The Safety of Genetically Modified Food

The FDA Advisory No. 2013-014 on the Safety of Genetically Modified Food Produced Through Modern Biotechnology dated June 24, 2013 elicited some reactions from Mr. Daniel Ocampo, which were published in some broadsheets. The following are additional information on the safety of food derived from modern biotechnology - Food produced through modern biotechnology that are currently in the market are as safe as the conventional food.

The Codex Alimentarius Commission (CAC) was established by FAO and WHO in 1963 to develop harmonized international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair trade practices in the food trade. The Commission also promotes coordination all food standards work undertaken by international governmental and non-governmental organizations, like European Food Safety Authority and International Life Science, Inc.. The Sanitary Phytosanitary Agreement (SPS) of the World Trade Organization (1995) ensures that internationally traded food meets the standards based on the scientific principles set by the CAC.

It can be said that food safety assessment for biotechnology products is more rigorous than for other crop produced by conventional breeding or other technologies. For the GM food crops that have undergone food safety assessment and approval process, the consensus of scientific opinion and evidence is that the application of GM technology introduces no unique food safety concerns and up to this time there is no single case of evidence of harm in man. This conclusion has been reached by numerous national and international organizations, like the:

- Food and Agriculture Organization/World Health Organization [FAO/WHO] of the United Nations,
- Organization for Economic Cooperation and Development, EU Commission,
- French Academy of Sciences,
- National Research Council of the U.S.,
- National Academy of Sciences of Australia, Canada, India, Mexico, UK, USA,
- Royal Society of London,
- National Academy of Science and Technology, Philippines
- Society of Toxicology, and
- OTHERS:
  - European Commission
  - The Royal Society of Medicine, England
  - American Society on Science and Health
  - American Council on Science and Health
  - American Dietetic Association
  - American Society for Cell Biology
  - American Society for Microbiology,
The milestones in the international consensus on the safety assessment of biotechnology-derived foods include the following:

- Guidelines on the Safety Assessment in General (IFBC 1990),
- OECD Report Describing Principles of Substantial Equivalence (OECD 1993),
- ILSI/IFBC Decision Tree for Assessment of Potential Allergenicity (Metcalfe et al. 1996),
- FAO/WHO Expert Consultation on Safety Assessment in General, Including the Principle of Substantial Equivalence (FAO/WHO 1996),
- OECD Installment of the Task Force for the Safety for Novel Foods and Feed, among others Compilation of Consensus Documents on Composition of Crops as Support for Comparative Evaluation (1991 to present),
- FAO/WHO Expert Consultation on Safety Assessment in General, Including the Principle of Substantial Equivalence (FAO/WHO 2000),
- ILSI Europe Concise Monograph Series Genetic Modification Technology and Food Consumer Health and Safety (Robinson 2001),
- EU-sponsored Research on Safety of Genetically Modified Organisms. “GMO Research in EU 2001 Perspective.” Report of a Workshop held by External Advisory Groups of the “Quality of Life and Management of Living Resources” Program, European Union,
- New Zealand Royal Commission on Genetic Modification (NZRC 2001),
- FAO/WHO Guidelines for Codex Alimentarius Committee, developed by Task Force for Foods Derived from Biotechnology Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (FAO/WHO 2002, 2003), and
- ILSI Crop composition database (www.cropcomposition.org) (ILSI 2003 to present).

Regulatory systems are in place to assure the safety of these products. In the Philippines, Executive Order No. 430, series of 1990 for contained use (laboratory, greenhouse, screen...
house, glasshouse) and confined field tests, Guidelines on Planned Release of Genetically Modified Organisms and Potentially Harmful Exotic Species (1998), DA AO No. 8, series of 2002 for field release and commercialization for direct use as food, feed and for processing, and EO 514 series of 2006, The National Biosafety Framework, are the rules and regulations for determining the safety of GM products.

It takes around 10 to 14 years of laboratory research, contained greenhouse, contained small scale field trials, and pre-commercial testing and evaluation before a GM crop is approved for commercial release. The following are analyzed: nutrient analysis, proximate composition, such as ash, moisture, protein, fat and carbohydrates, amino acid analysis, fatty acid analysis, carbohydrate analysis, vitamins and mineral analysis, level of anti-nutrients, level of naturally occurring toxins and level of naturally occurring allergens to determine the safety of GM crops compared with the conventional crops. Such comparisons also include agronomic performance, phenotype, expression of transgenes, and assessments of any proteins that are produced from the inserted DNA. Since food allergens are proteins, the potential allergenicity of newly expressed proteins in food are also considered. A decision-tree approach introduced by ILSI/IFBC (Metcalfe and others 1996) has become internationally acknowledged and was updated by Codex (FAO/WHO 2002).

It is worth mentioning that in the Philippines, the total arable land is 5.1 million hectares, and these are planted mostly to sugarcane, coconut, rice, corn, banana, cassava, pineapple and mango. In 2012, the area planted to GM corn increased to 719,446 hectares, up from 685,372 hectares in 2011, a steady increase from around 10,000 hectares in 2003, when it was first planted. Farm level economic gain from GM corn in the Philippines from 2003 to 2011 was estimated at USD 264.5 million. In 2010 alone, when there was corn shortage, the Philippines farm level economic gain was at USD 93.6 million. The number of small farmers, growing on average 2 hectares of GM corn, was estimated at 375,000 in 2012, up significantly by 53,000 from 322,000 in 2011.

Farmers have a choice. Farmers who do not want to plant biotech crops may use conventional seeds that are widely available.

The Philippine FDA is a science-based regulatory agency and all safety, efficacy or quality standards are based on scientific data and information. Health products are approved based on scientific evidences that support claims of safety, efficacy and quality. Any new findings related to safety, efficacy or quality of any health products that are submitted to the FDA are evaluated based on scientific merits. There is no scientific basis, or evidence, to retract the statement of the FDA that - Food produced through modern biotechnology that are currently in the market are as safe as the conventional food.