components.

Effects on growth and mortality of chicken (Gallus gallus domesticus) brought by food containing or not the GM soybean were measured in an experiment with 240 birds. The birds were fed with ration containing 18,25% of soybean during the first seventeen days of life. During this growth phase and after slaughtering the chicken, several parameters compiled in Table 13 were analyzed. Results showed that there was no significant change in analyzed zootechnical characteristics as well as in other parameters studied.
Assessment of PAT protein cumulative toxicity was conducted in Wistar rats. Rat groups (10 animals) were fed on different concentrations of PAT protein, from zero to 50,000 ppm. The results showed no clinical effects as a result of the treatments and parameters, such as body weight, were not affected. The full details of the study are in the Annexes to the proceedings.
Information and studies submitted, besides all other works in the literature (see references below) establish the safety of LibertyLink® soybean Event A5547-127. This variant shows low risk to human and animal health and has no risk of changing into a plant pest. Gene insertion failed to change plant composition and nutritive value. It was verified that PAT protein poses no significant risk to human and environmental health according to acute oral toxicity and in vitro digestibility studies. Studies showed absence of toxicity in rats and birds fed on PAT protein.
Gene pat introduced in soybean has no similarity to known allergens; PAT protein does not share any immunologically significant sequence of amino acids with known allergens. These results, coupled with the rapid rupture of the protein in digestive conditions, confirm that protein PAT shall not pose significant allergenic risk. PAT protein may be widely found in nature, has a safe use history and well known action mechanism.
In September, 2007, the European Food Safety Authority (EFSA) issued a positive opinion on LL soybean. LL soybean was approved in the United States, Canada for food and farming; LL soybean is approved for import by Australia, Japan, Mexico, New Zealand, Taiwan and South Africa and approved as foodstuff in Russia.
V. Environmental Aspects
Gluphosinate ammonium (GA) is a synthetic compound correspondent to phosphinothricin, which is naturally produced by some soil microorganisms and is regularly registered and traded in Brazil under the brand FINALE. Other commercial names (LIBERTY, BASTA, IGNITE) are internationally used. GA biodegradability is one of the main characteristics of the product, in addition to its low toxicity on fowl, insects, earthworms and bees; it is a non-mutagenic non-carcinogenic product with low risk of leaving residuals in soil and water given its low half-life. GA has a broad range and is a fast acting herbicide on monocotyledon and dicotyledon plants, controlling plants from its emergence in soil to more advanced stages. GA activity on the target-plant is exclusive and specific (inhibition of glutamine synthetase enzyme), acting in a way to minimize appearance of resistant plant pest populations.
Plants derived from Event A5547-127 display the same agronomic behavior and adaptability than the conventional lineage, with no changes on the traits that regulate the species survival and reproduction. Comparative analyses of morphologic, phenotypic and agronomic characteristics enable a conclusion that none of such variables was changed by the genetic modification of the Event A5547-127. There are no records of traits that may grant either selective advantage or atypical behavior to the species.
PAT protein, product of expression of the gene inserted in the Event, displays some characteristics in risk assessment, such as:
(i) lack of homology with allergenic protein, toxin or antinutrients;
(ii) lack of glycosilation site (that is present in a number of allergenic components);

(iii) the protein is unstable in acid environments;
(iv) the protein is rapidly degraded and denatured in gastric and intestinal fluids of mammals;
(v) the protein has substrate-specific activity (acts solely on gluphosinate); and
(vi) the protein failed to display any adverse effect in mammals, even when administered pure, in high doses, in the vein.
According to applicant, possible effects to relevant indicator organisms in experiments conducted in the United States and Porto Rico, with visual observations during the evolutionary cycle to assess occurrence of atypical plants or plants that respond differently to biotic pressure, suggested that insertion of the pat gene has failed to influence susceptibility/influence to pests and diseases of lineages derived from A5547-127, even when they are subject to different environmental conditions. Studies conducted in the cities of Paulínia and São Gabriel do Oeste revealed no anomaly in terms of insect and fungus occurrence and anomalies related to plant physiology.
Safety to environment aspects, analyzed in local field studies, demonstrated that the lineage originated from Event A5547-127 displays the same agronomic behavior and adaptability of the conventional lineage, with no changes on the species survival and reproduction regulating characteristics. Comparative analyses of morphologic, phenotypic and agronomic characteristics enabled a conclusion that none of such variables was changed as a result of the Event genetic modification. According to applicant, no traits that could grant selective advantage to the GM soybean or atypical behavior to the species were recorded. During post-harvest monitoring, carried out in experimental areas, few remaining soybean plants were recorded, and were easily eliminated. This is evidence that the GMP does not remain in the farming environment without human intervention, nor displays traits that make it more aggressive or invading on the ecosystem than its conventional parental lineage, according to applicant.
Event A5547-127 is already commercially released in Mexico (2003), United States of America (1998) and Japan (2006). Taking into account internationally accepted criteria in the process of analyzing genetically modified plant risks, one may conclude that Event A5547-127 is as safe as its conventional equivalent.
VI. Restrictions to the use of GMO and its derivatives
According to Article 1 of Law no. 11,460, of March 21, 2007, “research and cultivation of genetically modified organisms are forbidden in indigenous and conservation unit areas”.
Soybean is an exotic species in Brazil and there are no feral kindred able to cross and generate offspring. Gene flow among soybean plants is already studied in tropical conditions. Soybean is an autogamic species displaying full flowers, with crossed pollination rates ranging from 0.5% to 1% according to place and type of cultivar; gene flow may occur at no more than eight meters.
After ten years of use in different countries, no problem has been recorded as affecting human and animal health or the environment that may be attributable to transgenic soybeans. It shall be stressed that lack of negative results in farming transgenic plants is no guaranty that such results may not occur. Zero risk coupled with absolute safety do not exist in the biological world, although there is a host of reliable scientific information and a history of safe use of transgenic variety in agriculture. Therefore, applicant shall carry out post-commercial release monitoring under the provisions of CTNBio Ruling Resolution nº 5 and according to this Technical Opinion.
Proceedings nº 01200.003881/2008-92, Event A5547-127, submits a monitoring plan for Liberty Link soybean. The company intends to establish two areas (with about 2 ha of area each) in the States of Paraná, Rio Grande do Sul and Mato Grosso, totaling six

experimental areas for data collection and observation. Each experimental area shall contain two genotypes (LibertyLink and Conventional soybean). Each genotype shall occupy an area or 0.24 ha. The area shall include four repetitions of each genotype, totaling 0.96 ha/genotype. An isolation of 8m is intended around the experimental area. Monitoring shall take five years, with yearly reports.
Parameters to be analyzed by applicant:
• Plant nutritional state and sanity;
• Chemical attributes of the soil related to fertility (including pH, Al, P, K, Re, Mn);
• Community assessment of invading plants and development of resistance to the herbicide ammonium gluphosinate;
• Soil microbiota assessment (protozoan, mycorrhiza, microbian biomass, soil respirometry).
This intended monitoring shall be modified to include the parameter to be assessed: flow of ammonium gluphosinate resistance gene to other soybean plants; Assessing occurrence of ammonium gluphosinate pat gene flow to other soybean plants in areas of commercial farming.
VII. Considerations on particulars of different regions of the country (assistance to monitoring bodies):
As established in Article 1 of Law nº 11,460, of March 21, 2007, "research and cultivation of genetically modified organisms are forbidden in indigenous and conservation unit areas".
VIII. Conclusion
Whereas:
• Soybean is a domesticated species, highly dependent from the human species for its survival and, therefore, there are no scientific reasons to foresee survival of plants derived from lineage A5547-127 outside farming environments;
• Soybean is an exotic species, with no sexually compatible feral kindred in Brazil and crossed pollination with wild species in the natural environment may not occur in the Brazilian territory;
• Herbicide gluphosinate is rapidly degraded in soil by action of microorganisms that use this molecule as a nitrogen source, producing CO2 and phosphorus;
• Ammonium gluphosinate (AM) is a synthetic compound corresponding to phosphinothricin, produced in nature by some soil microorganisms;
• Protein PAT has homology to no allergenic or toxic protein;
• Protein PAT fails to display significant risk for human and animal health and to the environment according to oral acute toxicity and in vitro digestibility studies;
• Studies showed absence of toxicity in rats and birds fed on PAT protein;
• Gene pat introduced in soybean has no similarity with known allergens;
• Protein PAT fails to share immunologically significant sequences of amino acids with known allergens;
• Foods based on soybean derived from Event A5547-127 show compositional/nutritional equivalence to products coming from non-modified soybean varieties;
• Environmental safety aspects were analyzed in local field studies where it was shown that the lineage coming from Event A5547-127 displays the same agronomic behavior and adaptability of the conventional lineage, with no change on characteristics that regulate the species' survival and reproduction.
For the foregoing and taking into consideration internationally accepted criteria in the process of risk analysis for genetically modified raw materials, one may conclude that LibertyLink Soybean is as safe as its conventional equivalents. According to Article 14

of Law 11,105/05, CTNBio held that the request complies with the rules and laws in effect aimed at securing biosafety of the environment, agriculture, human and animal health, and concluded that LibertyLink Soybean is equivalent to conventional soybean, and its consumption safe for human and animal health. Regarding the environment, CTNBio held that LibertyLink Soybean is not a potential cause of significant degradation of the environment, keeping with the biota a relation identical to that of the conventional soybean.

CTNBio holds the activity as not being a potential cause of significant degradation to the environment and not harmful to human and animal health. Restrictions to the use of the GMO and its derivatives are contingent on the provisions of Law nº 11,460, of March 21, 2007.

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Edilson Paiva
President of CTNBio

Dissenting vote:
Members of CTNBio Dr. Paulo Kageiama and Leonardo Melgarejo voted against approval of LibertyLink Soybean, following the opinion of Dr. Paulo Brack, who recommended denial of the request on grounds that the soybean deserves all attention for aspects such as genetic instability and risks related to the promoter CaMV, as well as to effects not still fully assessed regarding equivalence of anti-nutritional compounds and due to absence of a structure to secure that the production and marketing chain of non genetically modified soybean. Dr. Rodrigo Roubach also voted against approval of LibertyLink Soybean.