NEED FOR CAPACITY-BUILDING ON HEALTH AND SAFETY PARAMETERS OF GENETICALLY MODIFIED FOODS FOR PAKISTAN

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ABSTRACT

Technologies have been changing quite rapidly and, in certain cases, innovations have been held back from introduction because consumer-driven economies sometimes do not have equally quick capacity to absorb them. The developments and practical applications of food-products in this field are leaving food laws, rules, regulations and standards much behind.

Therefore, it is becoming quite possible that not all developments in the field of Genetically Modified (GM) Foods would be ethically, socially or religiously acceptable. Biotechnology has raised many kinds of doubts, which cannot be brushed aside, due to its strong possible impacts on health and the environment. It is therefore important to build S&T capacity for sound research and development and to make, adapt and practice laws, rules and standards, in order to contain the negative implications of genetically modified foods on people and nature.

Among many issues arising from the use of genetic engineering, in agriculture, is the ethical concern regarding genetic manipulation itself. Although the application of modern biotechnology to agriculture has been underway for about 15 years, the discussion on genetically engineered foods has intensified in many countries more recently. This is because food is essential to life and, in many ways and for many reasons, also expresses cultural, religious and even the political vision of the society. The genetically engineered foods, which were quietly introduced into the marketplace in 1996, have now spread rapidly. According to estimates, 60-70% of all processed foods in USA, Europe and Japan contain genetically modified ingredients.

This field should receive the attention of the Government of Pakistan, as such foods have crossed the international barrier and are expected to make inroads into our market-place soon in commercial quantities. For overall sustainable development, Pakistan needs to work for speedy capacity-building in this sector, which would include development, monitoring, testing, on the one hand, and the devising and implementing of appropriate laws and regulations, on the other.

INTRODUCTION

The current scenario of S & T in the world has been changing fast. With the emerging new multidisciplinary sciences and technologies, the pace of scientific discoveries and innovations has rapidly increased. As a result, the gestation period of innovations in S & T is fast reducing , even forcing some of the 2nd Generation innovations, in certain fields, to be kept in the hold-back position , because the consumer-driven economies may not have equally quick capacity to absorb these innovations. Another very important change has been the rapid increase in the investment, by large private MNC/TNC's, in quick turn-over fields, like biotechnology, to reap quick and high profits. Their S & T budgets (Monsanto, Aventis, etc), in some cases, are many times more that the total national budgets of countries like Pakistan. There are 6 or 7 large multinationals investing in the new avenues of biotechnology in the world (Monsanto, DuPont, Novartis, Austra-Zeneca, Aventis, etc.).The race for competition in biotechnology is getting so intense and fast that it may be about to take over, from information technology, as the next big carrier of the world economies in this century.

Before considering the need for the capacity building on health and safety parameters of Genetically Modified Foods (GM Foods) in Pakistan, an in-depth examination of the whole issue of the use of genetic engineering in foods, meant for human consumption, is highly important. It would clarify the implications of using or not using such foods, or using them under appropriate checks and balances. Also, the current status of the GM Food technology would be better understood in the light of the latest available scientific/ technical knowledge and the ongoing research-activities in this field.

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ABOUT GENETICALLY MODIFIED FOODS

The application of modern biotechnology to agriculture has been underway for over 15 years, though discussion on genetically engineered foods has intensified within many countries more recently. The debate on the benefits and possible risks of the use of genetic engineering in food-production is often emotionally laden, even when both sides are assuredly objective. This might be expected, as food is not only essential to life, but for many it also expresses cultural, religious and even political visions of society. There are those who recognize the potential benefits of agricultural biotechnology to society and advocate its rapid development and dissemination. Others urge the adoption of a slower, more cautious strategy, moving forward only as more reliable scientific knowledge accumulates.

Food biotechnology is defined as the application of biological techniques to food crops, animals and microorganisms, with the aim of improving the attributes, quantity, safety, ease of processing and production-economics of our food. The most recent application of biotechnology to food is genetic modification (GM), also known as genetic engineering, genetic manipulation, gene technology and/or recombinant DNA technology. In such processes, the DNA is introduced into them by means other than by combination of an egg and a sperm or by natural bacterial conjugation. It has been suggested that eighty percent (80 %) of biotechnology research is directed at modification of food plants. The remaining biotechnology research is on non-food crops, such as cotton, ornamental plants, and pharmaceuticals.

Random genetic variation occurs naturally in all living things and is the basis of evolution of new species through natural selection. Even before its scientific basis was understood, mankind took advantage of this natural variation by selectively breeding wild plants and animals, and even microorganisms, such as yogurt cultures and yeasts, to produce domesticated variants better suited to the needs of humans and the environment. Traditional selective breeding methods are based on the transfer of genetic material between individuals of the same species. Many changes to food-processes brought about by gene-technology may not differ from those which can take place in nature, except that the gene technologist accelerates them and reduce their random nature. Thus, within-species GM involves few fundamentally new issues. However, gene technology has made it possible to move genes across the species barrier. This property makes the technique revolutionary, in terms of the potential benefits that it may bring but, at the same time, it has also caused concern regarding issues of safety, ethics, consumer choice and environmental impact.

Currently, the development of GM Food crops, is on two type of traits, ***Insect resistant-Bt crops*** are engineered, so as to contain a gene from the soil 'bacterium *Bacillus thurigiensis* that is specifically toxic to certain insect pests ***Herbicide resistant-HR-crops*** are genetically engineered to resist specific herbicides.

GENETIC MODIFICATION - PROCESS AND DETECTION

In simple words, the gene technologist uses a "cutting and pasting" approach to transfer genes from one organism to another. To achieve this, bacterial enzymes are required that recognize, cut and join DNA at specific locations, thereby acting as molecular "scissors-and-tape". During the process of genetic modification, the selected gene is copied billions-fold, with the result that the amount of original genetic material used in the modified organism is immeasurably small. In addition, since DNA does not always readily move from one organism to another, "vehicles" such as plasmids (small rings of bacterial DNA) may be used; alternatively, some plant-cells may be transformed by "shooting" small particles coated with the new DNA into the target-cell, using a special type of gun, the "Gene Gun". The modified cell can then be used to regenerate a new organism.

However, by currently available methods only small numbers of cells subjected to genetic modification-procedures are successfully modified. Furthermore, the regeneration of whole plants or animals from culture- cells may take months or years. Consequently, it is necessary to identify the modified cells in a culture mix, using "marker genes" closely linked to the genetic material to be transferred. Antibiotic-resistance has often been used to "tag" genes, since such a property can be detected easily and rapidly at the cellular level in the laboratory and so is useful as a basis for

selection. The use of antibiotic marker-genes is a source of concern, and other methods are being developed.

Until the mid-1990s, it was not possible to determine whether a food or food-ingredient had been genetically modified, due to a dearth of reliable analytical methods. More recently, however, new methods based on the polymerase chain reaction or PCR (a method of DNA amplification) have been developed. Although none of these new techniques has been validated internationally , many laboratories are already using them routinely to meet the growing demand for detection and labeling of foods containing GM ingredients or components. It is expected that validation and harmonization of methodologies may occur soon.

POTENTIAL ADVANTAGES OF GM FOOD-CROPS

For the development of improved food materials, GM may have the following advantages over traditional selective breeding of food crops:

- Allows a much wider selection of traits for improvement: e.g. not only pest, disease and herbicide resistance is achieved, to date, in plants but also potentially drought resistance, improved nutritional content and improved sensory properties;
- It is faster and lower in cost;
- Desired change can be achieved in very few generations;
- Allows selection for characteristics.

These advantages could, in turn, lead to a number of benefits described below for the consumer, industry, agriculture and the environment:

- Improved agricultural performance (yields), with reduced use of pesticides;
- Ability to grow crops in previously inhospitable environments. (e.g. drought, salinity, extremes of temperature, consequences of global warming, etc.);
- Improved sensory attributes of food (e.g. flavor, texture, etc.);
- Improved nutritional attributes, with the possibility of combating anti-nutritive and allergenic factors and increased Vitamin A content in rice;
- Improved processing characteristics, which may lead to reduced waste and lower food-costs to the consumer.

It is frequently argued by some that there is not enough food to feed the world and GM Food is the answer. I personally disagree with this notion in the current global food-production situation. The real problem is not shortage of food, but it is the prevalent status of poverty in the developing countries, so that people cannot buy food for themselves. However, sometime in the future, mankind may need the possibilities of GM Foods.

POTENTIAL DISADVANTAGES AND CONCERNS WITH GM FOOD CROPS

Numerous perceived concerns regarding the safety and other aspects of GM foods are mentioned here, the concern for the safety aspects are:

Antibiotic resistance: Currently marker genes are used in the development process of GM Food crops. The transfer of antibiotic resistance from a marker gene contained in a GM plant, to a microorganism, normally present in the human gut, is a potential risk-factor. It may cause spreading resistance to therapeutic antibiotics to have serious health consequences for humans. Most scientists recommend that antibiotic resistance marker-genes should be eliminated from GM food- microorganisms that have not been inactivated by processing or cooking (as in live yogurt).

Allergenicity: The possibility of the creation of allergens by the GM-process is another important concern for the common consumer. This concern should normally be addressed during the safety-assessment of a genetically modified-food produced from. There are comprehensive Recommendation by European Commission on the scientific information, required to support an application for approval of a novel (GM) food or ingredient. It has a section covering the testing and assessment of allergenicity, to identify the allergenic potential of both the donor and of the recipient organisms.

A situation has already occurred where a research attempt to produce a soya bean with an increased methionine content by a gene-transfer from a Brazil-

nut, was found to transfer the allergenicity from the Brazil-nut. If the situation had not been remedied, the resulting soya bean could have affected not only people, allergic to soya, but also those allergic to Brazil-nuts.

There are no inherent grounds for assuming that GM foods are more or less allergenic than traditional foods. However, when developing any GM Food, care must be taken that allergenicity is not inadvertently introduced into the diet. This requires assessment of the allergenicity of a new protein by predictive methods, experimental testing and a post-marketing surveillance, based on traceability.

Toxicity potential: The possible production of toxic substances in GM foods or toxic metabolites from GM fermentation organisms is a concern that has received considerable attention. It can be better understood by a case- example , which duly highlights this aspect of GM Food process. It was due to the EMS syndrome, in its first occurrence, that caused 37 deaths and over 1000 illnesses in USA in 1988-89 from a condition known as Eosinophilia-myalgia syndrome (EMS). Investigations traced the cause to dietary supplements containing L-tryptophan, and to toxic impurities in specific batches of L-tryptophan manufactured by a fermentation-process in Japan. The investigations showed that the fermentation had been carried out using a genetically modified strain of a Bacillus.

Environmental Concerns: There is a continuing need for studies on the possible risks from GM crops to the agricultural environment. Regulations in this regard will need continuous revision and updating, as new GM crops, data and improved methods on GMOs become available.

In most developed countries, any future release of GMOs into the environment is governed by regulations under the Environment Protection Acts, etc. EU Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms is applicable in Europe. Applications for the release of GM Food must include a considerable volume of data and a detailed assessment of the risk of harm to human health and the environment. All releases of GMO's are advertised locally and details are made available via a Public Register. Release-sites are subject to inspection by the Health and Safety Inspectorate and those making the release are required to report any incidents that may occur, during and after the completion of the trials.

Past experience with introductions of new species to environments where they are not naturally present has shown that potential problems may take several generations to manifest themselves. The problem of possible cross-pollination from GM crops to non-GM crops is of concern to traditional farmers. It has been suggested that the adoption of insect-resistant crops by farmers worldwide may lead to the extinction of certain insect-species (e.g. Lepidoptera), thereby reducing the biodiversity of the planet.

Some of the potential environmental risks are almost impossible to predict. Drafting environmental regulation for GM Food crops is difficult to enforce, when there are no clear standards against which the performance of a product can be measured (e.g. how many birds, butterflies and wild flowers should there be on a farm and to what extent can their numbers be affected before the environment is declared harmed?). However, consideration of some pertinent questions on environmental issues about GM in Food may be suggested here, like:

- Are GMOs harmful to the environment?
- What is the position of national experts on commercial growing of GM crops?
- Are we & who is doing research and how long will it take?
- Won't GM Food crops reduce the amount of pesticides and therefore benefit wildlife?
- Will genes from GM Food crops spread to wild plants?
- GM Food crops are widely grown in the USA, etc.. What is the effect on wildlife there?
- Is the regulatory regime for GMOs, in the country, adequate?
- Should there be statutory control of growing GM Food crops?

It is important to know that the common opinion of the multidisciplinary and GM-related experts is that only a well established statutory control of "how GM Food crops are grown" can and will ensure that biodiversity of our wildlife and the environments are protected and kept safe for our future generations.

Table - 1: Harvested Area of Genetically Engineered Crops

					Percentage share of world's area harvested for Genetically Engineered Crops
	1996	**1997**	**1998**	**1999**	**1999**
Argentina	0.1	1.4	4.3	6.7	17
Australia	<0.03	0.05	0.1	0.1	<1
Canada	0.1	1.3	2.8	4	10
China	1.1	1.8	n.a.	0.3	<1
France	0	0	<0.1	<0.1	<1
Mexico	0	0	<0.1	<0.1	<1
Portugal	0	0	0	<0.1	<1
Spain	0	0	<0.1	<0.1	<1
United States	1.5	8.1	20.5	28.7	72
World	**2.8**	**12.8**	**27.8**	**39.9**	**100**

Socio-economic concerns—Terminator gene technology: An example of a socio-economic concern is about the potential for misuse of the so-called terminator genes, which prevent seeds from germinating. Although patents exist for terminator-technology , it is not yet available commercially. There are fears, in the developing countries, that the commercial appetite of large biotechnology corporations might use such genes in all their patented GM crops to prevent farmers from storing seed for the next season. The plants using terminator-technology produce barren seed to make life more difficult for poor farmers in the developing world. Currently, our farmers grow conventional cultivars and save the seed from their produce for the next planting season in the traditional way. Furthermore, if cross-pollination occurs, GM plants with terminator genes could transfer their sterility to traditional plants grown nearby.

An example of a Canadian farmer who was fined by court in a lawsuit from a biotechnology company , should be more than enough to illustrate the future complex outlook of this technology, unless just consideration is given to the genuine concerns of the poor developing world. In this case, the farmer was fined because his traditional crop received GM traits into his seeds, from his adjacent GM crop-growing modern neighbor, as a result of cross pollination by natural process. The court upheld the view of the rich MNC, most probably represented by their high-profile attorneys, and fined the poor traditional farmer, for stealing the GMO through the air.

The ethical concerns are more regarding the genetic manipulation itself, in different socio-religious perception. Similarly, food is not only essential to life but for many it also expresses cultural, religious and even political vision of society. So, GM food with gene-

Table - 2: Globally Harvested Area of Genetically Engineered Crops (by Traits)

(%)

	1996	**1997**	**1998**	**1999**
Herbicide tolerant	23	54	71	71
Insect resistant	37	31	28	22
Virus resistant	40	14	<0.1	<0.1
Herbicide tolerant and insect resistant	--	<1	1	7
Quality traits	<1	<1	<1	<0.1

Table - 3: Harvested Area of Genetically Engineerd Crops: United States

GM Food Crops	1998 OYS	1999 OYS
HR Soybean	42	57
HR Maize	9	8
HR Cotton	33	39
Bt Maize	25	29
Bt Cotton	23	27

Note: OYS Stand for Objective Yield Survey

material from a pig for Muslims or animal for Hindus/ Budh, etc., would not be acceptable.

GM FOOD CROP IN FUTURE PIPELINE

The 2nd generation of products, many of which are already developed but not yet on the market, focus on a number of quality-traits, which will enhance their use in food-production systems, as well as improve their final use or quality characteristics. These include soybeans with improved animal nutritional qualities, through increased protein and amino-acid content. Crops with modified oils, fats and starches, to improve processing and digestibility, such as, high stearate canola, low phytate or low phytic-acid maize, are a few of the future products. Most of the output-traits of

Box-1: Summary of Consumer-Opinion Surveys on the use of Labeling for Genetically Engineered Products

Country	Survey: Author - Year - Coverage	Results
United States	International Food Information Council; October 2000	52% agree with current FDA labelling procedures. 43% agree with crities who say that any food produced through biotechnology should be labelled even if the safety and nutritional content is not changed;
	March 1997 and February 1999, International Food Council.	Question: Are you more likely agree with the labelling position of the FDA or its critics? (the positions were explained prior to the question) 58 per cent agree with FDA; 38 percent with critics.
	1997, Novartis,	93 percent of Americans want foods that are genetically altered to be clearly as such including 73 percent that strongly agree.
United Kingdom	February, 1999, Consumers Association; population representative survey, 1914 adults.	Of those that heard of Genetically modified foods, 94 percent supported clear labelling of GM foods.
European Union	1997, Eurobarometer, European Opinions on Biotechnology	Question: "It is not worth putting special labels on GM foods; 74 percent disagree and 18 percent agreed.
Australia	May-June 1999: ANZFA Stakeholders view from public consultations	Question: "Should the criteria for labelling foods produced using gene technology extend to those with the same properties as conventional foods? 91 percent strongly favoured mandatory labelling of all food produced with gene technology.
Newzealand	May-June 1999: ANZFA Stakeholders view from public consultations	Similar questions to the above: with a large majority favouring mandatory labelling of GM food products.

genetically engineered maize varieties are still in the pipeline, and have not reached the commercial market yet.

On the industrial side, we can expect colored cotton plants, so as to avoid the need for chemical dyes (some of these plants are already available). Other products, which are likely to be developed, will produce more end-user quality traits, such as nutraceuticals or 'functional foods', which are crops engineered to produce medicines or food-supplements within the plant. These could possibly provide immunity to disease or improve health characteristics of traditional foods, for instance beta-carotene canola or Vitamin A supplemented rice. Plants with greater nitrogen-fixing capacities, which reduce the need for fertilizers, or plants that resist drought, flood and extreme temperatures are also envisaged, as future developments, as are plants, which can be used for bioremediation. Some researchers also suggest that crops like cotton can be engineered to produce wrinkle-free and/or fire-resistant cotton or oilseed rape plants that produce biodegradable plastics.
Substantial research has also been devoted to the development of genetically engineered fish, such as salmon. Genetic engineering is also been applied to animals and crops for medicinal and therapeutic purposes, such as the production of vaccines or organs. Some of these are already available for use; however many are a number of years away from generalized commercial production.

It needs to be noted that the first GM food plants to be put on the market were the GM maize, resistant to the European corn-borer, a serious agricultural pest, and the GM soybean to be tolerant of the herbicide glyphosate. Both of these food-crops are of high commercial value for the developed countries, like USA & Europe. The major food-staples of the poor developing world are still in need of justified attention from the commercial priorities of the big MNC/TNC's, investing in the R & D of GM Food crops. It is food for thought, as well as height of commercialism, which needs to be noted by the national governments of the developing countries.

SAFETY AND REGULATION OF GM FOODS

When introducing any new technology, including gene technology, into the food chain, it is very important to adopt appropriate safeguards to protect human health. Most countries in the Western hemisphere started developing regulatory controls well before any GM foods reached the market, because the people were very apprehensive of lack of familiarity with GMOs.

Generally, in formulating GM regulatuions, most countries use the concept of Substantial Equivalence (SE). The concept was developed in the late 1980s by several national regulators and refined, in due time, for international recognition by the international agencies dealing in food-related matters, like FAO/ WHO & OECD. The concept is based on the idea that existing food or food-sources being used can serve as a basis for comparison when assessing the safety for humans, of GM foods or ingredients. If a new food or component, is considered to be substantially equivalent to an existing food or component the theory is that it can be treated in the same manner with respect to its safety and nutritional assessments.

G M Foods are generally assigned to three categories:

i. Products that are shown to be substantially equivalent to existing foods or food components;
ii. Products that are substantially equivalent to existing foods or food components except for defined differences;
iii. Products that are not substantially equivalent to existing foods or food components.

LABELING OF G M FOODS

GM Food labeling guidelines have been developed by a number of international organizations. Generally, the guidelines took into account the need for labeling of GM foods which contain material (e.g. allergens) that may have implications for the health of some sections of the population (e.g. infants or the elderly), as well as those which contain "ethically sensitive genes". Later on, the foods that contain copy-genes originally derived from humans or from animals were included, which are the subject of religious dietary restrictions (e.g. pig genes for Muslims) or any animal genes for vegetarians.

In Europe, the labelling of GM foods or foods obtained from GMOs, is mandatory since 1997, for those GM foods which, on the basis of a scientific assessment, were judged not to be substantially equivalent to an existing food.

"Further reaffirmation and official adoption has been recently voted by the European Parliament on July 2, 2003, requiring food and animal-feed to be labeled if they contain at least 0.9 % of GM ingredients. It may not be out of place to mention that a very common name 'Frankenstein Foods' is often used in the media to identify GM Foods all over the world."

RECOMMENDATIONS/SUGGESTIONS

Food scientists and technologists should ensure the responsible introduction of GM techniques, provided that issues of product-safety, environmental, social concerns, information and ethics are satisfactorily & adequately addressed. Furthermore, these issues need to be continuously addressed with the development of new or improved methods & procedures in this novel field. PSFST considers that there is strong and intensive need to concentrate on the capacity-building in the field of Genetically Modified Foods, at national level ,on the part of the government. In this way, the country is likely to benefit from this new technology. Provision and trade of safe and healthy food is a provincial subject, under the Pakistan constitution, but the matter of G M Foods is a new , high-tech field, requiring substantial investment, so it would need to be dealt at federal level for the establishment of uniform policy and practice, with large monetary inputs.

Currently, GM Food crops are not the answer to help feed Pakistan's or the world's escalating population. In the present scenario, the real culprit is the prevalent poverty in developing countries, as the poor are unable to buy the available food. However, in future, the long-term tested , safe and healthy GM Foods may be needed to remove the global hunger and malnutrition.

As far as Pakistan is concerned, there is strong & urgent need for the building of capacity in S & T infrastructures, specifically related to the Genetically Modified Foods and crops. It is understood that the Pakistan government has taken some initiatives on the development of National Biosafety Policy and Guidelines for the country, but the progress of the work is quite slow. Therefore, urgent political and technical attention needs to be given to fill the existing gaps in the adoption and implementation of the National Biotechnology Policy. The issue of GM Foods should be adequately included and addressed in the overall policy-framework of the Biosafety Guidelines.

It has been seen that, during the last few years, the activities in the field of biotechnology have picked up in the country at various levels, but the approach has been haphazard. So, there is a need for centrality & cohesiveness, at least in the beginning for a few years, to identify and direct priorities and avoid duplications in this expensive new domain. Without any further delay, the agricultural and other universities need to initiate special courses, at graduate level, on GM Foods at appropriate departments. Institutions involved in the education of biotechnology should add a course on Agriculture Biotechnology, which includes description and implications of GM Foods.

Last but not the least, the process of making standards, rules and regulations for the import and trading of GM Foods/products, ingredients, and seeds must be initiated at the earliest. International agencies like World Health Organization (WHO), Food and Agriculture Organization (FAO) are doing commendable scientific and technical work in this field, which we need to benefit from. Pakistan is a member of these UN bodies and is represented, or needs to be properly represented, by appropriate experts, in the Codex Alimentarius Task Force on Foods Derived from Biotechnology. The guidelines developed in their meetings can be useful starting point for evolving our own national regulations on GM Foods.

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