

FOOD SAFETY

Compositional Equivalence

2001. GM Food Crops and Application of Substantial Equivalence in the European Union. IN: The Commission of the Dutch Foundation 'Consument and Biotechnologie', June 2001: 1-67.

Aeschbacher, K., Messikommer, R., Meile, L., Wenk, C. 2005. Bt176 Corn in Poultry Nutrition: Physiological Characteristics and Fate of Recombinant Plant DNA in Chickens. *Poultry Science*. 84(3): 385 - 394.

Autran, J., Benetrix, F., Bloc, D., Burghart, P., Chaurant, M., Combe, N., Melcion, J. 2003. Composition and Technological Value of Genetically Modified and Conventional Maize - *Zea Mays L.* - Grains. *Sciences des Aliments*. 23: 223-247.

Baker, J., Hawkins, N., Ward, J., Lovegrove, A., Napier, J., Shewry, P., Beale, M. 2006. A Metabolomic Study of Substantial Equivalence of Field-grown Genetically Modified Wheat. *Plant Biotechnology Journal*. 4: 381-392.

Baudo, M., Lyons, R., Powers, S., Pastori, G., Edwards, K., Holdsworth, M., Shewry, P. 2006. Transgenesis Has Less Impact on the Transcriptome of Wheat Grain than Conventional Breeding. *Plant Biotechnology Journal*. 4: 369-380.

Berberich, S., Ream, J., Jackson, T., Wood, R., Stipanovic, R., Harvey, P., Patzer, S., Fuchs, R. 1996. The Composition of Insect-Protected Cottonseed Is Equivalent to that of Conventional Cottonseed. *Journal of Agricultural and Food Chemistry*. 44(1): 365-371.

Bertrand, J., Sudduth, T., Condon, A., Jenkins, T., Calhoun, M. 2005. Nutrient Content of Whole Cottonseed. *Journal of Dairy Science*. 88: 1470-1477.

Chassy, B. 2002. Food Safety Evaluation of Crops Produced through Biotechnology. Supplement to *Journal of the American College of Nutrition*. 21(3S): 166S-173S.

Cockburn, A. 2002. Assuring the Safety of Genetically Modified (GM) Foods - The Importance of An Holistic, Integrative Approach. *Journal of Biotechnology*. 98: 79-106.

Emlay, D. 1994. Compositional Analysis: The Key Component for the Safety Assessment of Flavr Savr™ Tomatoes or Why Would Anyone Want to Feed A Whole Food to Rats? Proceedings of the Third International Symposium on The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms. D. Jones, editor. November 13-16, 1994, Monterey, CA. Publisher: The University of California - Oakland: 209-211.

Engel, K., Gerstner, G., Rob. A. 1998. Investigation of Glycoalkaloids in Potatoes as an Example for the Principle of Substantial Equivalence. Proceedings of the International Symposium on Novel Foods Regulation In The European Union - Integrity of the Process of Safety Evaluation - November 18 - 20, 1997, Berlin, Germany. Publisher: Federal Institute of Consumer Health Protection And Veterinarian Medicine: 197-209.

- George, C., Ridley, W., Obert, J., Nemeth, M., Breeze, M., Astwood, J. 2004. Composition of Grain and Forage from Corn Rootworm-Protected Corn Event MON 863 Is Equivalent to that of Conventional Corn - *Zea Mays* L. *Journal of Agricultural and Food Chemistry*. 52: 4149-4158.
- Goda, Y., Akiyama, H., Suiyama, E., Takahashi, S., Kinjo, J., Nohara, T., Toyoda, M. 2002. Comparison of Soyasaponin and Isoflavone Contents Between Genetically Modified GM - and non-GM Soybeans. *Journal of the Food Hygienic Society of Japan*. 43(6): 339-347.
- Hamilton, K., Pyla, P., Breeze, M., Olson, T., Li, M., Robinson, E., Gallagher, S., Sorbet, R., Chen, Y. 2004. Bollgard II Cotton: Compositional Analysis and Feeding Studies of Cottonseed from Insect-protected Cotton -*Gossypium hirsutum* L.- Producing the Cry1Ac and Cry2Ab2 Proteins. *Journal of Agricultural and Food Chemistry*. 52(23): 6969 - 6976.
- Herman, R., Storer, N., Phillips, A., Prochaska, L., Windels, P. 2007. Compositional Assessment of Event DAS-59122-7 Maize Using Substantial Equivalence. *Regulatory Toxicology and Pharmacology*. 47(1): 37-47.
- Hill, J., Nelson, E., Tilman, D., Polasky, S., Tiffany, D. 2006. Environmental, Economic and Energetic Costs and Benefits of Biodiesel and Ethanol Biofuels. *Proceedings of the National Academy of Sciences*. 103(30): 11206-11210.
- Jonnala, R., Dunford, N., Chenault, K. 2005. Nutritional Composition of Genetically Modified Peanut Varieties. *Journal of Food Science*. 70(4): S254-S256.
- Jung, H., Sheaffer, C. 2004. Influence of Bt Transgenes on Cell Wall Lignification and Digestibility of Maize Stover for Silage. *Crop Science*. 44: 1781-1789.
- Kuiper, H., Kleter, G., Noteborn, H., Kok, E. 2002. Substantial Equivalence - An Appropriate Paradigm for the Safety Assessment of Genetically Modified Foods. *Toxicology*. 181-182: 427-431.
- Kumar, R., Singhal, K. 2004. Chemical Composition and Nutritional Evaluation of Transgenic Cottonseed for Ruminants. *Indian Journal of Animal Sciences*. 74(8): 868 - 871.
- Lavrik, P., Bartnicki, D., Feldman, J., Hammond, B., Keck, P., Love, S., Naylor, M., Rogan, G., Sims, S., Fuchs, R. 1995. Safety Assessment of Potatoes Resistant to Colorado Potato Beetle. *Genetically Modified Foods, Safety Issues*. Chapter 13: 148-157.
- List, G. R., Orthoefer, F., Taylor, N., Nelsen, T., Abidi, S. L. 1999. Characterization of Phospholipids from Glyphosate-tolerant Soybeans. *Journal of the American Oil Chemists' Society*. 76(1): 57-60.
- Love, S. L. 2000. When Does Similar Mean the Same: A Case for Relaxing Standards of Substantial Equivalence in Genetically Modified Food Crops. *HortScience*. 35(5): 803-806.

McCann, M., Trujillo, W., Riordan, S., Sorbet, R., Bogdanova, N., Sidhu, R. 2007. Comparison of the Forage and Grain Composition from Insect-Protected and Glyphosate-Tolerant MON 88017 Corn to Conventional Corn (*Zea mays* L.). *Journal of Agricultural and Food Chemistry*. 55(10): 4034-4042.

Millstone, E., Brunner, E., Mayer, S. 1999. Beyond 'Substantial Equivalence'. *Nature*. 401(6753): 525-526.

Momma, K., Hashimoto, W., Ozawa, S., Kawai, S., Katsube, T., Takaiwa, F., Kito, M., Utsumi, S., Murata, K. 1999. Quality and Safety Evaluation of Genetically Engineered Rice With Soybean Glycinin: Analyses of the Grain Composition and Digestibility of Glycinin in Transgenic Rice. *Bioscience, Biotechnology, and Biochemistry*. 63(2): 314-318.

Nida, D., Patzer, S., Harvey, P., Stipanovic, R., Wood, R., Fuchs, R. 1996. Glyphosate-tolerant Cotton: The Composition of the Cottonseed Is Equivalent to that of Conventional Cottonseed. *Journal of Agricultural and Food Chemistry*. 44(7): 1967-1974.

Oberdoerfer, R., Shillito, R., de Beuckeleer, M., Mitten, D. 2005. Rice (*oryza Sativa* L.) Containing the Bar Gene is Compositionally Equivalent to the Nontransgenic Counterpart. *Journal of Agricultural and Food Chemistry*. 53(5): 1457 – 1465.

Obert, J., Ridley, W., Schneider, R., Riordan, S., Nemeth, M., Tujillo, W., Breeze, M., Sorbet, R., Astwood, J. 2004. The Composition of Grain and Forage from Glyphosate-tolerant Wheat MON 71800 Is Equivalent to that of Conventional Wheat - *Triticum aestivum* L. *Journal of Agricultural and Food Chemistry*. 52(5): 1375-1384.

Padgett, S., Re, D., Barry, G., Eichholtz, D., Delannay, X., Fuchs, R., Kishore, G., Fraley, R. 1996. New Weed Control Opportunities: Development of Soybeans With a Roundup Ready® Gene. IN: *Herbicide-Resistant Crops: Agriculture, Environmental, Economic, Regulatory and Technical Aspects*. Chapter 4: 53-84.

Padgett, S., Taylor, N., Nida, D., Bailey, M., MacDonald, J., Holden, L., Fuchs, R. 1996. The Composition of Glyphosate-tolerant Soybean Seeds Is Equivalent to that of Conventional Soybeans. *Journal of Nutrition*. 126 (3): 702-716.

Petit, L., Barange, F., Bertheau, Y., Brunschwig, P., Diolez, A., Duhem, K., Duplan, M., Fach, P., Kobilinsky, A., Lamart, S., Schattner, A., Martin, P. 2005. Detection of Genetically Modified Corn (Bt176) in Spiked Cow Blood Samples by Polymerase Chain Reaction and Immunoassay Methods. *Journal of AOAC International*. 88(2): 654-664.

Ridley, W., Hartnell, G., Hammond, B. 2005. Role of Composition and Animal Feeding Studies in the Safety Assessment of Biotech Crops. *ACS Symposium Series 892*: 28-39.

Ridley, W., Sidhu, R., Astwood, J., Fuchs, R. 2004. Role of Compositional Analyses in the Evaluation of Substantial Equivalence for Biotechnology Crops. *Agricultural Biotechnology - Challenges and Prospects*. ACS Symposium Series 866. M. Bhalgat, W. Ridley, A. Felsot, J. Seiber, Editors. Chapter 11: 165-175.

Ridley, W., Sidhu, R., Pyla, P., Nemeth, M., Breeze, M., Astwood, J. 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(25): 7235-7243.

Rogan, G. J., Bookout, J. T., Duncan, D. R., Fuchs, R. L., Lavrik, P. B., Love, S. L., Mueth, M., Olson, T., Owens, E.D., Raymond, P.J., Zalewski, J. 2000. Compositional Analysis of Tubers from Insect and Virus Resistant Potato Plants. *Journal of Agricultural Food Chemistry*. 48: 5936-5945.

Rossi, F., Moschini, M., Florentini, L., Masoero, F., Piva, G. 2003. Analytical Composition and Rumen Degradability of Isogenic and Transgenic Corn Varieties. *Journal of the Science of Food and Agriculture*. 83(13): 1337-1341.

Sanders, P., Lee, T., Groth, M., Astwood, J., Fuchs, R. 1998. Safety Assessment of Insect-Protected Corn. IN: *Biotechnology and Safety Assessment*. Chapter 10: 241-256.

Shewry, P., Baudo, M., Lovegrove, A., Powers, S., Napier, J., Ward, J., Baker, J., Beale, M. 2007. Are GM and Conventionally Bred Cereals Really Different. *Trends in Food Science and Technology*. 18: 201-209.

Sidhu, R.S., Hammond, B.G., Fuchs, R.L., Mutz, J., Holden, L., George, B., Olson, T. 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(6): 2305-2312.

Taylor, N., Fuchs, R., MacDonald, J., Shariff, A., Padgett, S. 1999. Compositional Analysis of Glyphosate-tolerant Soybeans Treated With Glyphosate. *Journal of Agricultural and Food Chemistry*. 47(10): 4469-4473.

Protein Safety

2006. NASS USDA United States Crop Acreage Report 2006. USDA, Agricultural Statistics Board, NASS: 1-43.

Betz, F. S., Hammond, B. G., Fuchs, R. L. 2000. Safety and Advantages of Bacillus thuringiensis-Protected Plants to Control Insect Pests. Regulatory Toxicology and Pharmacology. 32: 156-173.

Bogdanov, S. 2006. Contaminants of Bee Products. Apidologie. 37: 1-18.

EPA. 1997. Name of Chemical(s): Bacillus thuringiensis subspecies kurstaki CryIA (c) Delta Endotoxin and the Genetic Material Necessary for its Production in Corn. EPA: Pesticide Fact Sheet: 1-22.

EPA. 1996a. EPA Fact Sheet for Bacillus thuringiensis subspecies kurstaki Strain EG 7841, September 1996 (Ecogen).

EPA. 1996b. EPA Fact Sheet for Bacillus thuringiensis subspecies kurstaki Cry 1A (b) Delta Endotoxin and its Controlling Sequences as Expressed in Corn. December 20, 1996 (Monsanto).

EPA. 1995a. EPA Fact Sheet for Bacillus thuringiensis subspecies kurstaki Cry 1A(b) Delta Endotoxin and Its Controlling Sequences in Corn, March 21, 1995 (Ciba Seeds).

EPA. 1995b. EPA Fact Sheet for Bacillus thuringiensis subspecies tenebrionis Cry 3A Delta Endotoxin and its Controlling Sequences in Potato, May 5, 1995 (Monsanto).

EPA. 1995c. EPA Fact Sheet for Bacillus thuringiensis subspecies kurstaki Cry 1Ac Delta Endotoxin and Its Controlling Sequences as Expressed in Cotton. October 1995 (Monsanto).

Federal Register. 1996. Bacillus thuringiensis Cry 1A (b) Delta Endotoxin and the Genetic Material Necessary for Its Production in all Plants; Exemption from Requirement of a Tolerance; Final Rule; 61 FR40340. August 2, 1996.

Fares, N., El Sayed, A. 1998. Fine Structural Changes in the Ileum of Mice Fed on Delta-endotoxin-treated Potatoes and Transgenic Potatoes. Natural Toxins: 219-233.

Finn, R., Leimgruber, R., Boyle, D., Jennings, M., Kimack, N., Smith, C., Bishop, B., Fraizer, R., Magin, K., Fuchs, R., Reed, A. 1996. Purification and Biochemical Comparison of 1-aminocyclopropane-1-carboxylic acid deaminase Proteins Expressed in Delayed Ripening Tomato and Escherichia coli: Studies for a Food Safety Assessment. Journal of Agricultural and Food Chemistry. 44(1): 381-387.

Franck-Oberaspach, S., Keller, B. 1997. Consequences of Classical and Biotechnological Resistance Breeding for Food Toxicology and Allergenicity. Plant Breeding. 116(1): 1-17.

Fuchs, R., Heeren, R., Gustafson, M., Rogan, G., Bartnicki, D., Leimgruber, R., Finn, R., Hershman, A., Berberich, S. 1993. Purification and Characterization of Microbially

Expressed Neomycin Phosphotransferase II (NPTII) Protein and Its Equivalence to the Plant Expressed Protein. *Bio/Technology*. 11(13): 1537-1542.

Fuchs, R., Ream, J., Hammond, B., Naylor, M., Leimgruber, R., Berberich, S. 1993. Safety Assessment of the Neomycin Phosphotransferase II (NPTII) Protein. *Bio/Technology*. 11(13): 1543-1547.

Hammond, B., Fuchs, R. 1998. Safety Evaluation of Food Crops Developed through Biotechnology. IN: *Biotechnology and Safety Assessment*, 2nd edition: 61-79.

Hammond, B. 1997. Assessment of Potential Protein Toxicity. Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Foods. Aussois, France, 5-8 March 1997. Organization for Economic Cooperation and Development, Paris: Page 26.

Harrison, L., Bailey, M., Naylor, M., Ream, J., Hammond, B., Nida, D., Burnette, B., Nickson, T., Mitsky, T., Taylor, M., Fuchs, R., Padgett, S. 1996. The Expressed Protein in Glyphosate-tolerant Soybean, 5-Enolpyruvylshikimate -3-Phosphate Synthase from *Agrobacterium* sp. Strain CP4, Is Rapidly Digested In Vitro and Is Not Toxic to Acutely Gavage Mice. *Journal of Nutrition*. 126(3): 728-740.

Herouet, C., Esdaile, D., Mallyon, B., Debruyne, E., Schulz, A., Currier, T., Hendrickx, D., van der Klis, R., Rouan, D. 2005. Safety Evaluation of the Phosphinothricin Acetyltransferase Proteins Encoded by the Pat and Bar Sequences that Confer Tolerance to Glufosinate-ammonium Herbicide in Transgenic Plants. *Regulatory Toxicology and Pharmacology*. 41(2): 134 - 149.

Hofmann, C., Vanderbruggen, H., Hofte, H., Van Rie, J., Jansens, S., Van Mellaert, H. 1988. Specificity of *Bacillus thuringiensis* Delta - Endotoxins Is Correlated With the Presence of High-Affinity Binding Sites in the Brush Border Membrane of Target Insect Midguts. *Proceedings of the National Academy of Sciences of the United States of America*. 85(21): 7844-7848.

Hupfer, C., Mayer, J., Hotzel, H., Sachse, K., Engel, K. 1999. The Effect of Ensiling on PCR-Based Defection of Genetically Modified Bt Maize. *European Food Research and Technology*. 209(5): 301-304.

Lee, T., Zeng, J., Bailey, M., Sims, S., Sanders, P., Fuchs, R. 1995. Assessment of Equivalence of Insect Protected Corn and *E. coli* Produced B.T.K. HD-1 Protein. *Plant Physiology Supplement*. 108(795): 151.

MacIntosh, S., Stone, T., Sims, S., Hunst, P., Greenplate, J., Marrone, P., Perlak, F., Fischhoff, D., Fuchs, R. 1990. Specificity and Efficacy of Purified *Bacillus thuringiensis* Proteins Against Agronomically Important Insects. *Journal of Invertebrate Pathology*. 56(2): 258-266.

MacIntosh, S., McPherson, S., Perlak, F., Marrone, P., Fuchs, R. 1990. Purification and Characterization of *Bacillus thuringiensis* Var. tenebrionis Insecticidal Proteins Produced in *E. coli*. *Biochemical and Biophysical Research Communications*. 170(2): 665-672.

McPherson, S., Perlak, F., Fuchs, R., Marrone, P., Lavrik, P., Fischhoff, D. 1988. Characterization of the Coleopteran-Specific Protein Gene of Bacillus thuringiensis Var. tenebrionis. *Bio/Technology*. 6(1): 61-66.

Nida, D., Kolacz, K., Buehler, R., Deaton, W., Schuler, W., Armstrong, T., Taylor, M., Ebert, C., Rogan, G., Padgett, S., Fuchs, R. 1996. Glyphosate-tolerant Cotton: Genetic Characterization and Protein Expression. *Journal of Agricultural and Food Chemistry*. 44(7): 1960-1966.

Noteborn, H., Rienenmann-Ploum, M., van den Berg, J., Alink, G., Zolla, L., Kuiper, H. 1993. Food Safety of Transgenic Tomatoes Expressing the Insecticidal Crystal Protein CryIA(b) from Bacillus thuringiensis and the Marker Enzyme APH(3')II. *Med. Fac. Landouww. Univ. Gent*. 58 (4b): 1851-1858.

Padgett, S., Kolacz, K., Delannay, X., Re, D., LaVallee, B., Tinius, C. N., Rhodes, W., Otero, Y., Barry, G., Eichholtz, D., Peschke, V., Nida, D., Taylor, N., Kishore, G. 1995. Development, Identification, and Characterization of a Glyphosate-tolerant Soybean Line. *Crop Science*. 35: 1451-1461.

Reed, A., Kretzmer, K., Naylor, M., Finn, R., Magin, K., Hammond, B., Leimgruber, R., Rogers, S., Fuchs, R. 1996. Safety Assessment of 1-Aminocyclopropane-1-carboxylic Acid Deaminase Protein Expressed in Delayed Ripening Tomatoes. *Journal of Agricultural and Food Chemistry*. 44(1): 388-394.

Reed, A., Magin, K., Anderson, J., Austin, G., Rangwala, T., Linde, D., Love, J., Rogers, S., Fuchs, R. 1995. Delayed Ripening Tomato Plants Expressing the Enzyme 1-aminocyclopropane-1-carboxylic Acid Deaminase. 1. Molecular Characterization, Enzyme Expression, and Fruit Ripening Traits. *Journal of Agricultural and Food Chemistry*. 43(7): 1954-1962.

Romeis, J., Dutton, A., Bigler, F. 2004. Bacillus thuringiensis Toxin (Cry1Ab) has No Direct Effect on Larvae of the Green Lacewing *Chrysoperla Carnea* (stephens) (neuroptera: Chrysopidae). *Journal of Insect Physiology*. 50(2-3): 175-183.

Sacchi, V., Parenti, P., Hanozet, G., Giordana, B., Luthy, P., Wolfersberger, M. 1986. Bacillus thuringiensis Toxin Inhibits K⁺ - Gradient-dependent Amino Acid Transport Across the Brush Border Membrane of *Pieris Brassicae* Midgut Cells. *FEBS (Federation of European Biochemical Societies) Letter*. 204 (2): 213-218.

Shimada, N., Miyamoto, K., Kanda, K., Murata, H. 2006. Binding of Cry1Ab Toxin, a Bacillus thuringiensis Insecticidal Toxin, to Proteins of the Bovine Intestinal Epithelial Cell: An In Vitro Study. *Applied Entomology and Zoology*. 41(2): 295-301.

Food Allergy

2003. Consensus Document on Compositional Considerations for New Varieties of Bread Wheat - *Triticum aestivum* - Key Food and Feed Nutrients and Toxicants. OECD. Joint Meeting of the Chemicals Committee and The Working Party on Chemicals, Pesticides and Biotechnology. Series on the Safety of Novel Foods and Feeds, No. 7: 1-37.

- Alibhai, M., Astwood, J., Joyce, E., Pershing, J., Sampson, H., Purcell, J. 2000. Re-engineering Patatin (Sol t 1) Protein to Eliminate IgE Binding. *Journal of Allergy and Clinical Immunology*. 04: S79.
- Astwood, J., Silvanovich, A., Bannon, G. 2002. Vicilins - A Case Study in Allergen Pedigrees. *Journal Allergy Clinical Immunology*. 110: 26-27.
- Astwood, J., Fuchs, R.; Editors: Baker, D. R., Umetsu, N. K. 2001. Status and Safety of Biotech Crops. ACS Symposium Series 774: Agrochemical Discovery Insect, Weed, and Fungal Control. Chapter 14: 152-164.
- Astwood, J. 2001. Preventing Food Allergy - The Impact of Biotechnology. *Journal of Animal Science*. 79 (Supplement 1): 55.
- Astwood, J., Nair, R., Lamb, I., Holleschak, G., Leach, J., Goodman, R., Hammond, B., Fuchs, R., English, L., Rangwala, S., Sampson, H. Yu, S., Choi, D., and Li, A. 2001. Neurobiology and Allergenicity of Plant Anti-Fungal Proteins. *The Toxicologist*. 60(1).
- Astwood, J., Tran, K., Liang, J., Goodman, R., Sampson, H. 2000. Digestibility and Allergenicity of Gamma-thionin from Wheat Flour. *Journal of Allergy and Clinical Immunology*. 104: S138.
- Astwood, J., Goodman, R. 2000. The Relevance of Protein Stability to Allergy Assessment. *Toxicology Letters*. 116: 6.
- Astwood, J., Alibhai, M., Lee, T., Fuchs, R., Sampson, H. 2000. Identification and Characterization of IgE Binding Epitopes of Patatin, A Major Food Allergen of Potato. *Journal of Allergy and Clinical Immunology*. 104: S184.
- Astwood, J., Leach, J., Ream, J., Fuchs, R. 1996. Allergenic Potential of Foods from Genetically Engineered Plants. *The Toxicology Forum: 1996 Annual European Meeting*, March 25-28, 1996, Green College Oxford, UK. Publisher: Toxicology Forum, Inc., Washington, DC: 136-170.
- Astwood, J., Fuchs, R. 1996. Allergenicity Assessment of Foods Derived from Genetically Modified Plants. *Food Technology*. 50 (2): 83-88.
- Astwood, J., Fuchs, R. 1996. Allergenicity of Foods Derived from Transgenic Plants. *Highlights in Food Allergy: Proceedings of the 6th International Symposium on Immunological and Clinical Problems of Food Allergy*, Lugano, September 1995. 32: 105-120.
- Astwood, J., Fuchs, R. 1996. Preventing Food Allergy- Emerging Technologies. *Trends In Food Science & Technology*. 7(7): 219-226.
- Astwood, J., Fuchs, R., Lavrik, P. 1996. Food Biotechnology and Genetic Engineering. *Food Allergy: Adverse Reactions to Foods and Food Additives*. Chapter 4: 65-92.
- Astwood, J., Fuchs, R. 1996. Food Allergens Are Stable to Digestion in a Simple Model of the Gastrointestinal Tract. *The Journal of Allergy and Clinical Immunology*. 97 (1) Part 3: 241.

Astwood, J., Leach, J., Fuchs, R. 1996. Stability of Food Allergens to Digestion In Vitro. *Nature Biotechnology*. 14 (10): 1269-1273.

Bannon, G., Goodman, R., Leach, J., Rice, E., Fuchs, R., Astwood, J. 2002. Digestive Stability in the Context of Assessing the Potential Allergenicity of Food Proteins. *Comments on Toxicology*. 8: 271 - 285.

Bannon, G., Fu, T., Kimber, I., Hinton, D. 2003. Protein Digestibility and Relevance to Allergenicity. *Environmental Health Perspectives*. 111(8): 1122-1124.

Batista, R., Nunes, B., Carmo, M., Cardoso, C., Sao Jose, H., de Almeida, A., Manique, A., Bento, L., Ricardo, C., Oliveira, M. 2005. Lack of Detectable Allergenicity of Transgenic Maize and Soya Samples. *Journal of Allergy and Clinical Immunology*. 116: 403-410.

Bernstein, J., Bernstein, I., Bucchini, L., Goldman, L., Hamilton, R., Lehrer, S., Rubin, C., Sampson, H. 2003. Clinical and Laboratory Investigation of Allergy to Genetically Modified Foods. *Environmental Health Perspectives*. 111(8): 1114 - 1121.

Bhalla, P. L., Swoboda, I., Singh, M. B. 1999. Antisense-Mediated Silencing of a Gene Encoding a Major Ryegrass Pollen Allergen. *Proceedings of the National Academy of Sciences*. 96: 11676-11680.

Buchanan, B. 2001. Genetic Engineering and the Allergy Issue. *Plant Physiology*. 126: 5-7.

Burks, A., Fuchs, R. 1995. Assessment of the Endogenous Allergens in Glyphosate-tolerant and Commercial Soybean Varieties. *Journal of Allergy and Clinical Immunology*. 96(6,1): 1008-1010.

Chang, H., Bae, Y., Lim, S., Jeong, T., Kim, H., Chung, S., Kim, D., Nam, D. 2001. Allergenicity Test of Genetically Modified Soybean in Sprague-dawley Rats. *Archives of Pharmacal Research*. 24(3): 256 – 261.

Chang, H., Kim, N.H., Park, M.J., Lim, S., Kim, S.C., Kin, J.Y., Kim, J.A., Oh, H.Y., Lee, C.H., Huh, K., Jeong, T., Nam, D. 2003. The 5-enolpyruvylshikimate-3-phosphate Synthase of Glyphosate-tolerant Soybean Expressed in *Escherichia coli* Shows No Severe Allergenicity. *Molecules and Cells*. 15(1): 20-26.

Chassy, B. 2002. Food Safety Evaluation of Crops Produced through Biotechnology. Supplement to *Journal of the American College of Nutrition*. 21(3S): 166S-173S.

Dearman, R.J., Kimber, I. 2001(b). Cytokine Fingerprinting and Hazard Assessment of Chemical Respiratory Allergy. *Journal of Applied Toxicology*. 21: 153-163.

del Val, G., Yee, B.C., Lozano, R.M., Buchanan, B.B., Ermel, R., Lee, Y., Frick, O. 1999. Thioredoxin Treatment Increases Digestibility and Lowers Allergenicity of Milk. *Journal of Allergy and Clinical Immunology*. 103(4): 690-697.

Fuchs, R. L.; Editors: Eisenbrand, G., Aulepp, H., Dayan, A. D., Elias, P. S., Grunow, W., Ring, J., Schlatter, J., Köhl, W., Baum, M. 1996. Assessment of the Allergenic Potential of Foods Derived from Genetically Engineered Plants: Glyphosate Tolerant Soybean as a Case Study. Food Allergies and Intolerances Symposium. Publisher: VCH Verlagsgesellschaft mbH, Weinheim, Germany. Chapter 17: 212-221.

Fuchs, R. 1998. Principles and Strategies for the Assessment of the Allergenic Potential of Foods Derived from Genetically Modified Plants. Proceedings of the International Symposium on Novel Foods Regulation in the European Union - Integrity of the Process of Safety Evaluation - November 18-20, 1997, Berlin, Germany. Publisher: Federal Institute of Consumer Health Protection and Veterinary Medicine: 287-292.

Fuchs, R., Goodman, R. 1998. Products from Plant Biotechnology. Allergy. 53 Issue: (Supplement 46): 93-97.

Germolec, D., Kimber, I., Goldman, L., Selgrade, M. 2003. Key Issues for the Assessment of the Allergenic Potential of Genetically Modified Foods - Breakout Group Reports. Environmental Health Perspectives. 111(8): 1131-1139.

Gendel, S. 1998. Sequence Databases for Assessing the Potential Allergenicity of Proteins Used in Transgenic Foods. Advances in Food Nutrition Research. 42: 63-92.

Gendel, S. 1998. The Use of Amino Acid Sequence Alignments to Assess Potential Allergenicity of Proteins Used in Genetically Modified Foods. Advances in Food Nutrition Research. 42: 45-62.

Gizzarelli, F., Corinti, S., Barletta, B., Iacovacci, P., Brunetto, B., Butteroni, C., Afferni, C., Onori, R., Miraglia, M., Panzini, G., Di Felice, G., Ringhino, R. 2006. Evaluation of Allergenicity of Genetically Modified Soybean Protein Extract in a Murine Model of Oral Allergen-specific Sensitization. Clinical and Experimental Allergy. 36: 238-248.

Goodman, R., Hefle, S., Taylor, S., van Ree, R. 2005. Assessing Genetically Modified Crops to Minimize the Risk of Increased Food Allergy - A Review. International Archives of Allergy and Immunology. 137: 153-166.

Goodman, R.E., Leach, J.N., Reed, A.J., Lee, J., Harrah, D., Astwood, J. 2000. Relative Reaginic and Inflammatory Responses to Extracts of Modified and Non-Transgenic Cottonseeds in Brown Norway Rats Fed Conventional Cottonseed Meal Diets. Journal of Allergy and Clinical Immunology. 104: S138.

Goodman, R., Silvanovich, A., Hileman, R., Bannon, G., Rice, E., Astwood, J. 2002. Bioinformatic Methods for Identifying Known or Potential Allergens in the Safety Assessment of Genetically Modified Crops. Comments on Toxicology. 8: 251-269.

Hefle, S., Nordlee, J., Taylor, S. (1996). Allergenic Foods. Critical Reviews in Food Science and Nutrition. 36(S): S69-89.

Herman, R., Woolhiser, M., Ladics, G., Korjagin, V., Schafer, B., Storer, N., Green, S., Kan, L. 2007. Stability of a Set of Allergens and Non-allergens in Simulated Gastric Fluid. International Journal of Food Sciences and Nutrition. 58(2): 125-141.

- Herman, R., Storer, N., Gao, Y. 2006. Digestion Assays in Allergenicity Assessment of Transgenic Proteins. *Environmental Health Perspectives*. 114(8): 1154-1157.
- Hileman, R., Silvanovich, A., Goodman, R., Rice, E., Holleschak, G., Astwood, J., Hefle, S. 2002. Bioinformatic Methods for Allergenicity Assessment Using a Comprehensive Allergen Database. *International Archives Allergy Immunology*. 128: 280-291.
- Kimber, I., Kerkvliet, N., Taylor, S., Astwood, J., Sarlo, K., Dearman, R. 1999. Toxicology of Protein Allergenicity: Prediction and Characterization. *Toxicological Science*. 48 (2): 157-162.
- Kimber, I., Dearman, R. 2002. Approaches to Assessment of the Allergenic Potential of Novel Proteins in Food from Genetically Modified Crops. *Toxicological Sciences*. 68: 4-8.
- Kimber, I., Dearman, R., Penninks, A., Knippels, L., Buchanan, R., Hammerberg, B., Jackson, H., Helm, R. 2003. Assessment of Protein Allergenicity on the Basis of Immune Reactivity - Animal Models. *Environmental Health Perspectives*. 111(8): 1125-1130.
- Kimber, I., Betts, C., Dearman, R. 2003. Assessment of the Allergenic Potential of Proteins. *Toxicology Letters*. 140: 297 - 302.
- Lack, G., Chapman, M., Kalsheker, N., Kings, V., Robinson, C., Venables, K. 2002. Report on the Potential Allergenicity of Genetically Modified Organisms and Their Products. *Clinical and Experimental Allergy*. 32: 1131-1143.
- Ladics, G., Holsapple, M., Astwood, J., Kimber, I., Knippels, L., Helm, R., Dong, W. 2003. Workshop Overview - Approaches to the Assessment of the Allergenic Potential of Food from Genetically Modified Crops. *Toxicological Sciences*. 73: 8-16.
- Lehrer, S., Bannon, G. 2005. Risks of Allergic Reactions to Biotech Proteins in Foods - Perception And Reality. *Allergy*. 60(5): 559 - 564.
- Lehrer, S. 2000. Potential Health Risks of Genetically Modified Organisms: How Can Allergens be Assessed and Minimized? *Agricultural Biotechnology and the Poor: Proceedings of an International Conference, Washington, DC, USA, 21-22 October 1999*: 149-155.
- Lehrer, S. B., Reese, G.; Editor: Thomas, J. A. 1998. *Food Allergens: Implications for Biotechnology. Biotechnology and Safety Assessment. Edition 2. Chapter 6.* Publisher: Taylor & Francis: 127-150.
- Lorenz, A., Scheurer, S., Haustein, D., Vieths, S. 2001. Review - Recombinant Food Allergens. *Journal of Chromatography B* 756: 255-279.
- Matsuda, T., Nakase, M., Adachi, T., Nakamura, R., Tada, Y., Shimada, H., Takahashi, M., Fujimura, T.; Editors: Eisenbrand, G., Aulepp, H., Dayan, A.D., Elias, P.S., Grunow, W., Ring, J., Schlatter, J., Köhl, W., Baum, M. 1996. *The Input of Molecular Biology: Transgenic Foods: Allergenic Proteins in Rice: Strategies for Reduction and Evaluation.*

- Food Allergies and Intolerances: Symposium. Chapter 12. Publisher: VCH, DFG, Weinheim: 161-169.
- Matsuda, T. 1998. Application of Transgenic Techniques for Hypo - Allergenic Rice. Proceedings of the International Symposium on Novel Foods Regulation in the European Union - Integrity of the Process of Safety Evaluation - November 18-20, 1997, Berlin, Germany. Publisher: Federal Institute of Consumer Health Protection and Veterinary Medicine: 311-319.
- Melo, V.M.M., Xavier-Filho, J., Lima, M.S., Prouvost-Danon, A. 1994. Allergenicity and Tolerance to Proteins from Brazil Nut (*Bertholletia excelsa* H.B.K.). *Food Agricultural Immunology*: 185.
- Metcalfe, D., Astwood, J., Townsend, R., Sampson, H., Taylor, S., Fuchs, R. 1996. Assessment of the Allergenic Potential of Foods Derived from Genetically Engineered Crop Plants. *Critical Reviews in Food Science and Nutrition*. 36 (supplement): S165-S186.
- Metcalfe, D. 2002. Allergenicity of Foods Produced by Genetic Modification. IN: *Allergenicity in GM Foods*. Chapter 5: 94-109.
- Mills, E., Madsen, C., Shewry, P., Wichers, H. 2003. Food Allergens of Plant Origin - Their Molecular and Evolutionary Relationships. *Trends in Food Science and Technology*. 14: 145-156.
- Nordlee, J., Talyor, S., Townsend, J., Thomas, L., Beach, L.; Editors: Eisenbrand, G., Aulepp, H., Dayan, A.D., Elias, P.S., Grunow, W., Ring, J., Schlatter, J., Köhl, W., Baum, M. 1996. Transgenic Soybeans Containing Brazil Nut 2S Storage Protein: Issues Regarding Allergenicity. *Food Allergies and Intolerances: Symposium*. Chapter 15. Publisher: VCH, DFG, Weinheim: 196-202.
- Nordlee, J., Taylor, S., Townsend, J., Thomas, L., Bush, R. 1996. Identification of a Brazil-Nut Allergen in Transgenic Soybeans. *New England Journal of Medicine*. 334: 726-728.
- Okunuki, H., Teshima, R., Shigeta, T., Sakushima, J., Akiyama, H., Goda, Y., Toyoda, M., Sawada, J. 2002. Increased Digestibility of Two Products in Genetically Modified Food - CP4-EPSPS and Cry1Ab - after Preheating. *Journal Food Hygiene Society*. 43(2): 68-73.
- Pasteau, S., Bannon, G., Astwood, J., Goodman, R., Cockburn, A. 2003. Evaluation of Potential Allergenicity of Genetically Modified Plants Evaluation Du Potentiel Allergene Des Aliments Derives De Plantes Genetiquement Modifiees. *Revue Francaise d'Allergologie et d'Immunologie Clinique*. 43(1): 24 - 30.
- Penninks, A.H., Knippels, L.M. 2001. Determination of Protein Allergenicity: Studies In Rats. *Toxicology Letters*. 120: 171-180.
- Poulsen, L.K. 2004. Allergy Assessment of Foods or Ingredients Derived from Biotechnology, Gene-modified Organisms, or Novel Foods. *Molecular Nutrition and Food Research*. 48(6): 413 - 423.

- Ramón, D., Morán, M., Costa, J., López, F., Arriola, A., Martín, A.C., Cuellar, R., Camacho, R., Rodríguez, F. 2005. Documentos de Divulgación. Biotecnología en el Sector Alimentario (In Spanish). Genoma Espana Foundation, Madrid: 1-77.
- Silvanovich, A., Nemeth, M., Song, P., Herman, R., Tagliani, L., Bannon, G. 2006. The Value of Short Amino Acid Sequence Matches for Prediction of Protein Allergenicity. *Toxicological Sciences*. 90(1): 252-258.
- Stadler, M., Stadler, B. 2003. Allergenicity Prediction by Protein Sequence. *FASEB (Federation of American Societies for Experimental Biology) Journal*. 17(6): NIL34 - NIL50.
- Sten, E., Skov, P., Andersen, S., Torp, A., Olesen, A., Bindslev-Jensen, U., Poulsen, L., Bindsley-Jensen, C. 2004. A Comparative Study of the Allergenic Potency of Wild-Type and Glyphosate-tolerant Gene-Modified Soybean Cultivars. *APMIS - Acta Pathologica, Microbiologica, et Immunologica Scandinavica*. 112(1): 21-28.
- Taylor, S.L.; Editors: Jones, D.D. 1994. Evaluation of the Allergenicity of Foods Developed Through Biotechnology. *Proceedings of the Third International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms*. Publisher: University of California, Oakland: 185-198.
- Taylor, S.L., Hefle, S.L. 2000. Will Genetically Modified Foods be Allergenic? *Journal of Allergy and Clinical Immunology*. 107: 765-771.
- Taylor, S. 2002. Protein Allergenicity Assessment of Foods Produced Through Agricultural Biotechnology. *Annual Review of Pharmacology and Toxicology*. 42: 99-112.
- Taylor, S. 2002. Assessment of the Allergenicity of Foods Produced through Agricultural Biotechnology. *American Chemical Society Symposium Series 829*: 205-216.
- Taylor, S., Hefle, S. 2002. Genetically Engineered Foods: Implications for Food Allergy. *Current Opinion in Allergy and Clinical Immunology*. 2(3): 249 - 252.
- Tsuji, H., Kimoto, M., Natori, Y. 2001. Allergens in Major Crops. *Nutrition Research*. 21: 925-934.
- Vieths, S. 1998. Allergenic Potential of Genetically Modified Plant Foods - How Reliable Is the Proposed Assessment Strategy? *Proceedings of the International Symposium on Novel Foods Regulation in the European Union - Integrity of the Process of Safety Evaluation - November 18-20, 1997, Berlin, Germany*. Publisher: Federal Institute of Consumer Health Protection and Veterinary Medicine: 295-309.

Animal Safety Studies

2000. The Effect of Genetically Modified Potatoes on Rat Small Intestine. *European Journal Of Pediatrics*. 159: 710-711.

Ash, J., Novak, C., Scheideler, S. 2003. The Fate of Genetically Modified Protein from Roundup Ready® Soybeans in Laying Hens. *Journal of Applied Poultry Research*. 12: 242-245.

Baker, B., Alexander, B., Mandel, J., Acquavella, J. 2005. Farm Family Exposure Study: Methods and Recruitment Practices for a Biomonitoring Study of Pesticide Exposure. *Journal of Exposure Analysis and Environmental Epidemiology*. 15(6): 491-499.

Coulston, F., Kolbye, A. 1990. Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification. *Regulatory Toxicology and Pharmacology*. 12: S1-S196.

Duggan, P., Chambers, P., Heritage, J., Forbes, J. 2003. Fate of Genetically Modified Maize DNA in the Oral Cavity and Rumen of Sheep. *British Journal of Nutrition*. 89(2): 159 - 166.

Ewen, S.W.B., Pusztai, A. 1999. Effect of Diets Containing Genetically Modified Potatoes Expressing Galanthus nivalis Lectin on Rat Small Intestine. *Lancet*. 354 (9187): 1353-1354.

Hammond, B., Dudek, R., Lemen, J., Nemeth, M. 2004. Results of a 13 Week Safety Assurance Study With Rats Fed Grain from Glyphosate Tolerant Corn. *Food and Chemical Toxicology*. 42: 1003-1014.

Hammond, B., Mayhew, D., Robinson, K., Mast, R., Sander, W.. 2001. Section 3 - Single-Generation Rat Reproduction Study. *Safety Assessment Of Dha-Rich Microalgae From Schizochytrium Regulatory*. *Toxicology and Pharmacology*. 33: 356-362.

Hammond, B., Mayhew, D., Holson, J., Nemec, M., Mast, R., Sander, W. 2001. Section 2 - Developmental Toxicity Evaluation in Rats and Rabbits. *Safety Assessment of DHA-Rich Microalgae from Schizochytrium*. *Regulatory Toxicology and Pharmacology*. 33: 205-217.

Hammond, B., Mayhew, D., Naylor, M., Ruecker, F., Mast, R., Sander, W. 2001. Section 1 - Subchronic Rat Feeding Study. *Safety Assessment Of Dha-Rich Microalgae From Schizochytrium*. *Regulatory Toxicology and Pharmacology*. 33: 192-204.

Hammond, B., Rogers, S.G., Fuchs, R.L. 1994. Limitations of Whole Food Feeding Studies in Food Safety Assessment. *OECD Workshop on Food Provisional Proceedings of the Safety Evaluation - Oxford England, 12-15 September 1994*. (BIO/94.153) Publisher: OECD, Paris: 70-80.

Hammond, B., Rogers, S.G., Fuchs, R.L. 1996a. Limitations of Whole Food Feeding Studies in Food Safety Assessment. IN: Food Safety Evaluation. OECD Documents, Paris: 85-97.

Hammond, B., Vicini, J., Hartnell, G., Naylor, M., Knight, C., Robinson, E., Fuchs, R., Padgett, S. 1996. The Feeding Value of Soybeans Fed to Rats, Chickens, Catfish, and Dairy Cattle is Not Altered by Genetic Incorporation of Glyphosate Tolerance. *Journal of Nutrition*. 126(3): 717-727.

Momma, K., Hashimoto, W., Yoon, H., Ozawa, S., Fukuda, Y., Kawai, S., Takaiwa, F., Utsumi, S., Murata, K. 2000. Safety Assessment of Rice Genetically Modified With Soybean Glycinin by Feeding Studies on Rats. *Bioscience, Biotechnology, and Biochemistry*. 64(9): 1881-1886.

Noteborn, H.P.J.M., Bienenmann-Ploum, M.E., van den Berg, J.H.J., Alink, G.M., Zolla, L., Reynaerts, A., Pensa, M., Kuiper, H.A.; Editors: Engel, K., Takeoka, G.R., Teranishi, R. 1995. Safety Assessment of the Bacillus thuringiensis Insecticidal Crystal Protein CryIA(b) Expressed in Transgenic Tomatoes. *Genetically Modified Foods Safety Issues*, Chapter 12(605). Publisher: American Chemical Society, Washington DC: 134-147.

Taylor, M., Hartnell, G., Nemeth, M., George, B., Astwood, J. 2001. Comparison of Broiler Performance When Fed Diets Containing YieldGard® Corn, YieldGard® and Roundup Ready® Corn, Parental Lines, or Commercial Corn. *Poultry Science*. 80(1): 319.

Taylor, M.L., Hartnell, G.F., Nemeth, M., George, B., Astwood, J. 2001. Comparison of Broiler Performance When Fed Diets Containing Roundup Ready® Corn Event NK603 Parental Line, or Commercial Corn. *Poultry Science*. 80, Supplement 1(1323): 320.

Teshima, R., Akiyama, H., Okunuki, H., Sakushima, J., Goda, Y., Onodera, H., Sawada, J., Toyoda, M. 2000. Effect of GM and Non-GM Soybeans on the Immune System of BN Rats and B10A Mice. *Journal of the Food Hygienic Society of Japan*. 41(3): 188-193.

Product Safety Assessment

1990. Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification. *Regulatory Toxicology and Pharmacology*. 12 (12): S1-S196.

1999. Review of Data on Possible Toxicity of GM Potatoes. The Royal Society: Prompting Excellence in Science: 1-5.

Ali, M., Luttrell, R., Young, S. 2006. Susceptibilities of *Helicoverpa Zea* and *Heliothis Virescens* (Lepidoptera - Noctuidae) Populations to Cry1ac Insecticidal Protein. *Journal of Economic Entomology*. 99(1): 164-175.

Astwood, J., Leach, J., Ream, J., Fuchs, R. 1996. Allergenic Potential of Foods from Genetically Engineered Plants. The Toxicology Forum: 1996 Annual European Meeting, March 25-28, 1996, Green College Oxford, UK. Publisher: Toxicology Forum, Inc., Washington, DC: 136-170.

Atherton, K. 2002. Safety Assessment of Genetically Modified Crops. *Toxicology*. 181-182: 421-426.

Aumaitre, A. 2004. Animals of Pest Protected -Bt- Plants and Herbicide Tolerant – (Glyphosate, Glufosinate) - Plants - Interpretation of Experimental Results Observed Worldwide on GM Plants. *Italian Journal Animal Science*. 3: 107-121.

Bajaj, S. 2001. Safety Assessment of Genetically Modified Insect Resistant Maize. Proceedings of 2001 National Seminar on Seed Science and Technology in the New Millenium - Vistas and Vision. Manasagangotri, Mysore, India, Aug 6-8, 2001: 205-207.

Brake, D., Evenson, D. 2004. A Generational Study of Glyphosate-tolerant Soybeans on Mouse Fetal, Postnatal, Pubertal and Adult Testicular Development. *Food and Chemical Toxicology*. 42(1): 29 - 36.

Bremmer, J. 1998. Hazard Evaluation of Glufosinate Tolerant Crops. Proceedings of the International Symposium on Novel Foods Regulation in the European Union - Integrity of the Process of Safety Evaluation - November 18-20, 1997, Berlin, Germany. Publisher: Federal Institute of Consumer Health Protection and Veterinary Medicine: 335-357.

Carpenter, J. 2001. Case Studies in Benefits and Risk of Agricultural Biotechnology: Roundup Ready® Soybeans and Bt Field Corn. National Center for Food and Agricultural Policy: 1-56.

Chen, Z., Gu, H., Li, Y., Su, Y., Wu, P., Jiang, Z., Ming, X., Tian, J., Pan, N., Qu, L. 2003. Safety Assessment for Genetically Modified Sweet Pepper and Tomato. *Toxicology*. 188: 297-307.

Chen, S., Huang, J., Zhou, B., Ni, W., Zhang, Z., Shen, X., Xu, Y., Gu, L., Li, S. 1996. A Safety Assessment of Feeding Rats and Quails With Cotton-Seed Meal from Bt-Transgenic Cotton Plants. *Jiangsu Journal of Agricultural Science*. 12: 17-22.

- Conner, A.J.; Editor: Jones, D.D. 1994. Biosafety Evaluation of Transgenic Asparagus. Proceedings of the Third International Symposium on The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms, November 13-16, 1994, Monterey, CA. Publisher: The University of California - Oakland: 363-369.
- Crawley, M. 1992. The Comparative Ecology of Transgenic and Conventional Crops. Second International Symposium on The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms, May 11 - 14, 1992, Goslar, Germany: 43-52.
- Delannay, X., LaVallee, B., Proksch, R., Fuchs, R., Sims, S., Greenplate, J., Marrone, P., Dodson, R., Augustine, J., Layton, J., Fischhoff, D. 1989. Field Performance of Transgenic Tomato Plants Expressing the Bacillus thuringiensis Var. kurstaki Insect Control Protein. *Bio/Technology*. 7(12): 1265-1269.
- Emlay, D.; Editor: Kim, L. 1993. Regulatory Considerations: The Flavr Savr™ Tomato and the Regulatory Process. *Advanced Engineered Pesticides*, Chapter 24. Publisher: Marcel Dekker, New York: 409-419.
- Engel, K., Gerstner, G., Ross, A. 1998. Investigation of Glycoalkaloids in Potatoes as Example for the Principle of Substantial Equivalence. IN: *Novel Food Regulation in the EU-Integrity of the Process of Safety Evaluation*. Berlin: Federal Institute of Consumer Health Protection and Veterinary Medicine: 197-209.
- Fenton, B., Stanley, K., Fenton, S., Bolton-Smith, C. 1999. Health Risks of Genetically Modified Foods. *The Lancet*. 53: 1811.
- Fuchs, R., Berberich, S., Serdy, F. 1992. The Biosafety Aspects of Commercialization: Insect Resistant Cotton as a Case Study. Second International Symposium on The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms, May 11 - 14, 1992, Goslar, Germany: 171-178.
- Fuchs, R., Berberich, S., Serdy, F. 1993. Safety Evaluation of Genetically Engineered Plants and Plant Products: Insect-Resistant Cotton. IN: *Biotechnology and Safety Assessment*. Chapter 10: 199-212.
- Fuchs, R., Berberich, S., Serdy, F. 1992. Regulatory Considerations for Pesticidal Plants: Insect-Resistant Cotton as a Case Study. IN: *Advanced Engineered Pesticides*. Chapter 23: 393-407.
- Fuchs, R., Re, D., Rogers, S., Hammond, B., Padgett, S. 1996. Safety Evaluation of Glyphosate-tolerant Soybeans. OECD Document: Food Safety Evaluation. Publisher: OECD, Paris: 61-70.
- Fuchs, R., Serdy, F. 1990. Genetically Modified Plants: Evaluation of Field Test Biosafety Data. International Symposium: The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms - November 27-30, 1990 Kiawah Island, South Carolina: 25-29.
- Gasson, M. 1999. Genetically Modified Foods Face Rigorous Safety Evaluation. *Nature*. 402 (6759): 229.

- Greenplate, J. 1999. Quantification of Bacillus thuringiensis Insect Control Protein CryIAc Over Time in Bollgard® Cotton Fruit and Terminals. *Journal of Economic Entomology*. 92 (6): 1378-1383.
- Hammond, B., Lemen, J., Dudek, R., Ward, D., Jiang, C., Nemeth, M., Burns, J. 2006. Results of a 90-day Safety Assurance Study with Rats Fed Grain from Corn Rootworm-protected Corn. *Food and Chemical Toxicology*. 44(2): 147-160.
- Halcomb, J., Benedict, J., Cook, B., Ring, D. 1996. Survival and Growth of Bollworm and Tobacco Budworm on Non-transgenic and Transgenic Cotton Expressing a CryIA Insecticidal Protein (Lepidoptera: Noctuidae). *Environmental Entomology*. 25(2): 250-255.
- Hammond, B., Fuchs, R. 1998. Safety Evaluation for New Varieties of Food Crops Developed Through Biotechnology. *Biotechnology and Safety Assessment*. Chapter 3: 61-79.
- Hashimoto, W., Momma, K., Katsube, T., Ohkawa, Y., Ishige, T., Kito, M., Utsumi, S., Murata, K. 1999a. Safety Assessment of Genetically Engineered Potatoes With Designed Soybean Glycinin; Compositional Analyses of the Potato Tubers and Digestibility of the Newly Expressed Protein in Transgenic Potatoes. *Journal of the Science of Food and Agriculture*. 79: 1607-1612.
- Hashimoto, W., Momma, K., Katsube, T., Ohkawa, Y., Ishige, T., Kito, M., Utsumi, S., Murata, K. 1999b. Safety Assessment of Transgenic Potatoes With Soybean Glycinin by Feeding Studies in Rats. *Bioscience, Biotechnology and Biochemistry*. 63: 1942-1946.
- Hattan, D. 1994. Evaluation of Toxicological Studies on FLAVR SAVR™ Tomato. OECD Workshop on Food Provisional Proceedings of the Safety Evaluation - Oxford England, 12-15 September 1994. (BIO/94.153) Publisher: OECD, Paris: 45-47.
- Kaeppler, H.F. 2000. Food Safety Assessment of Genetically Modified Crops. *Agronomy Journal*. 92(4): 793-796.
- Kaniewski, W., Lawson, C. 1998. Coat Protein and Replicase-mediated Resistance to Plant Viruses. In *Plant Virus Disease Control*. Hadidi, A., Khertarpal, R.K. and Kogenazawa, H. Eds., APS Press, St. Paul, MN. Pages 65-78.
- Kessler, D., Taylor, M., Maryanski, J., Flamm, E., Kahl, L. 1992. The Safety of Foods Developed by Biotechnology. *Science*. 256 (5065): 1747-1749.
- Kleter, G., Kuiper, H. 2003. Safety of Genetically Modified Crops for Food and Animal Feed. The BCPC International Congress - Crop Science and Technology 2003. 10-12 November: Pages 371-377.
- Konig, A., Cockburn, A., Crevel, R., Debruyne, E., Grafstroem, R., Hammerling, U., Kimber, I., Knudsen, I., Kuiper, H., Peijnenburg, A., Penninks, A., Poulsen, M., Schauzu, M., Wal, J. 2004. Assessment of the Safety of Foods Derived from Genetically Modified (GM) Crops. *Food and Chemical Toxicology*. 42: 1047-1088.

Kuiper, H.A., Noteborn, H.P.J.M. 1994. Food Safety Assessment of Transgenic Insect Resistant Bt Tomatoes. OECD Workshop On Food Provisional Proceedings of the Safety Evaluation - Oxford England, 12-15 September 1994. (BIO/94.153) Publisher: OECD, Paris: 38-44.

Lappe, M.A., Bailey, E.B., Childress, C., Setchel, K.D.R. 1999. Alterations in Clinically Important Phytoestrogens in Genetically Modified Herbicide-tolerant Soybeans. *Journal of Medicinal Food*. 1: 241-245.

Lau, L., Collins, R., Yiu, S., Xing, J., Yu, A. 2004. Detection and Characterization of Recombinant DNA in the Roundup Ready® Soybean Insert. *Food Control*. 15(6): 471-478.

Lavrik, P., Bartnicki, D., Feldman, J., Hammond, B., Keck, P., Love, S., Naylor, M., Rogan, G., Sims, S., Fuchs, R. 1995. Safety Assessment of Potatoes Resistant to Colorado Potato Beetle. *Genetically Modified Foods, Safety Issues*. Chapter 13: 148-157.

Matsuda, T. 1998. Application of Transgenic Techniques for Hypo - Allergenic Rice. Proceedings of the International Symposium on Novel Foods Regulation in the European Union - Integrity of the Process of Safety Evaluation - November 18-20, 1997, Berlin, Germany. Publisher: Federal Institute of Consumer Health Protection and Veterinary Medicine: 311-319.

Matsuda, T., Nakase, M., Adachi, T., Nakamura, R., Tada, Y., Shimada, H., Takahashi, M., Fujimura, T.; Editors: Eisenbrand, G., Aulepp, H., Dayan, A.D., Elias, P.S., Grunow, W., Ring, J., Schlatter, J., Köhl, W., Baum, M. 1996. The Input of Molecular Biology: Transgenic Foods: Allergenic Proteins in Rice: Strategies for Reduction and Evaluation. *Food Allergies and Intolerances: Symposium*. Chapter 12. Publisher: VCH, DFG, Weinheim: 161-169.

Mendelsohn, M., Kough, J., Vaituzis, Z., Matthews, K. 2003. Are Bt Crops Safe? *Nature Biotechnology*. 21(9): 1003-1009.

Moreno, O., Kang, M. 1999. Aflatoxins in Maize: The Problem and Genetic Solutions. *Plant Breeding*. 118: 1-16.

Nester, E., Thomashow, L., Metz, M., Gordon, M. 2002. 100 Years of Bacillus thuringiensis - A Critical Scientific Assessment. *American Academy of Microbiology*: 1-22.

Nielsen, C., Berdal, K., Holst-Jensen, A. 2004. Characterization of the 5' Integration Site and Development of an Event-specific Real-time PCR Assay for NK603 Maize from a Low Starting Copy Number. *European Food Research And Technology*. 219: 421-427.

Nordlee, J. A., Taylor, S. L., Townsend, J. A., Thomas, L. A., Townsend, R. 1994. Investigations of the Allergenicity of Brazil Nut 2S Seed Storage Protein in Transgenic Soybean. OECD Workshop on Food Provisional Proceedings of the Safety Evaluation - Oxford England, 12-15 September 1994. (BIO/94.153) Publisher: OECD, Paris: 121-125.

Noteborn, H., Bienenmann-Ploum, M., van den Berg, J.H.J., Alink, G.M., Zolla, L., Reynaerts, A., Pensa, M., Kuiper, H.A.; Editors: Engel, K., Takeoka, G.R., Teranishi, R. 1995. Safety Assessment of the Bacillus thuringiensis Insecticidal Crystal Protein CryIA(b) Expressed in Transgenic Tomatoes. Genetically Modified Foods Safety Issues. Chapter 12 (605). Publisher: American Chemical Society, Washington DC: 134-147.

Noteborn, H., Kuiper, H.; Editors: Jones, D. 1994. Safety Assessment Strategies for Genetically Modified Plant Products: A Case Study of Bacillus thuringiensis-Toxin Tomato. Proceedings of the Third International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms. Publisher: University of California, Oakland: 199-207.

Perlak, F.J., Stone, T.B., Muskopf, Y.M., Petersen, L.J., Parker, G.B., McPherson, S.A., Wyman, J., Love, S., Reed, G., Biever, D., Fischhoff, D.A. 1993. Genetically Improved Potatoes: Protection from Damage by Colorado Potato Beetles. Plant Molecular Biology. 22: 313-321.

Peterson, R., Shama, L. 2005. A Comparative Risk Assessment of Genetically Engineered, Mutagenic, and Conventional Wheat Production Systems. Transgenic Research. 14: 859-875.

Quemada, H. 1996. Food Safety Evaluation of a Transgenic Squash. OECD Document: Food Safety Evaluation. Publisher: OECD, Paris: 71-79.

Rang, A., Linke, B., Jansen, B. 2005. Detection of RNA Variants Transcribed from the Transgene in Roundup Ready® Soybean. European Food Research and Technology. 220(3-4): 438 - 443.

Re, D., Cline, M., Hartnell, G. 1996. Glyphosate-tolerant Soybeans Found Safe for Use in Feed, Food. Feedstuffs: 1-2.

Redenbaugh, K., Berner, T., Emlay, D., Frankos, B., Hiatt, W., Houck, C., Kramer, M., Malyj, L., Martineau, B., Rachman, N., Rudenko, L., Sanders, R., Sheehy, R., and Wixtrom, R. 1993. Regulatory Issues for Commercialization of Tomatoes with an Antisense Polygalacturonase Gene. In Vitro Cell and Developmental Biology-Plant. 29P (1): 17-26.

Redenbaugh, K., Hiatt, W., Martineau, B., Emlay, D.; Editors: Engel, K., Takeoka, G. R., Teranishi, R. 1995. Determination of the Safety of Genetically Engineered Crops. Genetically Modified Foods Safety Issues. Chapter 7 (605). Publisher: American Chemical Society, Washington DC: 72-87.

Redenbaugh, K., Hiatt, W., Martineau, B., Lindemann, J., Emlay, D. 1994. Aminoglycoside 3'-Phosphotransferase II (APH(3')II): Review of Its Safety and Use in the Production of Genetically Engineered Plants. Food Biotechnology. 8 (2&3): 137-165.

Redenbaugh, K., Hiatt, W., Martineau, B., Kramer, M., Sheehy, R., Sanders, R., Houck, C., Emlay, D. 1992. Safety Assessment of Genetically Engineered Fruits and Vegetables--A Case Study of the FLAVR SAVR™ Tomato. Library of Congress: iii-xvii.

Rhee, G., Cho, D., Won, Y., Seok, J., Kim, S. S., Kwack, S. J., Lee, R. D., Chae, S., Kim, J. W., Lee, B. M., Park, K. L., Choi, K. S. 2005. Multigeneration Reproductive and Developmental Toxicity Study of bar Gene Inserted into Genetically Modified Potato on Rats. *Journal of Toxicology and Environmental Health, Part A*. 68: 2263-2276.

Ridley, W., Hartnell, G., Hammond, B. 2005. Role of Composition and Animal Feeding Studies in the Safety Assessment of Biotech Crops. *ACS Symposium Series* 892: 28-39.

Rogan, G., Dudin, Y., Lee, T., Magin, K., Astwood, J., Bhakta, N., Leach, J., Sanders, P., Fuchs, R. 1999. Immunodiagnostic Methods for Detection of 5-Enolpyruvylshikimate-3-Phosphate Synthase in Roundup Ready® Soybeans. *Food Control*. 10 (6): 407-414.

Rogers, S. G. 1998. Biotechnology and the Soybean. *American Journal of Clinical Nutrition* 68: Issue: Supplement 1330S-1332S.

Sims, S., Berberich, S., Nida, D., Segalini, L., Leach, J., Ebert, C., Fuchs, R. 1996. Crop Physiology and Metabolism: Analysis of Expressed Proteins in Fiber Fractions from Insect-Protected and Glyphosate-tolerant Cotton Varieties. *Crop Science*. Issue 5: 1212-1216.

Taylor, S. 2001. Safety Assessment of Genetically Modified Foods. *Journal of Nematology*. 33(4): 178 - 182.

Trewavas, A. 2000. Toxins and Genetically Modified Food. *The Lancet*. 355 (9207): 931.

Tuteljan, V., Kravchenko, L., Lashneva N., Avrenieva, L., Guseva, G., Sorokina, E., Chernysheva, O. 1999. [Medical and Biological Evaluation of Safety of Protein Concentrate from Genetically-Modified Soybeans. *Biochemical Studies*]. *Mediko-Biologicheskaja Otsenka Bezopasnosti Belkovogo Kontsentrata, Poluchennogo Iz Geneticheskii Modifitsirovannoi Soi. Biokhimicheskie Issledovaniia.. VOPROSY PITANIIA* 68(5-6): 9 - 12.

Verachtert, B., Reynaerts, A. 1992. New Information on Food Safety and Effects on Non-Target Organisms. *Second International Symposium on The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms, May 11 - 14, 1992, Goslar, Germany*: 197-200.

Windels, P., Taverniers, I., Depicker, A., Van Bockstaele, E., De Loose, M. 2001. Characterisation of the Roundup Ready® Soybean Insert. *European Food Research and Technology*. 213 (2): 107 - 112. Yang, X., Harrison, S., Riedel, R., Venkatesh, R., Loux, M. 2005. Glyphosate Behavior in a Transgenic Glyphosate- and Soybean Cyst Nematode-Resistant Soybean Variety. *Journal of New Seeds*. 7(1): 23-4

