

**THE REPORT OF BIOSAFETY COMMITTEE
FOR GENETICALLY ENGINEERED PRODUCT
ON THE FOOD SAFETY ASSESSMENT RESULT OF
GEP SOYBEAN EVENT MON 87701**

- Agenda : **Food safety assessment result of GEP soybean event MON 87701**
- Applicant : PT Branita Sandhini
- Date of Assessment : 1. 22 September 2011
Core team meeting of food safety technical team
2. 28 Februari 2012
Core team meeting of food safety technical team
3. 19 Maret 2012
Core team meeting of food safety technical team
4. 2 Agustus 2012
Plenary meeting of food safety technical team
5. 5 November 2012
Core team meeting of food safety technical team

Indonesian Law No. 7 of 1996 on Food Article 13 Paragraph (1) stated “Every person who produces food or uses raw materials, food additives, and / or other auxiliary materials in food production activities or processes resulting from the genetic engineering process must first check food safety for human health before being circulated.”

In connection with a request from PT Branita Sandhini to assess the food safety of GEP soybean event MON 87701 for human health prior to circulation, the food safety technical team has conducted a food safety assessment of GEP event MON 87701. The assessment was carried out based on the Regulation of The Head of BPOM (ID NADFC) HK.03.1.23.03.12.1563 of 2012 concerning food safety assessment guideline for Genetically Engineered Products and Letter of Head of POM Agency to Chair of the Biosafety Commission on Genetic Engineering Products Number SD.11.05.1.52.04.11.03590 dated 13 April 2011 concerning the Genetic Engineered Product Safety Assessment (GEP) of GEP Event Soybean Commodities MON 87701.

Based on the results of the study concluded the following matters:

1. The results of the genetic information study revealed that the GEP event MON 87701 contained single copy of the gene (*Cry1Ac*) and it is stable in five generations.
2. The results of the food safety assessment concluded that:
 - a. GEP soybean event MON 87701 is substantially equivalent to non-GMO soybeans;
 - b. GEP soybean MON 87701 event containing the *Cry1Ac* protein does not indicate a potential for allergic reactions; and
 - c. GEP soybean MON 87701 event containing the *Cry1Ac* protein is not toxic.
3. Food safety technical team assessed that the proposed GEP soybean event MON 87701 is safe for food consumption
4. If any new data and information are found that are not in accordance with the food safety data that has been obtained so far, then the food safety status of the GEP event MON 87701 needs to be reviewed
5. If after food safety is determined, then the product is proven to have a negative impact on human health, the applicant must take controlling and prevention, and withdraw the GEP event MON 87701 from circulation.
6. GEP event MON 87701 may not be used as animal feed until it obtains a food safety certificate and must not be cultivated until it obtains an environment safety certificate.

A detailed report on the results of the study along with the name of the review team as listed in Appendix 1, Appendix 2 and Appendix 3.

Appendix 1. The Summary of Food Safety Assessment of GEP Soybean Event MON 87701

I. Introduction

Monsanto Company has developed biotechnology-derived, insect-protected soybean MON 87701 that produces the *Cry1Ac* insecticidal crystal (δ -endotoxin) protein derived from *Bacillus thuringiensis* (Bt) subsp. *kurstaki*. *Cry1Ac* provides protection from feeding damage caused by targeted lepidopteran pests. Bollgard I and Bollgard II cotton producing *Cry1Ac* protein has been commercialized in the USA for more than a decade to control Lepidopteran pest. The *Cry1Ac* protein expressed in MON 87701 shares > 99% amino acid identity with *Cry1Ac* from *B. thuringiensis* and 100% amino acid sequence identity with the *Cry1Ac* protein present in Bollgard® cotton, except for four additional amino acids at the N-terminus of the MON 87701-produced *Cry1Ac* protein.

based on the Regulation of The Head of BPOM (ID NADFC) HK.03.1.23.03.12.1563 of 2012 concerning food safety assessment guideline for Genetically Engineered Products and Letter of Head of BPOM to Chair of the

Biosafety Commission on Genetic Engineering Products Number SD.11.05.1.52.04.11.03590 dated 13 April 2011 concerning the Genetic Engineered Product Safety Assessment (GEP) of GEP Soybean Event MON 87701, food safety technical team has conducted food safety assessment for GEP soybean event MON 87701 based on genetic information and food safety information that consists of substantial equivalency, allergenicity, and toxicity as described below.

The GEP soybean event MON 87701 has received food safety certificate in 5 countries i.e. United States (2010), Australia (2010), Canada (2010), New Zealand (2010), Mexico (2010), and Japan (2011).

Appendix 1. The Summary of Food Safety Assessment of GEP Soybean Event MON 87701

II. Introduction

GEP soybean event MON 87701 is a genetically modified soybean product from PT Branita Sandhini. GEP soybean event MON 87701 produces 5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS) which tolerates glyphosate herbicide, and Cry3Bb1 protein from modified *Bacillus thuringiensis* (subspecies *kumamotoensis*) which is responsible for Coleoptera insect resistance especially soybean rootworm (*Diabrotica* spp; *Diabrotica barberi* called northern soybean rootworm and *D. Virgifera*, known as western soybean rootworm).

The GEP soybean event MON 87701 was approved in the United States in 2005 by the United States Department of Agriculture (USDA) and the United States Food and Drug Supervisory Agency (US FDA). GEP Soybean event MON 87701 has obtained environmental safety certificates in Argentina, Brazil, Canada, Japan and the United States as well as food / feed safety certificates in Australia, Brazil, Canada, Colombia, the European Union, Japan, Korea, Mexico, the Philippines, the Russian Federation, Singapore, South Africa, Taiwan, the United States, Malaysia, New Zealand, and Vietnam.

The GEP event MON 87701 food safety assessment was carried out based on the Regulation of The Head of BPOM (ID NADFC) HK.03.1.23.03.12.1563 of 2012 concerning food safety assessment guideline for Genetically Engineered Products which has been amended by Head of BPOM Regulation Number 19 of 2016 and letter of assignment of Chairman of the Biosafety Commission on Genetic Engineering Products to Deputy Chairperson of Food Safety for BCGEP Number B-38/GEP KKH/04/2016 concerning appointment of the Genetic Engineered Product Safety Assessment (GEP) of GEP Event Soybean Commodities MON 87701. The food safety technical team has conducted food safety assessment for GEP soybean event MON 87701 based on genetic information and food safety information that consists of substantial equivalency, allergenicity, and toxicity as described below.

III. Genetic Information

II.1. Genetic Elements

GEP soybean event MON 87701 contains two genes of interest, promoter and terminator, namely:

- 1) *Cry3Bb1* and *cp4 epsps* genes. The *cry3Bb1* gene encodes the Cry3Bb1 protein which is responsible for resistance to Coleoptera insects, especially soybean rootworm (*Diabrotica* spp; *Diabrotica barberi* called northern soybean rootworm and *D. virgifera* known as western soybean rootworm); while the *cp4 epsps* gene encodes the natural EPS4 CP4 protein which serves to tolerate glyphosate herbicide.
- 2) E35S promoter for *cry3Bb1* gene and P-ract1 promoter for *cp4 epsps* gene.
- 3) 3' tahsp17 terminator for the *cry3Bb1* gene and NOS for the *cp4 epsps* gene.

II.2. Source of Gene

The *cry3Bb1* gene is derived from the soil bacteria *Bacillus thuringiensis* subsp. *kumamotoensis* strain EG4691. The E35S promoter derived from the cauliflower mosaic virus. Terminator tahsp17 3' comes from the *hsp17.3* gene which encodes a heat shock protein in wheat (*Triticum aestivum*).

The *cp4 epsps* gene was isolated from *Agrobacterium* sp. strain CP4. The P-ract1 promoter is derived from the actin protein encoding gene from rice. NOS terminator (*nopaline synthase*) comes from the bacterium *Agrobacterium tumefaciens*.

II.3. Transformation System

MON 87701 was developed through *Agrobacterium*-mediated transformation of soybean meristem tissue from embryos of line LH198 seed using the binary transformation plasmid PV-ZMIR39. The plasmid vector PV-ZMIR39 contains *cry3Bb1* gene with the E35S Cauliflower mosaic virus (CaMV) promoter, and tahsp17 3' terminator; and the *cp4 epsps* gene with the P-ract1 promoter and NOS terminator.

II.4 Genetic Stability

The data of Southern blot analysis showed that soybean event MON 87701 contain only a single *cry3Bb1* dan *cp4 epsps* gene. The data showed that the backbone fragment from PV-ZMIR39 was not detected.

Based on the result of genetic information assessment, it is concluded that:

- a. soybean event MON 87701 contains a single copy of Cry1Ac gene
- b. soybean event MON 87701 does not contain backbone sequence of transformation plasmid PV-GMIR9

- c. the gene interest Cry1Ac introduced in soybean event MON 87701 is inherited according to Mendelian inheritance principles

IV. Food Safety Information

III.1 Substantial Equivalency

The substantial equivalency assessment for soybean event MON 87701 has been carried out using several documents below:

- (1) "Composition Analyses of Forage and Seed Collected from MON 87701 Grown in United States during 2007" (Kristina H. Berman, Susan G. Riordan, and Roy Sorbet. Company Report No. MSL0021413, November 12, 2008)
- (2) "Compositions of Seed, Forage, and Processed Fractions from Insect-Protected Soybean MON 87701 are Equivalent to Those of Conventional Soybean" (Kristina H. Berman, George G. Harrigan, Susan G. Riordan, Margaret A. Nemeth, Christy Hanson, Michelle Smith, Roy Sorbet, Eddie Zhu, and William P. Ridley. *J. Agric. Food Chem.* 2009, 57, 11360–11369)

The substantial equivalency assessment was conducted on the forage and seed collected from MON 87701, the conventional soybean control (A5547), and four commercial conventional soybean varieties. The soybeans were grown at five replicated trial sites in a 2007 U.S. field production and at Argentina in a 2007-2008 field production.

The soybean forage and seed samples were collected in U.S. in Baldwin County, Alabama; Jackson County, Arkansas; Clarke County, Georgia; Jackson County, Illinois; and Wayne County, North Carolina; and in Argentina in Buenos Aires Province (Tacuari, Gahan, and Berdier) and Cordoba (Alejo Ledesma) and Santa Fe province (San Francisco). The soybean forage and seed samples were analyzed in EPL Bio-Analytical Services Laboratory (EPL-BAS), 9095 W. Harristown Blvd., Niantic, IL 62551 and Certus International, Inc., 1422 Elbridge Payne Road, Suite 200, Chesterfield, MO 63017.

The parameters analyzed for soybean seeds were proximates (ash, fat, moisture, and protein), carbohydrates by calculation, ADF, NDF, amino acids and fatty acids composition, trypsin inhibitors, phytic acid, lectin, isoflavones (daidzein, glycitein, and genistein), vitamin E, raffinose, and stachyose. The parameters analyzed for toasted defatted (TD) meal were proximates (ash, fat, moisture, and protein), carbohydrates by calculation, ADF, NDF, amino acids composition, trypsin inhibitors, and phytic acid. The parameters analyzed for refined bleached deodorized (RBD) oil were fatty acids and vitamin E. The parameters analyzed for protein isolate were amino acids composition and water level. The parameters analyzed for soybean forage were proximates (ash, fat, moisture, and protein), carbohydrates by calculation, ADF, and NDF.

No significant differences ($p > 0.05$) were detected in the comparisons made between seed and forage of MON 87701 and the conventional soybean control collected from 2007 U.S. field production. No significant differences ($p > 0.05$) were detected in the comparisons made between seed and forage of MON 87701 and the conventional soybean control collected from Argentina field production.

Soybean samples grown in the U.S. have different values of carbohydrates, proteins, nine amino acids, fatty acids (C22:0), trypsin inhibitors, daidzein and vitamin E. Likewise for those grown in Argentina there are differences in the value of tryptophan, linolenic acid (C18:3), stachyose, and vitamin E, as well as TD meal and RBD oil. Nevertheless, the difference in value is small and is still included in the average range of testing for commercial non-GEP soybeans.

Based on the data and information presented above, it is concluded that the seed from MON 87701 is compositionally equivalent to conventional soybean with regard to the levels of nutrients.

III.2 Allergenicity

III.2.1 homology analysis to allergen proteins

The homology analysis between Cry1Ac protein structure and allergen protein were carried out using two search algorithms i.e. FASTA with allergen database from Food Allergy Research and Resource Program Database (FARRP) and AD-2010 database. The bioinformatics analysis showed Cry1Ac protein does not share any relevant structural similarities with known toxins, allergens, or other bioactive proteins that may be harmful to human or animal health contained in various protein databases (AD8, TOXIN6) (Bioinformatics Evaluation of the Cry1Ac Protein Present in MON 87701 Soybean Utilizing the AD8, TOXIN6, and PROTEIN Databases by Renee Girault. J. Scott McClain, Ph.D. December 12, 2008).

The analysis included comparison of amino acid sequences that comprise Cry1Ac proteins, secondary structure, tertiary structure, and 8 amino acid peptides which have the potential as allergenic epitopes with protein allergens in the AD8 database.

The results of the study showed that there is no structural homology between the Cry1Ac protein and other proteins that are allergenic to humans and animals.

III.2.2 Cry1Ac Protein Concentration Analysis

III.2.3 Protein Stability Analysis

The analysis carried out on the Cry1Ac protein produced by *E. coli*. Comparison of the Cry1Ac protein produced by GEP soybean MON 87701 with the Cry1Ac protein produced by *E. coli* confirmed the similarity between the two proteins.

Protein sensitivity to proteolytic degradation was evaluated by simulated gastric fluid (SGF) containing pepsin and simulated intestine fluid (SIF) containing pancreatin. The Cry1Ac protein produced by *E. coli* was tested with SDS-PAGE and Western blot. The results showed that at 30 seconds incubation in SGF, 99.7% of the Cry1Ac protein was hydrolyzed. Comparison with controls (buffer without SGF and SIF) confirmed that the breakdown of Cry1Ac protein was due to proteolytic activity of pepsin contained in SGF and not due to protein instability

when incubated under conditions of pH ~1.2 temperature ~37 °C. Protein fragments of ~4 kDa are seen during digestion but are hydrolyzed into smaller fragments, ie ~3.5 kDa. Western blot analysis showed that the Cry1Ac protein was digested at 30 seconds incubation inside the SGF. ~4 kDa fragments are then completely degraded within 30 seconds in the simulation of SIF intestinal fluid containing pancreatin.

The heat stability testing of Cry1Ac protein was done with Western blots. The test results show that the heated Cry1Ac protein has an immunodetectability level that significantly decreases below the limit of detection (LOD). This implies a significant decrease in the immunological reactivity of Cry1Ac proteins by heat. (Assessment of the In Vitro Digestibility of the Crystalline Protein in Simulated Gastric and Simulated Intestinal Fluids, by Brian E. Goertz, Erin Bell, Ph.D., and Elena A. Rice, Ph.D. December 16, 2008).

Based on the results of an assessment of the allergenicity of GEP soybean MON 87701, it can be concluded that the Cry1Ac protein does not show any potential that can cause allergies.

III.3 Toxicity

GEP soybean MON 87701 contains the Cry1Ac gene that expresses the Cry1Ac protein, which is toxic to the target pest of Lepidoptera, but not toxic to mammals. The US Environmental Protection Agency (EPA, 1998) has evaluated the potential impact of the Cry1Ac protein on non-target organisms, including mammals, birds, fish, beneficial insects, marine animals, and plants. The evaluation results concluded that the protein did not pose a risk of negative impacts on these organisms.

III.3.1 Comparison on Cry1Ac Protein and Toxin Protein Homology

Previous studies reported that the Cry1Ac protein contained in MON 87701 soybeans is not homologous with toxin proteins (R Girault & JS McClain, 2008. Bioinformatics Evaluation of the Cry1Ac Protein present in MON 87701 Soybean Utilizing the AD8, TOXIN6, and PROTEIN Databases. Monsanto Company, Regulatory Product Characterization Team, 800 North Lindbergh Blvd, St Louis, MO 63167).

The potential structural similarities possessed by the Cry1Ac protein and sequences in the protein toxin database are evaluated using the FASTA tool. The results of the bioinformatics analysis show that there is no structurally relevant similarity between Cry1Ac protein and any known toxin or other biologically active proteins that may be harmful to human or animal health.

III.3.2 Acute Toxicity Assessment

Acute toxicity testing of the Cry1Ac protein in mice (CD-1 mice) was carried out and the results were reported as a company report (Smedley JW, 2009. An Acute Toxicity Study of Cry1Ac Protein Administered by the Oral Route to Mice. Monsanto Study Report, CRO-2007-325).

The test sample was the pure Cry1Ac protein produced by *E. coli*, in the form of a solution for phase I and II experiments. Based on the research report (Erin Bell, Kathleen S. Crowley, Joshua P. Uffman, and Elena A. Rice, 2008. Characterization of the Crystalline Protein Purified from Harvested Seed of MON 87701 Soybean and Comparison of Physics and Functional Properties of MON 87701 Produced and *E. coli*-Produced Cry1Ac Proteins, Monsanto Study Report, Reg-07-270 MSL No.0021146), Cry1Ac pure protein obtained from *E. coli* was commensurate with the Cry1Ac soybean protein MON 87701. The sample used as a control was Bovine Serum Albumin (BSA) in solution. The experimental animals used were male CD-1 mice (around 8 weeks old, weighing around 28.4 - 33, 4 ram) and CD-1 female mice (around 10 weeks old with a body weight of around 23.1 - 29, 4 grams). For phase I testing, mice from Charles River Laboratories, St Constant, Quebec are used. For phase II testing, mice are used from Charles River Laboratories, Portage, Michigan.

Before being used in testing, all mice were allowed to adapt to the laboratory environment for a minimum of 5 days. Mice are maintained individually in stainless steel cages during the acclimatization period and during the testing period, in accordance with the USDA Animal Welfare Act protocol (9 CFR, Parts 1, 2, and 3) and the Guide to Care and Use of Laboratory Animals [NRC (National Research Council), 1996. Guide to Care and Use of Laboratory Animals. National Academy Press, Washington, DC].

Ration (PMI Nutrition International Certified Rodent Chow®) is given in ad libitum during the test, except when the animal is fasted, ie 2-3 hours before being given a test or control solution. Drinking water in the form of tap water which experiences reverse osmosis treatment and ultraviolet irradiation, is given in ad libitum.

In the first stage of testing, 20 male mice and 20 female mice were used, which were divided into 2 groups, namely control and treatment. The control group was fed with a BSA solution dose of 1280 mg prot / kg BW. Stroke is given in 2 stages with a period of 4 hours and a volume of 33.3 ml / kg BW. The treatment group was fed with a Cry1Ac protein solution dose of 1290 mg prot / kg BW. Stroke is given in 2 stages such as the control group. Provision of test and control materials was carried out on day 0, and the experiment lasted for 14 days.

In the second stage of testing, 20 male mice were used, which were divided into 2 groups, namely control and treatment. The control group was fed with a BSA solution dose of 1620 mg prot / kg BW. The treatment group was fed with a Cry1Ac protein solution dose of 1460 mg prot / kg BW. Other procedures are the same as in stage I testing.

The test results showed that: (1) there were no dead mice, both in stage I and stage II, (2) there were no signs of clinical abnormalities in mice, (3) no

significant differences were found in terms of ration consumption and weight changes between the control and treatment groups, and (4) no organ abnormalities were found in mice.

III.3.3 Feeding Study on Broiler

Feeding studies have been conducted on broiler chickens and the results were reported as a company report (Stephen W Davis, 2009. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Contain Soybean Meal Produced from MON 87701, Control, Reference Soybean, Monsanto Study No. CQR -08-032).

The sample was soybean meal from MON 87701, while A5547 soybean meal was used as a control. For comparison, Anand, Ozark, NK S38-T8, H437, NC + 2A86, and NK 25-J5 soybean meal were used. The soybean meal was mixed until it is homogeneous with chicken feed.

The experimental animals used were male and female commercial broiler DOC (Cobb x Cobb 500) obtained from Hoover's Hatchery, Inc. Rudd, IA.

The experimental design was carried out as follows: on day 0, 800 male and female broilers were randomly divided into 8 groups, according to the treatment. The experiment is carried out for 42 days, the starter period is day 0 to 20, the grower period of days 21 to 42. Feed and water are given in ad libitum.

The test results showed that: (a) chicken body weight per day on day 0 averaged 38.25 grams (MON 87701) and 38.46 grams (control and comparison); (b) chicken body weight per day on the 42nd day between the treatment and control groups was not significantly different, which averaged 2.54 kg (MON 87701) and 2.52 kg (control and comparison). (c) average feed consumption is 3.79 kg (MON 87701) and 3.85 kg (control and comparison); (d) feed conversion averaged 1.52 kg / kg (MON 87701) and 1.55 kg / kg (control and comparison). During testing there were deaths in all groups of chickens with an average of 2.6% during the first 7 days of the experiment; and averaged 1.3% during day 7 to day 42. The cause of early death was identified because of dehydration and bacterial infections that are common in commercial chicken production and not related to feeding. The cause of death after day 7 was caused by symptoms of sudden death and ascites which are common in broiler chickens. There were no statistically significant differences for all test parameters between the treatment group, the control group and the comparison group. Chickens from all groups are in good health. Based on the results of studies of feeding in broiler chickens it can be concluded that the GEP event MON 87701 was considered to have nutritional value comparable to control soybeans and comparison.

Based on the results of the toxicity assessment above, it can be concluded that the GEP soybean MON 87701 event containing the Cry1Ac protein is not toxic.

V. Conclusion

Based the assessment results on genetic information, substantial equivalency, allergenicity and toxicity, it can be concluded that:

- 1) The results of the genetic information study show that the GEP event MON 87701 contains one copy of the *Cry1Ac* gene and is stable in five generations.
- 2) The results of the food safety assessment concluded that:
 - a. the GEP soybean event MON 87701 soybean is substantially equivalent to non-GEP soybeans;
 - b. the GEP soybean event MON 87701 event containing the *Cry1Ac* protein does not indicate a potential for allergic reactions; and
 - c. GEP soybean MON 87701 event containing *Cry1Ac* protein is classified as non-toxic ingredients.
- 3) The food Safety Technical Team assessed that the proposed GEP MON 87701 soybean is safe for consumption as food.
- 4) If new data and information are found that are not in accordance with the present food safety data obtained, then the food safety status of the GEP event MON 87701 needs to be reviewed.
- 5) If after food safety has been determined, then the product is proven to have a negative impact on human health, the applicant must take control and control measures, and withdraw the GEP event MON 87701 from circulation.
- 6) GEP event MON 87701 may not be used as animal feed until it obtains a feed safety certificate and must not be cultivated until it obtains an environmental safety certificate.

VI. References

1. Arackal, S.M., K.R. Lawry, Z. Song, J.R. Groat, J.F. Rice, J.D. Masucci, Q. Tian. 2009. Amended Report for MSL0021167: Molecular Analysis of Insect-Protected Soybean MON 87701, Monsanto Study Report MSL0021960.
2. Bell, E., K.S. Crowley, J. P. Uffman and E.A. Rice. 2008. Characterization of the *Cry1Ac* Protein Purified from the Harvested Seed of MON 87701 Soybean and Comparison of the Physicochemical and Functional Properties of the MON 87701-Produced and *E. coli*-Produced *Cry1Ac* Protein. Monsanto Study Report, MSL0021146
3. Betz, F.S., B.G. Hammond and R.L. Fuchs. 2000. Safety and Advantages of *Bacillus thuringiensis*-protected Plants to Control Insect Pests. *Regulatory Toxicology and Pharmacology* 32:156-173.
4. Girault R. and J. S. McClain. 2008. Bioinformatics Evaluation of the *Cry1Ac* Protein Present in MON 87701 Soybean Utilizing the AD8, TOXIN6, and PROTEIN Databases. Monsanto Study Report, MSL0021658.
5. James, C. 2003. Preview: Global Status of Commercialized Transgenic Crops: 2003. ISAAA Briefs no. 30. ISAAA. Ithaca, New York.

6. Katherine E. Niemeyer, Andre Silvanovich, Ph.D., August 28, 2008. Assessment of the Cry1Ac Protein Levels in Soybean Tissues Collected from MON 87701 Produced in U.S. Field Trials During 2007.
7. Kristina H. Berman, George G. Harrigan, Susan G. Riordan, Margaret A. Nemeth, Christy Hanson, Michelle Smith, Roy Sorbet, Eddie Zhu, and William P. Ridley. 2009. Compositions of Seed, Forage, and Processed Fractions from Insect-Protected Soybean MON 87701 are Equivalent to Those of Conventional Soybean. *J. Agric. Food Chem.*, 57, 11360–11369.
8. Kristina H. Berman, Susan G. Riordan, and Roy Sorbet. 2008. Composition Analyses of Forage and Seed Collected from MON 87701 Grown in United States during 2007. Monsanto Study Report No. MSL0021413
9. Smedley, J. W. 2009. An Acute Toxicity Study of Cry1Ac Protein Administered by the Oral (Gavage) Route to Mice. Monsanto Study Report, CRO-2007-325.
10. U.S. EPA. 1988. Guidance for the Registration of Pesticide Products Containing *Bacillus thuringiensis* as the Active Ingredient. NTIS PB 89-164198. U.S. Environmental Protection Agency, Washington, D.C.
11. U.S. EPA. 2001. Biopesticides Registration Action Document: *Bacillus thuringiensis* (Bt) plant-incorporated Protectants (October 15, 2001). U.S. Environmental Protection Agency, Washington D.C.

Appendix 2. The small team member of Food Safety Technical Team and the full team member of Food Safety Technical Team

The Small/Core Team Member of Food Safety Technical Team

1) Genetic Information

Dr. M. Herman – Member of Food Safety Technical Team - Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD/BB-BIOGEN), Indonesian Agency for Agricultural Research and Development. Ministry of Agriculture.

2) Food Safety

Substantial Equivalency

Prof. Dr. Ir. Dedi Fardiaz, M.Sc. - Member of Food Safety Technical Team – Bogor Agricultural University (IPB)

Allergenicity

Prof. Dr. Ir. Maggy T. Suhartono - Member of Food Safety Technical Team – Bogor Agricultural University (IPB)

Toxicity

Prof. Dr. Ir. Deddy Muchtadi, MS - Member of Food Safety Technical Team – Bogor Agricultural University (IPB)

3) Production and Circulation

National Agency of Drug and Food Control of Republic of Indonesia (ID NADFC/BPOM RI)

The Full Team Member of Food Safety Technical Team

- 1) Ir. Tetty Helfery Sihombing, MP (Coordinator, ID NADFC/BPOM RI)
- 2) Yusra Egayanti, S.Si., Apt (Vice of Coordinator, Directorate of Food Product Standardization, ID NADFC/BPOM RI)
- 3) Prof. Dr. Ir. Deddy Muchtadi, MS (Faculty of Agricultural Technology, Bogor Agricultural University (IPB))
- 4) Prof. Dr. Ir. Maggy T. Suhartono, MS (Faculty of Agricultural Technology, Bogor Agricultural University (IPB))
- 5) Prof. Dr. Ir. Dedi Fardiaz, MSc ((Faculty of Agricultural Technology, Bogor Agricultural University (IPB))
- 6) Dr. Dahrul Syah (Faculty of Agricultural Technology, Bogor Agricultural University (IPB))
- 7) Dr. Maksum Radji, M. Biomed (Faculty of Mathematics and Science, University of Indonesia)
- 8) Dr. Muhammad Herman (Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD/BB-BIOGEN), MoA)
- 9) Dr. Tri Joko Santoso (Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD/BB-BIOGEN), MoA)
- 10) Dra. Daroham Mutiatikum, MSi (Agency on Health Research and Development, Ministry of Health)
- 11) Dra. Sutanti Siti Namtini, PhD., Apt. (National Drug and Food Testing Center / PPOMN, BPOM)
- 12) Drh. Sukirno, MP. APVet (Food and Drug Research Center, BPOM)

Appendix 3. Attendance List

1. Assessment Date : 22 September 2011
(Small/core team meeting of Food Safety Technical Team)

Food Safety Technical Team

- Prof. Dr. Deddy Muchtadi, MS IPB, Member of Food Safety Technical Team
- Prof. Dr. Dedi Fardiaz, M.Sc. IPB, Member of Food Safety Technical Team
- Prof. Dr. Maggy T. Suhartono IPB, Member of Food Safety Technical Team
- Dr. M. Herman BB Biogen, Member of Food Safety Technical Team
- Yusra Egayanti, S.Si. Apt. Badan POM, Member of Food Safety Technical Team

2. Assessment Date : 28 February 2012
(Small/core team meeting of Food Safety Technical Team)

Food Safety Technical Team

- Prof. Dr. Dedi Fardiaz, M.Sc. IPB, Member of Food Safety Technical Team
- Prof. Dr. Deddy Muchtadi, MS IPB, Member of Food Safety Technical Team
- Prof. Dr. Maggy T. Suhartono IPB, Member of Food Safety Technical Team
- Dr. M. Herman BB Biogen, Member of Food Safety Technical Team
- Yusra Egayanti, S.Si. Apt. BPOM, Member of Food Safety Technical Team

3. Assessment Date : 19 March 2012
(Small/core team meeting of Food Safety Technical Team)

Food Safety Technical Team

- Prof. Dr. Dedi Fardiaz, M.Sc. IPB, Member of Food Safety Technical Team
- Prof. Dr. Deddy Muchtadi, MS IPB, Member of Food Safety Technical Team
- Prof. Dr. Maggy T. Suhartono IPB, Member of Food Safety Technical Team
- Dr. M. Herman BB Biogen, Member of Food Safety Technical Team

- Yusra Egayanti, S.Si. Apt. BPOM, Member of Food Safety Technical Team

4. Assessment Date : 2 August 2012
(Plenary meeting of Food Safety Technical Team)

Food Safety Technical Team

- Ir. Tetty Helfery Sihombing, MP. BPOM, Coordinator of Food Safety Technical Team
- Dr. Bambang Risdiono P. Balitnak MoA, Coordinator of Feed Safety Technical Team
- Dr. Ir. Bahagiawati A.H, M.Sc. Balitnak MoA, Vice Coordinator of Food Safety Technical Team
- Sugeng Harmono, S.Hut, M.Si MoEF, Coordinator of Food Safety Technical Team

Members of Food Safety Technical Team

- Prof. Dr. Ir. Deddy Muchtadi, MS IPB
- Prof. Dr. Ir. Dedi Fardiaz, MSc IPB
- Prof. Dr. Ir. Maggy T. Suhartono, MS IPB
- Dr. M. Herman BB Biogen, MoA
- Dr. Dahrul Syah IPB
- Prof. Dr. Maksum Radji, M. Biomed UI
- Dr. Tri Joko Santoso BB Biogen, MoA
- Dra. Daroham Mutiatikum, MSi Agency on Health Research and Development, Ministry of Health
- Dra. Sutanti Siti Namtini, PhD., Apt. BPOM
- Drh. Sukirno, MP.APVet BPOM
- Yusra Egayanti, S.Si. Apt. BPOM

5. Assessment Date : 5 November 2012
(Small/core team meeting of Food Safety Technical Team)

Food Safety Technical Team

- Prof. Dr. Dedi Fardiaz, M.Sc. IPB, Member of Food Safety Technical Team
- Prof. Dr. Deddy Muchtadi, MS IPB, Member of Food Safety Technical Team
- Prof. Dr. Maggy T. Suhartono IPB, Member of Food Safety Technical Team

- Dr. M. Herman BB Biogen, Member of Food Safety Technical Team
- Yusra Egayanti, S.Si. Apt. BPOM, Member of Food Safety Technical Team