ENSURING THE SAFETY OF GENETICALLY MODIFIED FOOD CROPS

Dolores A. Ramirez and Evelyn Mae Tecson-Mendoza
Institute of Plant Breeding,
College of Agriculture,
University of the Philippines at Los Banos, College, Laguna 4031,
Philippines

ABSTRACT

This paper discuses genetically modified (GM) food crops, and how different countries are trying to ensure their safety. It summarize the different regulatory mechanisms, both national and international, which govern the research into such crops, and their development and use.

INTRODUCTION

Modern biotechnology is often equated with genetic engineering or recombinant DNA technology, which began in the 1970s. This technology has been found by plant breeders to be a very precise tool in crop improvement. It has helped in breeding for higher yields, resistance to pests and diseases, tolerance to both biotic and abiotic stresses, improved nutritional quality, and improved processing, storage and post-harvest qualities.

The adoption of genetically modified (GM) crops has been phenomenal from 1.7 million hectares in 1996 to 52.6 million hectares in 2001. This represents an increase of more than 30-fold in only six years (James 2001). Globally, the principal GM crops are soybean, maize, cotton and canola. Other GM crops grown commercially are potato, papaya and squash.

However, in spite of perceived benefits from GM crops, several health and environmental concerns have been raised. As a result, there is widespread opposition among consumers, and a general lack of public acceptance. On the other hand, pharmaceutical products produced by the same procedures have generally been accepted.

REGULATION OF RESEARCH INTO GM CROPS

Field testing and commercialization

Countries which are undertaking research and development which use modern tools of biotechnology have established mechanisms to regulate such activities. For example, in the Philippines, an inter-agency committee created by a Presidential Executive Order, the National Committee on Biosafety of the Philippines, deals with biosafety issues, including field testing. Commercialization of GM crops, however, as well as their importation, are under the supervision of the Department of Agriculture. Biosafety guidelines pertaining to research and development, importation and commercialization of GM crops are now in place.

REGULATIONS ON THE SAFETY OF GM CROPS

Safety assessment procedures for GM food and food products have been studied carefully since the early 1990's. The United Nations Food and Agriculture Organization (FAO), the World Health Organization (WHO)

Keywords: Allergens, biotechnology, GM foods, regulatins, substantial equivalence

and the organization for Economic Cooperation and Development (OECD) have held consultations on the issue. They have recommended science-based safety assessment strategies for food and food additives produced by genetic engineering. Such strategies have been adopted by various countries, including Australia, Canada, EC countries, Japan, New Zealand, Philippines, and the USA.

In general, the safety assessments are based on **substantial equivalence**. This means that if a new food or food component is substantially the same as an existing food or food component, it can be treated in the same manner with respect to safety (FAO-WHO 1996). It should be noted, however, that substantial equivalence is only the starting point in the biosafety assessment procedure. In other words, it helps to identify potential safety and nutritional issues, but it is not the assessment itself. The procedure requires the submission by the applicant of the following information.

- The characteristics of the traditional or parental product or organism, compared to those of the new product;
- The techniques and components used to produce the new product;
- Whether the new product might cause allergic reactions;
- Whether genes might be transferred from the GM plant to microorganisms in the gut of human beings or livestock; *and*
- Possible toxic effects.

These data are evaluated by panels of scientists from different disciplines. It should be noted, therefore, that safety assessments starts, not with the GM crop or product, but at the research phase: from the choice of genes/proteins (their function, or mechanism of action, should be known), to the source of the gene (ecological or environmental considerations) to be used. The GM crop undergoes a rigid evaluation of its agronomic performance and efficacy. It is subjected to food/food safety assessment tests, as well as environmental safety tests. Furthermore, assessments must be done on a case by case basis.

Requirements for evaluation

All the GM crops that have been released onto the market in various countries have undergone rigorous evaluation for food safety. For instance, the European Union requires the following information on GM crops/food for evaluation:

- The specifications of the novel food;
- The effects of production process applied to the novel food;
- A history of the organisms used as the source of the novel food;
- The effects of genetic modification on the properties of the host organism;
- The genetic stability of the genetically modified crop;
- Specificity of the expression of novel genotypes;
- The ability of genes from the GM crop to survive in, and colonize, the human gut;
- The anticipated intake or use of the novel food;
- Information about any effects of previous human exposure to the novel food or its source;
- Nutritional information about the novel food; *and*
- Information about the possible toxic effects of the novel food.

Many countries have approved different GM crops. For example, Canada issued letters for 42 GM products, indicating that it had no health concerns over these products. Japan has approved about 40 different GM products although no GM foods are yet on sale in Japan. The EU has approved various GM crops, such as soybean, maize, cotton, potato and rapeseed, although it has recently passed strict labeling laws governing GM crops used as food and feed.

FOOD SAFETY OF GM CROPS

Issues and assessments

Food safety issues are based on the possible effects of the genes from two or more species, the “transgenes”. There is particular concern where such genes might cause allergies or have toxic effects. There is also concern over the possible effects of the antibiotic selection markers, whether these might induce resistance to antibiotics used as medicine.

There are risks inherent to the

technology but these are amenable to science-based evaluation. It is, however, a fact that these traits are not unique to GM crops. Many foods contain allergens and toxins. For example, peanuts, seafoods and even wheat and rice contain allergens which affect many people. Cassava, almonds, and sorghum contain cyanogenic glycosides which produce cyanide, and cause death or nerve damage. Legumes contain trypsin inhibitors, lectins and saponins, all of which may have a toxic effect. Many people are intolerant to milk. All these risks have been managed through the years. However, the only treatment for food allergies is dietary avoidance. This depends on being able to identify the source of exposure.

A study by a panel of experts convened by the International Life Sciences Institute (ILSI) and the International Food Biotechnology Council developed a decision tree for the assessment of allergenic potentials of foods derived by modern biotechnology (Metcalfe *et al.* 1966). Some of the general properties of proteins which do not have cause allergies (Lehrer 2000) are as follows:

- No history of allergenicity;
- Different in structure or character from known allergens;
- Rapidly digestible;
- Unstable when heated (cooked); *and*
- Expressed at low levels, compared to the expression of major allergens.

The risks posed by the allergenic potentials of GM foods should be weighed against their potential benefits. As in many conventionally bred crops that contain toxicants and allergens, their risks should be managed.

All GM crops which have been commercially released have undergone and passed rigid food safety tests. For example, the insect-resistant and the herbicide-resistant soybeans and maize have been found to cause no oral toxicity in mice. Many animal feeding studies, using chickens, cattle, sheep and growing bull calves, showed that animals fed with GM crops had the same performance as those fed with the conventional counterparts. Furthermore, selection markers such as the kanamycin resistance gene and its product are digestible and are not allergenic.

Another type of risk related to GM crops is that which is a result of the political and social context in which a technology is used (Leisinger 1999). This includes unequal access to the new technology. This will lead to further widening of the economic gap between the technology users and the non-users, and further disparity in income between rich and poor farmers. This risk can be addressed by developing technologies which are expressly designed to meet the needs of the poor and instituting measures that will provide them affordable access to the new technology. Leisinger (1999) contends that this kind of risk occurs because of the existence of a gap between human scientific technical ability, and human willingness to shoulder moral and political responsibilities.

LABELLING OF GM FOODS

Another important concern is the segregation and labeling of GM crops and GM-derived foods. There is a world-wide debate over whether we need to legally require the labeling of GM crops, and food or feed derived from GM crops. The prevailing position in Canada and United States is that if the GM crop is substantially similar to its conventional counterpart, there is no need to label it. However, there is a powerful lobby to require that all GM crop be labeled, so that consumers can exercise their right to choose. The EU has recently passed legislation requiring that all food which contains more than 1% GM materials must be labelled. Japan has similar legislation, but with a threshold of 5%.

CONCLUSION

Modern biotechnology promises to contribute to agricultural productivity and sustainability. As is true with all innovations and changes involving complex systems, there will always be trade-offs. There will always be some unwanted consequences that come with the gains. Making the best choices will always be a matter of weighing the risks against the benefits, so as to avoid or mitigate the unwanted consequences, and intelligently deciding which to accept and which to reject.

At present, what do we have in the case of GM crops?

- Firstly, regulatory mechanisms to ensure biosafety of GM crops are in place and are operational in countries which carry out research and development, and commercial production of such crops. Assessments of biosafety, as safety for use as food or feed, are done on a case-by-case basis.

- Secondly, food safety assessment protocols have been established in countries that have approved the commercial production of GM crops as food or feed;
- Finally, all GM crops released for commercial sale have undergone voluntary and required food safety assessment, and have been established to be safe to humans and animals.

REFERENCES

De Vries J. and W. Wacjernagel. 1998. *Mol. Gen. Genet.* 257, 606-613.

FAO/WHO. 1996. *Biotechnology and Food Safety*. Report of Joint FAO/WHO Consultation, Sept. 30 to Oct. 1996, Rome. 31 pp.

Ferber, Dan. 1999. Risks and benefits: GM crops in the cross hairs. *Science* 286: 1662-1668.

Javier E.Q. 2001. Sustainably productive agriculture and genetically modified crops. In: *Modern Biotechnology and Philippine Agriculture, NAST* (Phil): 21-34.

Leisinger K.M. 1999. Ethical challenges of agricultural biotechnology for developing countries. In: *Agricultural Biotechnology and the Poor: Proceedings of an International Conference, 21-22 Oct. 1999*, G. Persley and M. Lantin (Eds): Washington, DC., pp. 173-180.

Losey J. L. Raynor and M.E. Carter. 1999. *Nature* 399: 214.

ILSI & SSMB. 1998. Foods Derived from Genetically Modified Plants. Paper presented at the Science-Based Safety Assessment Seminar-Workshop, April 24 & 25, 1998, Singapore. Organized by International Life Sciences Institute and Singapore Society of Microbiology and Biotechnology, in collaboration with FAO and the National Science and Technology Board of Singapore.

Lehrer S.B. 2000. Potential health risks of genetically modified organisms: How can allergens be assessed and minimized? In: *Agricultural Biotechnology and the Poor: Proceedings of an International Conference. Washington DC. 21-22 October 1999*, Persley G.J. and M.M. Lantin (Eds.). Consultative Group on International Agricultural Research, Washington, DC.

Maryanshi J.H. 1995. FDA's policy for foods developed by Biotechnology. In: *Genetically Modified Foods: Safety Issues*, Engel, Takeoka and Teranishi (Eds.). American Chemical Society, Symposium Series No. 605, pp 12-22.

Maryanski J.H. 1996. Safety assurance of foods derived by modern biotechnology in the United States. Paper presented at the BioJapan '96 Symposium, July 24-27, Tokyo, Japan.

Tecson-Mendoza E.M. 2001. Genetically Modified Crops: Biosafety and Food Safety Issues and Concerns. In*: Modern Biotechnology and Philippine Agriculture, NAST (Phil.)*, pp. 6-20.

Metcalfe D.D., J.D. Astwood, R. Townsend, H.A. Sampson, SI Taylor and RL Fuchs. 1996. Assessment of the allergenic potential of foods derived from genetically engineered crop plants. In: *Critical Reviews in Food Science and Nutrition*, F.M. Clydesdale (Ed.). Organization for Economic Co-Operation and Development (OECD). OECD Publications, France. 79 pp.

Organization for Economic Co-Operation and Development (OECD). 1999. Bio Track Online Product Database: www.oecd.ord/ehs/service/htm. OECD, Paris.

Pruett CJH, HD Burgens and CH Wyborn. 1980. Effect of exposure to soil on potency and spore viability of *Bacillus thuringiensis. Jour. Invertebrate Pathology* 35: 168-174.

Sanders, PR, TC Lee, ME Groth, JD Astwood and RL Fuchs. 1998. Safety assessment of insect-protected corn. In: *Biotechnology and Safety Assessment.* (2nd Edition), Thomas J.A. (Ed.). Taylor and Francis, pp. 241-256.

Shelton AM and RT Roush. 1999. False reports and the ears of men (Commentary). *Nature Biotechnology* 17: 832.

Syvanen M. 1999. In search of horizontal gene transfer (Commentary*)*. *Nature*

Biotechnology 17: 833.
Tecson Mendoza EMT. Molecular crop breeding-strategies for food, health, environmental and industrial uses. Visiting Professorial Lecture presented at the Research Institute for Food Science, Kyoto University, Uji, Japan, June 09, 1999. (Unpublished Mimeograph).
Tecson Mendoza EMT. Safety assessment of food products derived by modern biotechnology. Based on the paper presented during the Symposium on Biosafety of Biotechnology held on August 26, 1999 at the Institutes of Biological Sciences, University of the Philippines at Los Banos and Symposium on Biosafety of Biotechnology Products; Effects on Human Health, held on November 05, 1999 at the National Institute of Molecular Biology and Biotechnology, University of the Philippines, Manila.
UK Royal Society. 1999a. Genetically modified plants for food use. Statement of the U.K. Royal Society p. 11.
US Food and Drug Administration (FDA). October 1996. FDA Talk Paper.
US Food and Drug Administration (FDA). Center for Food Safety and Applied Nutrition (CFSAN). 1998. Guidance for industry: Use of antibiotic resistance marker genes in transgenic plants.
World Food Regulation Review, February 2000, p. 6.