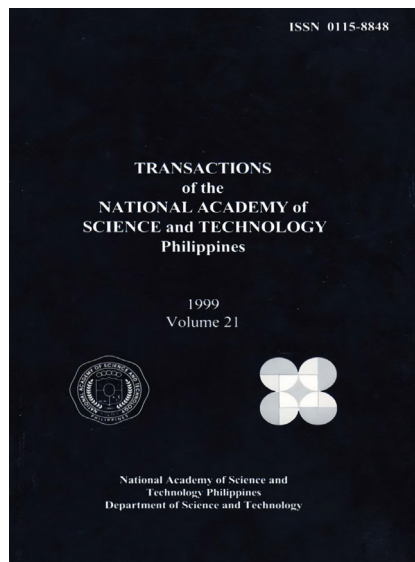


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## The Safety of Novelty Foods

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## THE SAFETY OF NOVEL FOODS

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### ABSTRACT

This paper focuses on the food safety assessment and issues of foods derived by modern biotechnology, those produced by manipulation of living organisms at the cellular and molecular levels. Some of the food safety concerns of modern biotech or genetically engineered foods are: allergenicity, possible gene transfer from GMO to microorganisms. International organizations such as FAO-WHO and OECD have held expert consultations to establish food safety assessment procedures. Several countries such as the US, the European Union and Japan have established their food safety procedures for modern biotech foods. In the Philippines, the biosafety guidelines of the National Committee on Biosafety of the Philippines (NCBP) covers R&D activities in contained facilities up to controlled field tests. The author recommends the issuance of a clear government policy on GMOs so that regulatory agencies can have a framework within which rules, guidelines and procedures can be established. Since several agencies will be involved, the author further recommended the establishment of an overarching body that can span departmental responsibilities.

**Keywords:** modern biotechnology, genetically modified organisms, genetically engineered organisms, biosafety, food safety

Food is a basic necessity and the concern on the safety of food is universal. General awareness on food safety has been heightened through information technology. When any food poisoning outbreak occurs, particularly if it involves a vulnerable group such as children, the news is immediately disseminated to all parts of the world. Reports of the incidents have dramatically increased in the last few years, so that the ordinary consumer has started asking difficult questions such as: Is this a new phenomenon? Does this mean that the population is becoming

more susceptible? Or, are we creating new substances or re-engineering microorganisms which have some harmful effects on men and making them stronger and more resistant? And finally, what is the impact of globalization on the safety of the food supply?

Competent bodies and individuals will have to find the answers to all these questions. But today I propose that we look more closely at the specific concern on the use of new technologies to create new substances or engineer organisms vis-a-vis their impact on the safety of the food supply. The application of new technologies can result in “novel foods” which has been defined by the European Commission in its novel Foods Regulation (EC/258/97) to include the following categories: (1) Food consisting of or containing genetically modified organisms (GMOs), or produced by use of GMOs without containing them; (2) Food with a chemically modified molecular structure; (3) Food made from microorganisms, fungi, or algae, or food from plants or animals produced by new breeding methods; and (4) Food produced by an unusual procedure that leads to a change in the composition or structure of the food so that the nutritional value, the metabolism, or the amount of undesirable substances differs from that of conventional food.

One technology which has been receiving a lot of attention is biotechnology which is really not new, if we consider its classical definition: any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses. Fermented foods and alcoholic beverages are examples of products of traditional biotechnology. For the purposes of this paper, however, we shall limit the discussion to modern biotechnology which is narrowly confined to the manipulation of living organisms at the cellular and molecular levels. That is, this paper will deal only with the first category of novel foods.

Modern biotechnology has made possible the production of plant varieties with specific traits such as resistance to crop pests, delayed ripening and improved nutritional quality. Within the past few years, a variety of foods produced using modern biotechnology have been approved in many countries. In the U.S., for example, seven new genetically engineered plants have successfully completed the USFDA’s safety assessment process. These include three varieties of delayed ripening tomatoes, a virus-resistant squash, potatoes resistant to the Colorado potato beetle and herbicide-tolerant soybeans. However, just as with any new means of food production, while there are anticipated benefits, there are also potential human health risks that must be considered when foods are developed using modern biotechnology.

### **Biotechnology and Food Safety**

“Food Safety” is defined as providing assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use. In the global market, the multilateral trade agreements established under the auspices of the World Trade Organization (WTO) recognize the standards and related texts of the

Codex Alimentarius Commission (CAC) as international points of reference for food safety. At present, however, there are no Codex standards that deal directly with the safety aspect or other technical requirements of genetically modified foods. But the current Medium Term Plan of the CAC has identified the work of relevant Codex Committees on various aspects of biotechnology to be of high priority.

When the subject of biotechnology and food safety was first introduced to the Commission, it realized the complexity of the matter and it also recognized the fact that much work had already been done on this topic. Therefore, the CAC at that time urged FAO and WHO to hold a joint meeting of experts who would recommend the appropriate strategy to deal with the safety of foods produced by biotechnology.

At least two such consultative meetings have been held, one in 1990 entitled "Expert Consultation on Strategies for Assessing the Safety of Foods Produced by Biotechnology" and another in 1996 entitled "Biotechnology and Food Safety". Some of the recommendations of the 1990 meeting include those addressed to national regulatory agencies to establish, maintain and enforce comprehensive food regulations for foods produced from biotechnology, that are based on sound scientific principles and data. The 1996 meeting, on the other hand, focused on the drawing up of recommendations for international guidelines for safety assessment of foods and food components which have been produced by techniques that change the heritable traits of an organism.

### **Food Safety Considerations**

Food safety considerations regarding organisms produced by techniques that change the heritable traits of an organism such as rDNA technology, are basically of the same nature as those that might arise from other ways of altering the genome of an organism, such as conventional breeding techniques. These include the following:

1. Direct consequences (e.g., nutritional, toxic or allergenic effects) of the presence in foods of new gene products encoded by genes introduced during genetic modification.
2. Direct consequences of altered levels of existing gene products encoded by genes introduced or modified during genetic modification.
3. Indirect consequences of the effects of any new gene product(s), or of altered levels of existing gene product(s), on the metabolism of the food source organism leading to the presence of new components or altered levels of existing components.
4. Consequences of mutations caused by the process of genetic modification of the food source organism, such as the interruption of coding or control sequences or the activation of latent genes, leading to the presence of new components or altered levels of existing components.

## Safety Assessment Principles

“Substantial equivalence,” as the guiding principle in the assessment of genetically modified foods and food ingredients, was first articulated in 1993 by a Committee of the Organization for Economic Cooperation and Development (OECD). This concept was subsequently endorsed by the 1996 Joint FAO/WHO Consultative Meeting of Experts. Substantial equivalence embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety, i.e., the food or food component can be considered to be as safe as its conventional food or food component counterpart. This is established by a demonstration that the characteristics assessed for the GMOs or the food derived therefrom are equivalent to the same characteristics of the conventional foods or food ingredients already available in the food supply, within the natural variation for such characteristics. Examination of the GMO-derived food or food ingredient for substantial equivalence is not a safety assessment in and of itself, but can lead to its categorization into one of three possible groupings.

The first is when substantial equivalence is established, in which case the food is regarded to be as safe as its conventional counterpart, and if the latter has been judged to be safe, then no further safety consideration need to be taken with regard to the GMO-derived food or food component.

The second group comprises those foods which have been demonstrated to have substantial equivalence to their conventional counterparts, except for specific new traits or gene products. The safety assessment for these foods should then focus on the new traits or products arising from the inserted gene. An example is the herbicide-tolerant soybean which derived its inserted gene from *agrobacterium* sp. CP4. The gene expresses the enzyme 5-enolpyruvylshikimate-3 phosphase synthase (CP4 EPSPS). The safety assessment of the GMO will have to include a thorough evaluation of the toxicity and allergenicity of this expressed protein.

In the third category are genetically modified foods which have no substantial equivalence to conventional foods. This does not mean that they are unsafe, but each must undergo a comprehensive testing program which will have to be designed on a case-by-case basis.

## Food Safety Issues

Concerns on the safety of foods derived through modern biotechnology arise from the direct and indirect consequences of altering the genome of an organism, which can also take place in the conventional breeding techniques. These had been touched on earlier. But let us focus on two of the more prominent issues.

### *Allergenicity*

Observations show that while there are not a large number of potential allergens in the food supply, recent food introductions (such as the kiwi fruit) have proven

to be additional sources of food allergens. There is a need therefore to pay particular attention to allergenicity when assessing the safety of foods produced through modern biotechnology. True food hypersensitivity is an immunologic, i.e., Immunoglobulin E- mediated, reaction to allergens in foods. Virtually all allergens are proteins.

Predicting the potential allergenicity of foods from genetically modified plants, animals and microorganisms requires the examination of a number of parameters which are common to many food allergens. Examples of these parameters are molecular weight (most food allergens have molecular weights between 10,000 and 40,000) and amino acid sequence homology to known allergens. The amino acid sequence of many allergens is readily available and the amino acid sequence of the gene product can be compared against these known databases.

Other physico-chemical attributes which may be useful in the assessment of the allergenicity potential of proteins expressed by the introduced genes are: (a) vast majority of allergens are resistant to heat and digestion juices; (b) allergens are usually the major proteins of the food; (c) allergens tend to be stable to processing (e.g., allergens in peanut butter, soybean meal).

In the identification of potentially allergenic gene products, an important criterion to consider is the source of the transferred genetic material. A gene transferred from a source known to be allergenic should be assumed to encode for an allergen, until proven otherwise. If the protein's amino acid sequence and other physico-chemical attributes raise concerns about the allergenic potential of the molecule, a series of additional tests is conducted, the first of which is a serological test to determine whether or not it is recognized by serum from individuals with known allergies. Confirmatory skin prick testing followed by an oral food challenge should be done following protocols for the use of human subjects.

### ***Gene Transfer from Genetically Modified Organisms***

The most relevant food safety issue concerning gene transfer is the potential consequence of the transfer of an introduced gene from a GMO to microorganisms in the intestinal tract, such that the gene can be successfully incorporated and expressed and thus impact on human safety.

The greatest concern in connection with possible gene transfer from the GMO to the gut microorganisms has to do with antibiotic resistance. Antibiotic resistance genes are present in transgenic plants as a result of their use as marker genes to facilitate identification of genetically modified cells or tissues during development.

The potential for transfer and expression of antibiotic resistance genes from transgenic plants to gastrointestinal microflora is of concern, as this could potentially affect the therapeutic efficacy of antibiotics. While the likelihood of transfer of an antibiotic resistance marker from plants to microorganisms in the gut is remote considering the complexity of steps required for gene transfer and expression, the USFDA believes that the use of antibiotic marker genes in crops should still be

evaluated on a case-by-case basis taking into account such information as: (1) whether the antibiotic is an important medication; (2) whether it is frequently used; (3) whether it is orally administered; (4) whether it is unique; (5) whether there would be selective pressure for transformation to take place; and (6) the level of resistance to the antibiotic present in the microbial populations. If a careful evaluation of the data suggests that the presence of the marker genes or gene product in the food compromise the use of relevant antibiotic(s), the marker gene or gene product should not be present in the finished food. The USFDA also notes that certain antibiotics are the only drugs available to treat certain clinical conditions (e.g., vancomycin for the treatment of certain staphylococcal infections). Therefore, marker genes that encode resistance to such antibiotics should not be used in transgenic plants used as food source.

There is greater probability of gene transfer from genetically modified microorganisms to microorganisms in the gut, as there are well known mechanisms of transfer of genetic material between microorganisms. The likelihood of maintenance of the transferred gene in a recipient organism increases if the gene confers to the microorganism a selected advantage. If this is so, the possible health consequences need to be assessed, based on the function and specificity of the gene.

Although the insertion of marker genes is a necessary part of the selection process, it should be noted that such genes can be removed at a later time. Moreover, there are recent developments that demonstrate the feasibility of using alternative marker systems not dependent on antibiotic resistance.

### **Regulations of the U.S., the European Union and Other Asian Countries on the Safety of Genetically Modified Foods**

#### **The United States**

In the U.S., the regulatory authority for most foods is the USFDA while the USDA is responsible for meats, poultry and egg products. The FDA's authority is embodied in the Federal Food, Drug and Cosmetic Act of 1938. Fruits, vegetables, cereals, oils, milk, fish and shellfish may be introduced without pre-market approval although the agency may take legal action for violations of the Act. But producers of food additives must get pre-market approval for all additives that do not qualify for Generally Recognized as Safe (GRAS) exemptions.

The USFDA maintains that it has sufficient authority to regulate foods developed by biotechnology, such as foods derived from new plant varieties, under the Federal Food, Drug and Cosmetic Act, particularly the adulteration provisions of Section 402(a)(1) and the food additive provision (Section 409). It was this latter provision that was invoked in the evaluation of a specific substance in Calgene's Flavr Savr tomato. To develop this tomato, Calgene used recombinant DNA techniques to introduce an antisense polygalacturonase (PG) gene into the tomato. The sense PG gene, normally present in tomatoes, encodes the enzyme PG, which is associated with the breakdown of pectin (a constituent of the tomato cell wall)

and the resulting softening of ripe tomatoes. The antisense PG gene encodes a messenger RNA that suppresses the production of the PG enzyme. The result is a tomato that remains on the vine longer for enhanced flavor. In developing the Flavr Savr tomato, Calgene used a marker gene for kanamycin resistance, that encodes the enzyme, aminoglycoside-3'-phosphotransferase II (APH(3')II), to identify plant cells carrying the antisense gene. APH(3')II inactivates the antibiotics kanamycin and neomycin, and its presence in plant cells permits cells to survive and grow in the presence of these antibiotics, unlike normal cells which are killed by these antibiotics. This allows scientists to select transformed cells that have successfully taken up the desired gene. The USFDA, in addition to evaluating the safety and conducting a nutritional assessment of the tomato per se, also looked at APH(3')II enzyme, the only new substance in the Flavr Savr tomato, as an additive.

In 1992, the USFDA issued a policy statement clarifying its legal and regulatory framework for oversight of food derived from new plant varieties, developed by both conventional and new breeding techniques such as rDNA. The policy paper stressed the Agency's stand that irrespective of the method by which a food or food ingredient is produced, all products must meet the same stringent safety standards. The Agency recognizes that many of the food crops currently being developed with gene splicing techniques do not contain substances that are significantly different from substances already in the diet, and thus would not require pre-market approval as a food additive. However, the 1992 policy paper makes it clear that the USFDA will require pre-market approval as food additives for proteins (or other substances such as fatty acids and carbohydrates) produced by introduced genes if the protein differs substantially in structure and function from the many proteins that comprise conventional foods.

### **The European Union**

Together with the Council Directive on the Deliberate Release of Genetically Modified Organisms into the Environment (90/220/EEC), the so-called "Novel Food" Regulation (EC 258/97) is part of a legislative framework for biotechnology in the EU. The regulation provides a scheme for those responsible for placing foods on the market and also for the control authorities to identify those cases where there is need to scientifically evaluate a food which is being offered for sale in the European Union for the first time. The underlying principle is a pre-market safety assessment of novel foods and food ingredients, either through a simplified notification procedure or a more stringent authorization procedure. The authorization procedure starts with the submission of a request to one of the Member States that leads to a Union-wide decision on the product. If foods and food ingredients produced from, but not containing GMOs (i.e., the inserted genes and their expressed proteins) can be shown to be substantially equivalent to existing foods, their placing on the market only requires a notification to the EU Commission. However, if objections are raised, the application will be shunted to an authorization procedure.

## Japan

In Japan, the Guidelines for Safety Assessment of Food and Food Additives Produced by rDNA Techniques were established in February 1996, based on the OECD concept of “substantial equivalence”. The assessment focuses on:

1. Properties of hosts, vectors, inserted genes;
2. Properties of the genetically modified crop, with emphasis on:
  - (a) toxicity and allergenicity of the expressed protein;
  - (b) difference from host in terms of composition, amino acid profile, fatty acid profile, presence of anti-nutrients, etc.

Since 1996, the Ministry of Health and Welfare has confirmed the safety of 22 genetically modified crops, clearing the way for the entry of these crops and their products into the Japanese market. To date, however, no genetically modified crop is grown commercially in Japan, but field trials are on-going.

It may be noted that while countries with regulations on the safety of GM foods have invoked the principle of “substantial equivalence” in the establishment of their regulations, their operationalization of this principle can differ. Let us take the difference between the US and EU regulations as a case in point. The US does not impose a pre-market approval on a GM food, except when it contains a new substance which warrants its regulation as a non-GRAS additive and therefore would require a pre-market approval. The EU, on the other hand, requires all such foods to go through a pre-market assessment procedure.

The difference is understandable, considering that there are cultural elements involved in the setting up of regulations which have to be acceptable to the community in general. Surveys have shown that Europeans are more suspicious of anything regarded as interference with nature, while Americans are more inclined to accept products of new technologies.

### Labeling of Genetically Engineered Foods

Aside from the safety of novel foods, the labeling of novel foods is another issue that may not be easy to resolve, since products derived from GMOs or processed using GMOs may be indistinguishable from the conventional product. Examples are starch products derived from genetically modified (GM) maize, oil from GM soya bean, or beer prepared using enzymes derived from GMOs. These materials may be further processed before reaching the consumer, e.g., starch into glucose syrups which may in turn be used in jams. Thus, the tagging of every ingredient in a food product as consumed may be a formidable task indeed. There are some consumer groups, however, who believe that this can be done if GM crops are segregated from the point of agricultural production and monitored as they go through the food chain.

The issue on labeling, which should not be confused with food safety issues, has to do with public perceptions of risk and the information that should be provided on the product label to enable the consumer to assess the risk. Labeling requirements are in keeping with the principle that the consumer has the right to know the product and to choose whether or not to buy the product based on the information given to him.

Labeling requirements in the EU differ radically from those in the U.S.

### **The European Union**

The EC Regulation on Novel Foods requires the labeling of products if the food contains or consists of a GMO. It further stipulates that the consumer must be informed if the novel food or food ingredient is no longer equivalent to the corresponding conventional food because of differences in the composition, nutritive value or use of the food. The regulation, however, does not say how the labeling is to be carried out and discussions are underway on the labeling scheme to be adopted. One particular aspect that is being looked at is the labeling requirement for foods containing or contaminated with genetically modified materials (i.e., the transgene and expressed proteins) at very low levels. In this regard, the usefulness of setting detection thresholds is being considered. The detectable limit for identifiable genetically modified material is currently 0.1%. It has been suggested that a practical threshold for GM foods might be 2%.

### **The United States**

The USFDA, on the other hand, does not require, as a rule, labeling to describe the technique used in the development of a new plant variety, be it conventional or the use of biotechnology. However, if the technique used significantly changes the composition of a food, then labeling will be required. For example, if a tomato variety is developed without any Vitamin C, then it will have to be labeled to disclose the radical difference from the traditional varieties. The USFDA policy also requires that foods to which potential allergens have been added must be so labeled. Thus, tomatoes bred to contain a peanut protein would need to be labeled to disclose the presence of the peanut protein, unless it had been conclusively demonstrated that the new tomato was not allergenic to those allergic to peanuts. Notwithstanding this general policy of not requiring the labeling of GMOs, the USFDA allows producers or manufacturers to label a food as being a GMO (or not) if such information is deemed useful to the consumer or if it gives the product some marketing advantage.

The Wirthlin survey conducted for the International Food Information Council (IFIC) in February 1999, which asked 1000 US adult consumers about their attitudes toward food biotechnology, showed that four out of five US - based consumers support the current USFDA's labeling policy for GM foods that requires that these foods be labeled only if they had been significantly changed.

## Japan

In Japan, labeling of GM foods is not required at the present time, since existing laws cannot enforce the labeling of GM foods whose safety and quality are equivalent to existing ones. However, in response to the request of consumer groups to make the labeling of GM foods mandatory, the authorities have started to re-examine regulations on food labeling.

A difficulty that arises in requiring food products derived from or containing GM materials to be properly labeled is the identification of these products. Research and regulatory laboratories are developing tests, usually based on polymerase chain reaction (PCR) that will enable such products to be clearly identified, in anticipation of the full implementation of national and regional labeling requirements.

## Philippine Regulations on GMOs

In the Philippines, except for the biosafety guidelines of the National Committee on Biosafety of the Philippines (NCBP), which covers R&D activities in contained facilities up to the controlled field release of GMOs, I am not aware of regulations that relate directly to the safe consumption of foods or food ingredients from GMOs. This situation is similar to that in other ASEAN countries such as Thailand. At the Regional Symposium on Genetically Modified Foods held in Bangkok in March 1999, a Thai scientist (Dr. Saipin Maneepun) stated that this lack has adversely affected Thailand's trade with the EU. It has deterred its control agencies from ascertaining which portion of its soybean imports is genetically modified, and therefore, Thailand cannot comply with the requirement of EU for a certification that its exported soybean products do not contain genetically modified material.

I think the time has come for us to make hard decisions on genetically modified foods and food ingredients. As a start, we must have a clear national policy on GMOs. Should such materials be allowed for human consumption? If government deems it wise to ban such materials, a clear and unequivocal statement should be made so that even research activities of academic institutions and the rules regulating such activities can be made to comply with such a policy.

But if government decides to allow the entry and commercial production of GMO-derived foods and food ingredients under certain conditions, those conditions will have to be explicitly spelled out. For example, the policy could disallow the production and use of certain GM crops in a particular part of the country, not for food safety reasons, but because it is deemed that such a prohibition is necessary in order to preserve the rich biodiversity of that area.

Once a public policy on GMOs is in place, regulatory agencies can then have a framework within which rules, guidelines and procedures can be established, and the individual applications for clearances of developers and producers of GM foods/food ingredients can be considered.

Since its creation in 1990, the NCBP has been functioning without a broad public policy on GMOs to guide it in dealing with individual applications for clearances for R&D activities, including the planned release of GM plants, on a case-by-case basis. Indeed, the NCBP has been doing a yeoman's job of regulating R&D on GMOs inspite of this policy vacuum.

The government entities that will be mainly responsible for the setting up and implementing of regulations on the safety of GM foods will be the pertinent bureaus of the Department of Agriculture and the Bureau of Food and Drugs (BFAD) of the Department of Health, with the participation of the Department of Trade and Industry, as these will definitely have implications on trade. The NCBP, however, should be ready to provide scientific inputs, such as results of the activities conducted during the development of the novel food, to assist the relevant regulatory agency in evaluating applications for clearances.

Since there will be many agencies involved, each one regulating a particular aspect of GM foods, it may be worthwhile to consider the establishment of an overarching body that can span departmental responsibilities. Such a body will be in the best position to effectively oversee the enforcement of existing or future regulations on GM foods and the close monitoring of GM technologies on human health and the environment.

There are some initiatives to put policies in place on the regulation of GMOs, but these are generally limited in scope. An example is Senate Bill 1313 entitled "Genetically Modified Organisms and Substances Ban Act" filed by Senator Gregorio Honasan in late 1998. The proposed legislation would make illegal the release of any genetically modified organism into the environment. It is silent, however, on the importation of GMOs.

While we should welcome initiatives such as those of Sen. Honasan to establish national policies on GMOs, such policies should be based on a careful weighing of our options, as each option would have potential risks as well as benefits.

Ultimately, whatever policy and regulatory decisions are made should be acceptable to the people, and therefore should have taken account of common values, as well as the wealth of scientific and technical knowledge already existing on the matter. These are time-bound. A decision made at a particular point in time will have to be revisited when additional knowledge is gained or when cultural values have changed.

The Philippines is fortunate in that other countries have gone ahead in the setting up and enforcement of regulations on the safety of GM foods. We should learn from the experiences and benefit from the know-how of the advisory and regulatory bodies of these countries if we wish to fast-track the development of a regulatory system to deal with this important category of novel foods.

## Conclusion

Recombinant DNA technology has the potential for making a difference on the food security and economies of all countries, especially those that are agriculture-based. However, issues on the safety of foods derived from GMOs will have to be addressed in order to bring down the barriers to their acceptance before we can fully benefit from this technology. The safety assessment of foods derived from GMOs requires up-to-date legislation, and a food control system as well as trained manpower for the effective implementation of the laws and regulations. This is true not only for the Philippines but for all countries in the world. In this era of globalization, when raw material producers, processors and consumers of all regions of the world are interconnected, it is imperative that proper safety assessment of food and food components produced by genetic modification be practiced worldwide. We should do no less in the Philippines, otherwise we may find ourselves consuming food that had been rejected for being unsafe elsewhere. Or equally damaging, we may be rejecting as unsafe food commodities or products that can add to our food supply. Therefore, we should develop the capacity to screen and safety-test GMOs, as well as manage their release and use.

While it is of utmost importance to ensure that the food supply is safe, it is just as important to ensure the adequacy of that supply. To be able to do this, we should not be afraid to explore new technologies or non-traditional sources of foods.

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