RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 88017 FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/19

APPLICANT: MONSANTO MALAYSIA SDN. BHD.

DATE SUBMITTED: 9 APRIL 2015

I - Summary of Assessment Process

The Genetic Modification Advisory Committee, under the purview of the National Biosafety Board, was given the dossier by the Department of Biosafety on 27 August 2014 for an application for approval for importation for release (sale/placing on the market for direct use as food, feed and for processing (FFP)) of a product of a Living Modified Organism (YieldGard Rootworm herbicide tolerant MON 88017 corn). The application was filed by Monsanto Malaysia Sdn. Bhd. (hereafter referred to as “the applicant”).

A public consultation for this application was conducted from 30 Sept 2014 to 30 Oct 2014 via advertisements in the local newspapers. A few technical and scientific issues were raised through the Public Consultation for this application regarding the release. These issues have been considered by GMAC in the risk assessment.

GMAC had three meetings pertaining to this application and prepared the Risk Assessment Report and Risk Assessment Matrix along with its recommended decision, for consideration by the National Biosafety Board.

II - Background of Application

This application is for approval to import and release products of a Living Modified Organism MON 88017 (Yield Gard Rootworm herbicide tolerant corn). The aim of the import and release is to supply or offer to supply for sale/placing on the market for direct use as food, feed and for processing (FFP). According to the applicant, MON 88017 has been registered in a number of countries for cultivation as well as for food, feed and for processing. MON 88017 corn is grown in a number of countries, e.g. United States, Canada, Argentina, Philippines, Brazil and South Africa, and may be imported, stored and processed for use in food, animal feed and industrial products in the same way as other conventional, non transgenic corn. The type of expected use of the products derived from MON 88017 corn in Malaysia will be the same as the expected usage for products derived from conventional corn. Potential users of products derived from MON 88017 corn such as grains are feed millers, food processors and other industrial use.

Information about MON 88017 Corn

The recipient or parental plant is *Zea mays* L.spp *mays* (field or sweet corn). Corn is extensively cultivated and has a long history of safe use as a food or feed. It is the largest cultivated crop in the world followed by wheat (*Triticum* sp.) and rice (*Oryza sativa* L.) in total global metric ton production (FAOSTAT, 2009).

MON 88017 is a corn product that are tolerant to the action of the Roundup family of agricultural herbicides and are protected from damage caused by corn rootworm (CRW) larval feeding. MON 88017 produces a 5-enolpyruvylshikimate-3-phosphate synthase protein from

Agrobacterium sp. strain CP4 (CP4 EPSPS), which confers tolerance to glyphosate, the active ingredient in Roundup agricultural herbicides, and a modified *Bacillus thuringiensis (*subspecies *kumamotoensis)* Cry3Bb1 protein that selectively controls CRW species.

III - Risk Assessment and Risk Management Plan

GMAC evaluated the application with reference to the following documents:

(i) CODEX Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants**.**

(ii) Roadmap for Risk Assessment of Living Modified Organisms, (according to Annex III of the Cartagena Protocol on Biosafety produced by the *Ad Hoc* Technical Expert Group (AHTEG) on Risk Assessment and Risk Management of the Convention on Biological Diversity).

(iii) The risk assessment and risk management plan submitted by the applicant.

GMAC took cognizance of the following as suggested within the AHTEG guidelines:

(i) That the risk assessment exercise be specific to the details of this particular application

(ii) That the risk assessment exercise be specific to the receiving environment in question, and

(iii) That any risk identified be compared against that posed by the unmodified organism.

A Risk Matrix was prepared based on an assessment mechanism developed by Office of the Gene Technology Regulator, Australia (OGTR, 2009). In applying this matrix, GMAC identified potential hazards, and then added a value/rank for the likelihood of each hazard as well as its consequences. The likelihood of each hazard occurring was evaluated qualitatively on a scale of 1 to 4, with 1 for 'highly unlikely', and 4 for 'highly likely'. The consequences of each hazard, if it were to occur, were then evaluated on a scale of 1 to 4, with 1 for 'marginal' and 4 to denote a 'major consequence'. A value was finally assigned for the overall risk from the identified potential hazard. The general formula: Overall Risk = Likelihood x Consequence was employed. GMAC also proposed risk management strategies for potential hazards, where appropriate. This methodology of assessment follows the procedure of Risk Assessment in Annex III of the Cartagena Protocol on Biosafety.

The Risk Assessment was conducted over a series of three meetings. To start with, the possible pathways to risk/hazard arising from release of the products were identified and listed. The potential hazards were identified in three main areas:

(i) **Effects on human health**

Relevant scientific publications on corn were reviewed for potential human health risks and issues pertaining to acute toxicity of novel protein / altering / interference of metabolic pathways, potential allergenicity of the novel protein, production of proteins or metabolites with mutagenic / teratogenic / carcinogenic effects, reproductive toxicity, potential transfer of antibiotic resistance genes in digestive tract, pathogenic potential of donor microorganisms and nutritional equivalence.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity and compromised nutritional content.

(iii) **Effects on the environment**

Issues pertaining to accidental release of seeds, unintentional release and planting, potential of transgenes being transferred to bacteria, weediness, cross pollination leading to transfer of transgenes, toxic effect on non-target organisms were examined.

Based on the above, a final list of 27 potential hazards was identified. Most of these hazards were rated as having an Overall Risk of 1 or "negligible" (please refer to the **Lampiran IIB*/Risk Matrix*** for details). The safety assessment reports were based on studies conducted by independent experts on the molecular characterization, biochemical, toxicological, nutritional, and allergenicity data of the introduced proteins, in accordance with guidelines from World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the Codex Alimentarius Commission. These data have showed the stability of expression of Cry1F and PAT protein. While a number of putative Open Reading Frames (ORFs) adjacent to the gene insertion site were detected using bioinformatics, none of these appears to encode sequences with similarity to known allergens or toxins. There are also no indications that any of these ORFs are transcriptionally active.

GMAC also took extra caution and further discussed pre-emptive mitigation procedures for hazards where the Overall Risk was estimated to be above the minimal, and also for a few hazards that required further evaluation and data acquisition. Some of these risks are expected to be managed effectively with the risk management strategies proposed (please refer to section IV of this document).

A few potential hazards where the Overall Risk was found to be 2 or "low" are highlighted below along with the appropriate management strategies (please refer to **Lampiran IIB*/Risk Matrix)***.

a) Accidental release of viable seeds

Seeds may be accidentally released during transportation and these spilled seeds may germinate and become established in the ecosystem. Spillage of seed is likely, however, it is

unlikely that these spilled seeds will germinate and become established in the ecosystem as the post-harvest drying process of forcing hot air through the grains (seeds) would affect the viability of the seeds. Furthermore, corn generally does not survive well without human cultivation. It is an annual plant. Outcrossing with any locally cultivated corn or wild relative of corn is unlikely as corn is not grown as an economic crop in Malaysia and there is no wild relative. However, as some baby corn and sweet corn are grown in this country, there is a likelihood of outcrossing of the GM corn with these. As spillage of seed during transportation is likely, it is proposed that a post monitoring plan should be implemented and any spillage incident should be managed.

b) Planting of seeds

Plants may be grown through the ignorance of uninformed farmers and perpetuated through small scale cultivations. It is noted that the post-harvest drying process of forcing hot air through the grains, affects the viability of the corn grains. Corn is not a major crop in Malaysia. Nevertheless, there could be persistence of GM crop plants in the environment, albeit at low level. These GM corn may pollinate the non-GM baby corn and/or sweetcorn. It is proposed that a post monitoring plan should be implemented and any spillage incident should be managed. There should also be clear labeling of the product to state that it is only for the purpose of food, feed and processing, and is not to be used as planting material.

c) Compromised Nutritional Content

Compositional analyses of the forage samples included proximates (protein, fat, ash, and moisture), acid detergent fiber (ADF), neutral detergent fiber (NDF), minerals (calcium, phosphorous), and carbohydrates by calculation. Compositional analyses of the grain samples included proximates (protein, fat, ash, and moisture), ADF, NDF, total dietary fiber (TDF), amino acids, fatty acids (C8-C22), minerals (calcium, copper, iron, magnesium, manganese, phosphorous, potassium, sodium, and zinc), vitamins (B1, B2, B6, E, niacin, and folic acid), anti-nutrients (phytic acid and raffinose), secondary metabolites (furfural, ferulic acid, and p-coumaric acid), and carbohydrates by calculation. Sixty-two components were statistically assessed and 15 components were below the limit of quantitation. Results of the analysis showed that there were no statistically significant differences between MON 88017 and conventional corn for 232 of the 248 comparisons conducted. No statistically significant differences were found in forage. Statistically significant differences ($p<0.05$) were observed for only 16 comparisons in grain and all values fell within the 99% tolerance interval. It is concluded, based on these data, that the forage and grain produced from MON 88017 are compositionally equivalent to the forage and grain produced from other commercial corn currently on the market.

However, applicant is required to update NBB immediately if additional tests indicates potential adverse effects or the possible presence of toxin or allergen proteins.

IV - Proposed Terms and Conditions for Certificate of Approval

Based on the 27 potential hazards identified and assessed, GMAC has drawn up the following terms and conditions to be included in the certificate of approval for the release of this product:

a) There shall be clear documentation describing the product by the exporter which shall be declared to the Customs of the importing country.

b) Any spillage (during loading/unloading) shall be collected and cleaned up immediately. The approved person shall submit a yearly report to the National Biosafety Board in compliance with procedures for handling any spillage.

c) Transportation of the consignment from the port of entry to any destination within the country shall be in closed containers.

d) A post monitoring plan for reporting adverse health effects in human and animals shall be implemented.

e) Should the approved person receive any scientifically proven information/evidences that confirms any adverse effect of MON 88017 corn, the National Biosafety Board authority shall be informed immediately for a review (as in Section 18 of the Biosafety Act).

f) There shall be clear labeling of the product from importation down to all levels of marketing stating that it is only for the purpose of food, feed and processing and is not to be used as planting material.

V - Other Regulatory Considerations

a) Administrative regulatory procedures shall be arranged between the Department of Biosafety, Royal Malaysian Customs Department and relevant agencies to ensure accurate declaration of product information and clear labeling of the product is implemented.

b) Administrative regulatory procedures shall be arranged between the Department of Biosafety and the Malaysian Quarantine and Inspection Services (MAQIS) to impose post entry requirements for accidental spillage involving the GM product.

c) Administrative regulatory procedures shall be arranged between the Department of Biosafety and the Malaysian Quarantine and Inspection Services (MAQIS) and other competent agencies to impose post entry requirements for food safety compliance.

d) Administrative regulatory arrangements shall be carried out between the Department of Biosafety and the Department of Veterinary Services (DVS) so that any unanticipated adverse effects in animals caused by any consumption of the GM products shall be reported immediately.

e) The Maximum Residual Level should be reevaluated for glyphosate resistant crops based on recent findings from International Agency for Research on Cancer (IARC) on march 2015 that glyphosate is classified as “probably carcinogenic to humans”. Therefore, every consignment that may contain GM corn should be tested for glyphosate MRL.

f) Applicant is responsible to ensure that the user and/or importer of the technology are aware of the Terms and Conditions for Certificate of Approval as given in Section IV.

VI - Identification of issues to be addressed for long term use release of this product

No additional issues have been identified that would be important during the assessment of an application for the long-term usage of this product. Continuous monitoring is required from the approved person to report any unanticipated adverse effect caused by the MON 88017 corn.

VII –Conclusion and Recommendation

GMAC has conducted a thorough evaluation of the application for approval for importation for release (sale/placing on the market for direct use as feed and for processing (FFP)) of a product of a Living Modified Organism (YieldGard Rootworm herbicide tolerant MON 88017 corn) and has determined that the release of this product does not endanger biological diversity or human, animal and plant health. GMAC recommends that the proposed application for release be **APPROVED WITH TERMS AND CONDITIONS** as listed in section IV - Proposed Terms and Conditions for Certificate of Approval.

VIII - Bibliography

1. Aalberse, R.C. 2000. Structural biology of allergens. *Journal of Allergy and Clinical Immunology.* 106: 228-238.

2. Aalberse, R.C., J.H. Akkerdaas and R. van Ree. 2001. Cross-reactivity of IgE antibodies to allergens. *Allergy*. 56: 478-490.

3. Astwood, J.D., J.N. Leach and R.L. Fuchs. 1996. Stability of food allergens to digestion in vitro. *Nature Biotechnology*. 14: 1269-1273.

4. Bravo, A. 1997. Phylogenetic relationships of Bacillus thuringiensis δ-endotoxin family proteins and their functional domains. *Journal of Bacteriology.* 179: 2793-2801.

5. Choi, I.H., J.H. Son and K.H. Nahm. 1999. Dietary fiber fraction for grains containing high levels of water-soluble non-starch polysaccharides. *Japanese Journal of Poultry Science.* 36: 269-274.

6. Classen, D., J.T. Arnason, J.A. Serratos, J.D.H. Lambert, C. Nozzolillo and B.J.R. Philogène. 1990. Correlation of phenolic acid content of maize to resistance to Sitophilus zeamais, the maize weevil, in CIMMYT's collections. *Journal of Chemical Ecology*. 16: 301-315.

7. CRA. 2005. Corn: Part of our daily lives. *Annual Report*. 2005. Corn Refiners Association, Inc., Washington, D.C.

8. Donovan, W.P., M.J. Rupar, A.C. Slaney, T. Malvar, M.C. Gawron-Burke and T.B. Johnson. 1992. Characterization of two genes encoding Bacillus thuringiensis insecticidal crystal proteins toxic to Coleoptera species. *Applied and Environmental Microbiology.* 58: 3921-3927.

9. Dowd, P.F. and F.E. Vega. 1996. Enzymatic oxidation products of allelochemicals as a basis for resistance against insects: Effects on the corn leafhopper Dalbulus maidis. *Natural Toxins*. 4: 85-91.

10. Ensminger, M.E., J.E. Oldfield and W.W. Heinemann. 1990. *Feeds & nutrition*. Second Edition. The Ensminger Publishing Company, Clovis, California.

11. FAO-WHO. 1991. Strategies for assessing the safety of foods produced by biotechnology. *Report of joint FAO/WHO consultation*. World Health Organization, Geneva, Switzerland.

12. FAO-WHO. 2001. Evaluation of allergenicity of genetically modified foods. *Report of a joint FAO/WHO expert consultation on allergenicity of foods derived from biotechnology*. Food and Agriculture Organization of the United Nations, Rome, Italy.

13. FAOSTAT. 2009. Food and Agricultural Organization statistical database. *Food and Agricultural Organization of the United Nations, New York, New York*. http://faostat.fao.org/site/567/default.aspx#ancor [Accessed August 16, 2010].

14. Galinat, W.C. 1988. The origin of corn. Pages 1-31 in *Corn and Corn Improvement. Third Edition*. G.F. Sprague and J.W. Dudley (eds.). American Society of Agronomy, Inc., Crop Science Society of America, Inc., Soil Science Society of America, Inc., Madison, Wisconsin.

15. Goodman, M.M. 1988. The history and evolution of maize. *Critical Reviews in Plant Sciences*. 7: 197-220*.*

16. Hardeman, N.P. 1981. The monarch. Pages 1-5 in *Shucks, Shocks, and Hominy Blocks: Corn as a Way of Life in Pioneer America*. Louisiana State University Press, Baton Rouge, Louisiana.
17. Harrison, L.A., M.R. Bailey, M.W. Naylor, J.E. Ream, B.G. Hammond, D.L. Nida, B.L. Burnette, T.E. Nickson, T.A. Mitsky, M.L. Taylor, R.L. Fuchs and S.R. Padgette. 1996. The expressed protein in glyphosate-tolerant soybean, 5-enolypyruvylshikimate-3-phosphate synthase from Agrobacterium sp. strain CP4, is rapidly digested in vitro and is not toxic to acutely gavaged mice. *Journal of Nutrition.* 126: 728-740.

18. Haslam, E. 1993. Introduction, commentary and overview. Pages 1-16 in *Shikimic Acid: Metabolism and Metabolites*. John Wiley and Sons, Inc., Chichester, England.

19. Höfte, H. and H.R. Whiteley. 1989. Insecticidal crystal proteins of Bacillus thuringiensis. *Microbiological Reviews*. 53: 242-255.

20. James, C. 2003. Preview: Global status of commercialized transgenic crops: 2003. *ISAAA briefs no. 30*. International Service for the Acquisition of Agri-biotech Applications, Ithaca, New York.

21. Jugenheimer, R.W. 1976. Corns for special purposes and uses. Pages 215-258 in *Corn: Improvement, Seed Production, and Uses*. John Wiley and Sons, New York, New York.

22. Kastner, J. 1980. The conundrum of corn. Pages 14-29 in *American Heritage Magazine*. Volume 31(5). American Heritage Publishing Company, Rockville, Maryland.

23. Mangelsdorf, P.C. 1974. *Corn: Its origin, evolution and improvement*. Harvard University Press, Cambridge, Massachusetts.

24. McClintock, J.T., C.R. Schaffer and R.D. Sjoblad. 1995. A comparative review of the mammalian toxicity of Bacillus thuringiensis-based pesticides. *Pesticide Science*. 45: 95-105.
25. Metcalfe, D.D., J.D. Astwood, R. Townsend, H.A. Sampson, S.L. Taylor and R.L. Fuchs. 1996. Assessment of the allergenic potential of foods derived from genetically engineered crop plants. *Critical Reviews in Food Science and Nutrition.* 36: S165-S186.

26. Newcomb, M.D. 1995. *Corn and animal nutrition in the United States*. U.S. Food and Drug Administration, Washington, D.C.

27. Noteborn, H.P.J.M. 1994. Safety assessment of genetically modified plant products. Case study: Bacillus thuringiensis-toxin tomato. Pages 17-22 in *Biosafety of Foods Derived by Modern Biotechnology- Basel Forum on Biosafety, BATS, Agency for Biosafety Research and Assessment of Technology Impacts of the Swiss Priority Programme Biotechnology.* Basel, Switzerland.

28. NRC. 2001. Nutrient requirements of dairy cattle. *Seventh Revised Edition*. National Research Council, National Academy Press, Washington, D.C.

29. OECD. 2002. Consensus document on compositional considerations for new varieties of maize (Zea mays): Key food and feed nutrients, anti-nutrients and secondary plant metabolites. ENV/JM/MONO (2002)25. *Series on the Safety of Novel Foods and Feeds, No. 6*. Organisation for Economic Co-operation and Development, Paris, France.

30. Okunuki, H., R. Teshima, T. Shigeta, J. Sakushima, H. Akiyama, Y. Goda, M. Toyoda and J. Sawada. 2002. Increased digestibility of two products in genetically modified food (CP4-EPSPS and Cry1Ab) after preheating. J*ournal of the Food Hygienic Society of Japan*. 43: 68-73.

31. Ouellet, D.R., H. Lapierre and J. Chiquette. 2003. Effects of corn silage processing and amino acid supplementation on the performance of lactating dairy cows. *Journal of Dairy Science*. 86: 3675-3684.

32. Padgette, S.R., D.B. Re, G.F. Barry, D.E. Eichholtz, X. Delannay, R.L. Fuchs, G.M. Kishore and R.T. Fraley. 1996. New weed control opportunities: Development of soybeans with a Roundup ReadyTM gene. Pages 53-84 in *Herbicide-Resistant Crops: Agricultural, Environmental, Economic, Regulatory, and Technical Aspects.* S.O. Duke (ed.). CRC Press, Inc., Boca Raton, Florida.

33. Pariza, M.W. and E.M. Foster. 1983. Determining the safety of enzymes used in food processing. *Journal of Food Protection*. 46: 453-468.

34. Pearson, W.R. 2000. Flexible sequence similarity searching with the FASTA3 program package. *Methods in Molecular Biology*. 132: 185-219.

35. Ridley, W.P., R.S. Sidhu, P.D. Pyla, M.A. Nemeth, M.L. Breeze and J.D. Astwood. 2002. Comparison of the nutritional profile of glyphosate-tolerant corn event NK603 with that of conventional corn (Zea mays L.). *Journal of Agricultural and Food Chemistry*. 50: 7235-7243.

36. Rooney, L.W. and S.O. Serna-Saldivar. 2003. Food uses of whole corn and dry-milled fractions. Pages 495-535 in *Corn: Chemistry and Technology*. Second Edition. P.J. White and L.A. Johnson (eds.). American Association of Cereal Chemists, St. Paul, Minnesota.

37. Sacchi, V.F., P. Parenti, G.M. Hanozet, B. Giordana, P. Lüthy and M.G. Wolfersberger. 1986. Bacillus thuringiensis toxin inhibits K+ -gradient-dependent amino acid transport across the brush border membrane of *Pieris brassicae* midgut cells. *FEBS Letters*. 204: 213-218.

38. Salvador, R.J. 1997. Maize. Pages 769-775 in *Encyclopedia of Mexico: History, Society & Culture*. M.S. Werner (ed.). Fitzroy Dearborn Publishers, Chicago, Illinois.

39. Sidhu, R.S., B.G. Hammond, R.L. Fuchs, J.-N. Mutz, L.R. Holden, B. George and T. Olson. 2000. Glyphosate-tolerant corn: The composition and feeding value of grain from glyphosate-tolerant corn is equivalent to that of conventional corn (Zea mays L.). *Journal of Agricultural and Food Chemistry*. 48: 2305-2312.

40. Sjoblad, R.D., J.T. McClintock and R. Engler. 1992. Toxicological considerations for protein components of biological pesticide products. *Regulatory Toxicology and Pharmacology.* 15: 3-9.

41. Sleisenger, M.H. and J.S. Fordtran. 1989. The stomach and duodenum: Anatomy, physiology, and disease. Pages 685-689 in *Gastrointestinal Disease: Pathophysiology Diagnosis Management*. Volume 1. Fourth Edition. W.B. Saunders Company, Philadelphia, Pennsylvania.

42. Steinrücken, H.C. and N. Amrhein. 1980. The herbicide glyphosate is a potent inhibitor of 5-enolpyruvylshikimic acid-3-phosphate synthase. *Biochemical and Biophysical Research Communications*. 94: 1207-1212.

43. Thomas, K., M. Aalbers, G.A. Bannon, M. Bartels, R.J. Dearman, D.J. Esdaile, T.J. Fu, C.M. Glatt, N. Hadfield, C. Hatzos, S.L. Hefle, J.R. Heylings, R.E. Goodman, B. Henry, C. Herouet, M. Holsapple, G.S. Ladics, T.D. Landry, S.C. MacIntosh, E.A. Rice, L.S. Privalle, H.Y. Steiner, R. Teshima, R. van Ree, M. Woolhiser and J. Zawodny. 2004. A multi-laboratory evaluation of a common in vitro pepsin digestion assay protocol used in assessing the safety of novel proteins. *Regulatory Toxicology and Pharmacology.* 39: 87-98.

44. U.S. EPA. 1988. *Guidance for the reregistration of pesticide products containing Bacillus thuringiensis as the active ingredient*. 540/RS-89-023. U.S. Environmental Protection Agency, Washington, D.C.

45. U.S. EPA. 1995a. Plant pesticide Bacillus thuringiensis CryIIIA delta-endotoxin and the genetic material necessary for its production; Tolerance exemption. *Federal Register*. 60: 21725-21728.

46. U.S. EPA. 1995b. Plant pesticide *Bacillus thuringiensis* CryIA (b) delta-endotoxin and the genetic material necessary for its production (Plasmid vector pCIB4431) in corn. *Federal Register*. 60: 42443-42446.

47. U.S. EPA. 1995c. Plant pesticide *Bacillus thuringiensis* CryIA(c) delta-endotoxin and the genetic material necessary for its production in cotton; Tolerance exemption. *Federal Register.* 60: 47871-41874.

48. U.S. EPA. 1996. *Bacillus thuringiensis* Cry1A(b) delta-endotoxin and the genetic material necessary for its production in all plants; Exemption from requirement of a tolerance. *Federal Register.* 61: 40340-40343.

49. U.S. EPA. 1997. *Bacillus thuringiensis* subspecies kurstaki Cry1A(c) and the genetic material necessary for its production in all plants; Exemption from the requirement of a tolerance on all raw agricultural commodities. *Federal Register*. 62: 17720-17722.

50. U.S. EPA. 1998. *Reregistration eligibility decision (RED): Bacillus thuringiensis*. EPA738-R-98-004. U.S. Environmental Protection Agency, Washington, D.C.

51. U.S. EPA. 2001a. *Bacillus thuringiensis* Cry3Bb1 and Cry2Ab2 protein and the genetic material necessary for its production in corn and cotton; Exemption from the requirement of a tolerance. Final rule*. Federal Register.* 66: 24061-24066.

52. U.S. EPA. 2001b. *Biopesticides registration action document: Bacillus thuringiensis (Bt) plant-incorporated protectants* (October 15, 2001). U.S. Environmental Protection Agency, Washington D.C. http://www.epa.gov/pesticides/biopesticides/pips/bt_brad.htm.

53. U.S. EPA. 2002. *Biopesticides registration action document: Bacillus thuringiensis Cry2Ab2 protein and its genetic material necessary for its production in cotton* (Chemical PC Code 006487). Amended. U.S. Environmental Protection Agency, Washington, D.C.

54. U.S. EPA. 2003. *Biopesticides registration action document: Event MON 863 Bacillus thuringiensis Cry3Bb1 corn*. U.S. Environmental Protection Agency, Washington, D.C.

55. U.S. FDA. 1992. Statement of policy: Foods derived from new plant varieties. *Federal Register.* 57: 22984-23005.

56. USDA-NASS. 2006. *Crop production: 2005 summary*, January 2006. U.S. Department of Agriculture, National Agricultural Statistics Service, Washington, D.C.

57. USP. 1995. Test solutions. Page 2053 in the *National Formulary*. The United States Pharmacopeia, Washington, D.C.

58. Van Mellaert, H., J. Van Rie, C. Hofman and A. Reynaerts. 1988. Insectidical crystal proteins from Bacillus thuringiensis: Mode of action and expression in transgenic plants. Pages 82-87 in *Biotechnology, Biological Pesticides and Novel Plant-Pest Resistance for Insect Pest Management*. Boyce Thompson Institute, Cornell University, New York.

59. Watson, S.A. 1982. Corn: Amazing maize. General properties. Pages 3-29 in *CRC Handbook of Processing and Utilization in Agriculture. Volume II: Part 1 Plant Products*. I.A. Wolff (ed.). CRC Press, Inc., Boca Raton, Florida.

60. Watson, S.A. 1987. Structure and composition. Pages 53-82 in *Corn: Chemistry and Technology*. S.A. Watson and P.E. Ramstad (eds.). American Association of Cereal Chemists Inc., Saint Paul, Minnesota.

61. White, P.J. and L.M. Pollak. 1995. Corn as a food source in the United States: Part II. *Processes, products, composition, and nutritive values. Cereal Foods World.* 40: 756-762.

62. White, P.J. and E.J. Weber. 2003. Lipids of the kernel. Pages 355-405 in *Corn: Chemistry and Technology*. Second Edition. P.J. White and L.A. Johnson (eds.). American Association of Cereal Chemists, Inc., St. Paul, Minnesota.

63. Yagami, T., Y. Haishima, A. Nakamura, H. Osuna and Z. Ikezawa. 2000. Digestibility of allergens extracted from natural rubber latex and vegetable foods. *Journal of Allergy and Clinical Immunology.* 106: 752-762.