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BIOTECHNOLOGY AND FOOD

Introduction

The Convention on Biological Diversity (CBD 2000) defines *biotechnology* as “any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use”. It thus includes activities such as traditional food fermentations, waste treatment, drug development, fish farming and crop development. *Food biotechnology* has been defined as “the application of biological techniques to food crops, animals and microorganisms to improve the quality, quantity, safety, ease of processing and production economics of food. It thus includes the traditional manufacturing processes used for bread, beer, cheese and various fermented milk products” (IFST 2004).

Genetic modification has been used by humans for at least 10,000 years through selective breeding methods of crops and animals to achieve higher yields, disease resistance and quality. During the past 25-30 years a range of modern genetic modification (or manipulation or engineering) techniques have been developed that enable selected genes to be transferred within or from a species, or from one species to another, using molecular biology techniques including recombinant DNA technologies.

While traditional plant and animal breeding required decades for substantial changes to be introduced, modern genetic engineering of plants, animals and microorganisms can now take place over much shorter periods of time, and between species that was previously unattainable. The commercial and societal effects of such technical developments have been substantial, and will continue to be so.

World population has increased from about 4.5 billion in 1980, to about 5.8 billion in 1995 and about 6.5 billion today. Borlaug (2004) and others predict that it may reach 8.5 billion by 2035 and 10 billion by 2050. Food production and availability has also had to increase commensurately. Food crop production increased dramatically during the 20 years of the Green Revolution and in the years beyond. FAO data show wheat yields rose 208% from 1960 to 2000, rice 109%, corn 157%, potato 78% and cassava 36% from increases in yield per hectare rather than increases in area under cultivation, and from increased adoption of modern varieties (up from 9% in 1970 to 63% by 1998), now into second and third generations. Future expansions, however, will need to be provided by land already in use. With world cereal demand predicted to increase by 50% over the next 20 years driven by increased meat consumption and hence animal feed use, the increased productivity must come from continued genetic improvement of food crops (both conventional and biotechnology) and a reduction in wastage from postharvest losses. Had 1961 average world cereal yields (1531 kg/ha) still prevailed, nearly 850 Mha of additional land would have been needed to equal the 1999 cereal harvest of 2.06 billion tonnes.

While the proportion of undernourished in the world's population has decreased from 20% in 1990-92 to 17% in 1999-2001 (FAO 2004), and dietary energy supply increased by nearly 0.5% over the same period, most of the world's nearly 800 million undernourished people live in countries with marginal lands

and largely depend on agriculture for their livelihoods. The world's poor will need to rely more heavily on biotechnology-related improvements in crop and animal yields and use of marginal lands if the UN's World Food Summit goals of reducing the world's poverty to 50% of 1996 levels by 2015 are to be attained. The principal needs will be further increases in food production (with lack of water as a major constraint), environmental protection, reducing postharvest losses and increasing food quality, both sensory and nutritional (Serageldin 2003). The predicted increase in world population coupled with increasing "affluence" in many countries (as reflected for example in the increasing demand for animal products) will result in the need for twice or three times the amount of food currently available.

Technology used in genetic modification of food

Genetic changes occur spontaneously over long periods in living cells, but the processes can be accelerated by traditional selective breeding or by modern methods of insertion or removal of genes. Examples of new types of plants developed by hybridisation include triticale and seedless grapes. Modern genetic manipulation enables scientists to cut, copy and reassemble strands of DNA at specific locations in order to insert one or more genes for desirable characteristics, or remove gene(s) for undesirable characteristics. The techniques to produce recombinant DNA are now relatively routine laboratory procedures with highly specific outcomes. Modern recombinant genetic engineering techniques can be used to transfer genes from microorganisms, plants or animals into cells from each of these living forms.

To enable modified cells to be easily recognised in the laboratory, marker genes coding for characteristics such as antibiotic resistance have been included, and this has led to some concerns that these traits may be transferred into microorganisms of public health significance in the human body (e.g. gut), thus increasing their resistance to therapeutic antibiotics. While scientific opinion about the risk of antibiotic resistance marker genes is that it is very low in most cases, their further use is to be discouraged until newer techniques become established (IFT 2000, IFST 2004).

Genetically modified (commonly known as GM or transgenic) foods in the market place

Plants

The first recombinant DNA-derived food plant was a tomato carrying an anti-sense gene to reduce the level of the softening enzyme polygalacturonase to increase the shelf life of the fruit. Many GM crops have now been developed, including soybean, corn, potato, canola and cotton. In 2003, the estimated global area of GM crops was 67.7 million hectares, of which 41.4 Mha (61%) was herbicide-tolerant soybean grown in seven countries, 9.1 Mha Bt corn (containing the gene for endotoxin production from the soil organism *Bacillus thuringiensis*) grown in nine countries, 3.6 Mha herbicide tolerant canola (2 countries), and 3.2 Mha each of herbicide-tolerant corn and Bt/herbicide-tolerant corn. In 2003, 30% of the transgenic crop area (20.4 Mha) was in developing countries, up from 14% in 1997. Notably, 90% of the beneficiary farmers were resource-poor farmers from developing countries, whose increased incomes from GM crops contributed to the slight reduction in the proportion of the world's population living in poverty (James 2004).

To date more than 80 crops have been modified for agronomic performance and more than 25000 field trials conducted (IFST 2004). The major countries for GM crop cultivation are the USA, Argentina, Canada, Brazil and China (James 2004).

Animals

The genetic modification of animals can be applied to biomedical research, modelling of human disease, production of proteins or other substances for therapeutic aims, as an alternative source of cell tissues and organs for xenotransplantation, and to improve desired features of farm animals and fish, such as disease resistance and food production (FAO/WHO 2003). The development of transgenic agricultural animals has lagged behind similar developments for agricultural crops as it is challenging and expensive and because of the low reproductive rate. Cloning of some animals is now possible but raises more issues. GM fish are currently available, but there are no food products derived from GM livestock or poultry. Their role in feeding the world will depend on consumer acceptability.

Microorganisms

Although GM microorganisms and ingredients produced from them (e.g. GM chymosin in cheese making) have been available for many years, use of GM bacteria and yeasts in foods and in food production has been limited. Many applications are possible, including improvement of traditional food fermentations, production of a variety of metabolic end products, and development of bacteria with enhanced probiotic and other health benefit properties.

Advantages and benefits of GM foods

Genetic modification of food raw materials offers several potential advantages and benefits compared to traditional selective breeding techniques (IFT 2000, IFST 2004, TIFS 2003). It can:

- provide more food, more economically,
- be faster and cheaper,
- be more precise in selecting particular desirable characteristics,
- allow more traits to be improved, e.g. herbicide and insecticide tolerance, insect resistance, stress (e.g. drought), temperature and virus resistance, salt tolerance,
- reduce the number of food-deficient regions of the world through the development of stress-resistant varieties more amenable to growing on poor soils,
- improve the shelf life of fresh fruits and vegetables,
- more easily reduce the levels of allergens, naturally-occurring toxicants and other undesirable constituents in food crops,
- increase the levels of desirable disease-resisting and health-promoting food constituents (i.e. functional foods and nutraceuticals),
- improve the sensory and nutritional qualities of foods (e.g. levels of vitamins A, E, desirable fatty acids, iron, fibre),
- produce a variety of ingredients and processing aids (e.g. enzymes, microorganisms),
- enable optimum feed composition and quality for optimal conversion by animals selected for such feeds, with concomitant benefits for the environment (e.g. development of low-phytate seeds that reduce phosphorus and nitrogen levels in wastes),
- reduce pesticide and herbicide usages, with environmental and cost reduction benefits,
- reduce tillage with consequent soil benefit, and reduce hand-weeding, and
- be used to improve desired features of farmed animals, including fish, such as disease resistance and food production with improved qualities (e.g. lower in fat or fat modified, higher yields of prime cuts, better feed conversion).

Advantages and benefits of GM foods to developing countries are likely to be considerable. With increased populations in the developing world in the decades ahead, coupled with problems of water availability and quality and insufficient land to provide food by conventional means, GM technologies in combination with other technical and socio-economic approaches have the capability to achieve the UN dream of reducing world hunger to 50% of 1996 levels by 2015. Such benefits, however, are not achieved without problems: poor farmers will (and where permitted already do) embrace GM products if it is to their benefit, while for poor non-farming individuals the problem is affording any kind of food, whether GM or not. There are huge political and economic issues involved that cannot be solved by widespread introduction and consumption of GM foods: they are part of but not the whole solution. Countries must have the necessary infrastructure, financial support (including research expenditure) and expertise to make full use of these technologies, including the necessary regulatory framework to minimise the risks. Many developing countries lack these prerequisites and must be assisted to further build their capacity to meet the challenges for the benefit of their citizens.

As IFST (2004) has stated: "Food scientists and technologists can support the responsible introduction of GM techniques provided that issues of product safety, environmental concerns, ethics and information are satisfactorily addressed so that the benefits that this technology can confer become available both to improve the quality of the food supply and to help feed the world's escalating population in the coming decades."

Concerns about GM foods

Concerns about GM foods include the following issues:

- the safety of GM foods, especially in the long term: can they be 'proven' to be safe, and are there unintended consequences?

- the environmental impacts of GM organisms and crops,
- the role of “big business” in patenting GM organisms and preventing public access to GM technologies, especially in developing countries, and
- potential allergenicity of novel proteins in GM foods.

Safety and safety evaluation

GM crops and foods have now been available and consumed for over 10 years, and there appears to be no credible scientific evidence to show that the ingestion of transgenic products is injurious to human health or the environment.

GM foods and ingredients currently available on the international market have passed risk assessments conducted by appropriate national and international bodies. Risk is usually defined as “the probability of harm”, while a hazard is anything that might conceivably go wrong. Risk is thus a combination of the hazard involved, the probability of its occurrence, and the consequences of that occurrence.

Risk analysis generally follows the Codex Alimentarius principles (FAO/WHO 2003) and consists of the following components:

- *Risk assessment* is a scientific examination of the nature of the hazard involved (hazard identification), the extent of the hazard and its risk (hazard characterisation), the likelihood of its effects on particular segments of the population (exposure assessment), and an overall assessment of the severity of the risk and its consequences (risk characterisation).
- *Risk management* is usually undertaken by legislators (state or national jurisdictions) who consider a variety of options before and after their implementation, taking into account, where appropriate, “other legitimate factors”.
- *Risk communication* involves a dynamic interchange of views among all those involved in assessing and managing risk and the public.

Risk assessments are thus a science-based examination and interpretation of the facts available in the scientific and technical literature carried out by scientists who are expert in both the topic being assessed and in the modern techniques of risk assessment.

In practice, few traditional foods consumed today have been subjected to any detailed safety or toxicological study, yet they are generally regarded as safe to eat. “Food is considered safe to eat if there is a reasonable certainty that no harm will result from its consumption under anticipated conditions of use” (OECD 1993). Due to practical difficulties in applying traditional toxicological testing and risk assessment procedures to whole foods, the concept of *substantial equivalence* was developed. Substantial equivalence is not in itself a safety assessment, but a starting point to identify any intended and unintended differences between the GM organism (plant, animal or microorganism) and its traditional counterpart. Thus the safety assessment of a GM food compares its characteristics with a conventional counterpart, and involves assessment of factors such as (FAO/WHO 2000):

- identity
- source
- composition
- effects of processing/cooking
- transformation processes
- the recombinant DNA (e.g. stability of insertion, potential for gene transfer)
- protein expression product of the novel DNA (e.g. effects on function, potential toxicity and allergenicity)
- possible secondary effects from gene expression or disruption of host DNA or metabolic pathways (e.g. macro/micronutrients, anti-nutrients, toxicants, allergens)
- potential intake and dietary impact of the GM food.

Factors are assessed on a case-by-case basis, particularly for GM animals and microorganisms.

The *precautionary principle* states that where scientific evidence for safety is insufficient, inconclusive or uncertain, it should be invoked or be considered as part of the assessment; some have interpreted this as a means of blocking all progress. It should, however, be recognised that scientific evidence can never be conclusive. Science can never *prove* that anything in life, including food, is safe, i.e. without hazard, because absence of evidence is not evidence of absence (IFST 2004). A recent case in point is the

recognition (since April 2002) of acrylamide as a potential hazard in roast and fried potatoes. It is now recognised that there is no scientific justification for requiring long-term animal feeding studies for GM foods or major ingredients as they would be unlikely to provide meaningful information in the great majority of cases (FAO/WHO 2000, OECD 2000).

To date several National Academies of Science, as well as FAO/WHO, OECD, IFT and others have stated that there is no credible evidence to demonstrate that GM foods or food ingredients are any less safe than traditional foods or ingredients (Royal Society 2000). However, the Academies also stated that it was imperative that public funding for research on genetic engineering was maintained; that government and international agencies place the results of such research in the public domain; and that vigorous public/private collaboration continue if the benefits of recombinant DNA biotechnology are to be realised for all of the world's population.

As more research data become available, early concerns are being answered. For example, the many deaths and injuries in the USA in 1989 from consumption of the amino acid L-tryptophan have been shown to have been caused by errors in the purification procedures and not because the amino acid was produced by a GM organism.

Environmental impacts

Much has been made of the potential long term environmental consequences of the dispersal of GM crops and microorganisms into the environment. The issues include their survival in the wild, cross-pollination with non-GM crops, transfer of herbicide-resistance to weeds or wild relatives, reductions in insect biodiversity through widespread use of insect-resistant crops, and transfer of selective marker genes (such as antibiotic resistance) in GM microorganisms to gut microorganisms with consequences for antibiotic therapy. To date, after thousands of field trials, there is no evidence of any significant environmental problems with GM organisms. Of concern to organic farmers and those marketing products claiming a "clean, green" image is the potential for contamination of non-GM crops by GM material. Widely reported concerns based on limited experiments that populations of the Monarch butterfly would be adversely affected or eliminated by GM corn have now been shown to be unfounded and the result of inadequate experimental procedures. Pests have not developed resistance to Bt, and superweeds have not invaded agricultural or natural ecosystems. There is some evidence of environmental and social benefits emerging, e.g. less pesticide and fuel use, less soil compaction, and less mycotoxin content observed with insect-resistant corn.

Public sector access

Concern has been expressed over potential controls of GM technology through aggressive patenting by some multinational companies, and the inability of subsistence farmers in developing countries to compete, such as the issue of farmers having to pay licensing fees for the modified seeds or not being able to save and use the seed from a previous crop for later planting. However, 30% of areas under GM crop cultivation are in developing countries, and the proportion is increasing, thus farmers in those regions are competing satisfactorily. As noted above, 90% of the beneficiary farmers are resource-poor farmers from developing countries, whose increased incomes from GM crops contributed to the alleviation of poverty (James 2004). In time, patents will expire, and agreements such as those for golden rice (containing high levels of beta-carotene, the precursor of vitamin A) may enable products to be more widely available. Rationalisations amongst large chemical and agricultural companies and poor communications in the past with consumers and regulators in some countries will no doubt lead to changes in marketing strategies and perhaps lead to increased public sector funding of food biotechnology and the capture by public organisations of GM benefits. It is particularly important for research to be directed to indigenous crops of importance in developing countries.

Allergenicity and naturally occurring toxicants

Food allergens involve abnormal immunological consequences in some consumers to some food constituents, usually particular proteins. The most common types of allergies are mediated by allergen-specific IgE antibodies, and the outcomes can be mild to fatal. The most common allergenic foods

(peanuts, soybeans, milk, eggs, some fish, crustaceans, wheat and tree nuts, sometimes called the big 8), account for over 90% of all reactions, although more than 160 foods have been associated with sporadic reactions (Hefle *et al.* 1996).

The potential allergenicity of GM foods can be assessed using the decision-tree approach of the International Food Biotechnology Council of the International Life Sciences Institute (Metcalf *et al.* 1996, FAO/WHO 2000) now adopted and refined by the agricultural biotechnology industry. The assessment examines the source of the gene(s), the amino acid sequence homology of the newly introduced protein(s) to known allergens, the immunoreactivity of the introduced protein with IgE antibodies from individuals known to suffer allergic reactions, and the physicochemical properties (effects of digestion and heat) on the proteins. The IFBC–ILSI strategy is continuously being refined to improve the detection of known and potentially allergenic material, or to test the allergenicity of proteins from foods with no history of allergenicity.

The enzyme introduced into glyphosate-tolerant soybeans and the Bt proteins used in insect-resistant crops have no sequence homology to known allergens and are rapidly digested in mammalian systems. Reports that a Brazil nut gene had caused allergies in consumers eating GM soybean products have been shown to be incorrect, as the transfer of Brazil nut allergenicity to the GM soybean was identified during development work and the product was never released onto the market.

Some foods or crops contain natural toxicants (e.g. solanine, enzyme inhibitors), although the major human crops and animals contain few of such constituents through millennia of selective breeding. It is essential that adequate assessments be undertaken to maintain this status with GM foods.

Ethical issues

Discussion on ethical issues of GM by its opponents centre on “man is playing God” by transferring genes; or people who follow a religion that does not allow consumption of a food such as pork should not be expected to eat a food containing pig genes, but do not address the ethics of denying to millions of starving or malnourished people the opportunity of addressing these imbalances by access to GM foods or ingredients. The latter are, however, fully addressed by the two reports of the Nuffield Council on Bioethics (1999, 2003), the latter specifically directed at the needs of developing countries. Ethical considerations are also addressed in the TIFS report (2003). On the matter of choice for those who, for religious or other reasons, do not wish to consume GM foods, one key would be to adopt distinctive labelling as practiced in some countries; another would be for them to purchase organic foods in which GM ingredients are prohibited. The issues involved are complex, and the diametrically opposed views unlikely to be reconciled.

Public attitudes to GM foods

Consumer attitudes to GM foods are dependent on their assessment of risk and benefit of the foods produced and the technologies involved, and on the nature and extent of the communications provided to them. Although many national biotechnology or food standards organisations or agencies undertake surveys on consumer acceptance of GM foods and processes, few truly international studies have been undertaken. Most of the research on consumer attitudes has focussed on the USA and Europe.

In one extensive study, more than 35,000 respondents were asked whether the benefits of GM crops (with respect to reduced pesticide use) were greater than the risks. Over two thirds of respondents from USA, Colombia, Cuba, Dominican Republic, China, India, Indonesia and Thailand believed the benefits outweighed the risks, while less than one third of respondents from France, Greece, Italy, Spain and Japan did so. The USA led the industrialised countries in support for biotechnology. Overall, people in developing countries were supportive of GM crops (Hoban 2004).

Support for GM foods or ingredients is generally less than for other food biotechnology applications where the benefit or involvement is less direct. Factors influencing support for acceptance of GM products or technologies include, for example, whether the GM product is eaten or not; whether there is a direct benefit to consumers (e.g. golden rice); why the genetic modification was done, and how exotic the

transformation was; the necessity for the genetic modification considering the food choices available; and the level of technical information obtained, especially on risk and safety assessment, and trust in the information. In some studies, government agencies and universities generally ranked high in credibility of the information provided, while activist groups and agribusiness companies ranked low. Some population groups have shown more concern for environmental and biodiversity issues than for food-related issues.

Of considerable importance to many consumers is adequate labelling of GM products in order to make an informed decision. Labelling requirements for GM foods, ingredients and processes vary for different countries. Deciding what to label, and the level of GM in the food to trigger the labelling requirement, are issues that require debate and uniform implementation.

International regulation of food biotechnology

In July 2003 the 26th session of the Codex Alimentarius Commission approved principles for the risk analysis of foods derived from biotechnology, and guidelines for the conduct of food safety assessments of foods produced from recombinant plants and microorganisms (FAO/WHO 2003a,b, c). These procedures now form the basis for assessments of GM foods and ingredients used widely by national regulatory agencies.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was accepted on 29 January 2000 and came into force on 11 September 2003. To date 111 countries are parties to the agreement. The definitions used in the Codex Principles are the same as those used in the Protocol so that the documents are compatible and supportable. The Protocol is a legally binding instrument that regulates the international movement of living modified organisms (LMOs) resulting from modern biotechnology to protect the environment. On 27 February 2004 the member states of the Cartagena Protocol adopted handling, transport, packaging and identification requirements for promoting the safety of LMOs or GMOs.

The implementation of international agreements for the regulation of GM foods and ingredients and processes for genetic modification of plants, animals and microorganisms at the national or regional level is a complex issue and will be outlined later in an addendum to this Bulletin.

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http://www.who.int/fsf/GMfood/FAO-WHO_consultation_report_2000.pdf

Safety Assessment of Foods Derived from Genetically Modified Microorganisms. Report of 3rd FAO/WHO Expert Consultation on Foods Derived from Biotechnology, 24-28 September 2001. Geneva, Switzerland. 29 pp.

http://www.who.int/foodsafety/publications/biotech/en/ec_sept2001.pdf

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The International Union of Food Science and Technology (IUFoST) is the global scientific organisation representing over 200,000 food scientists and technologists from more than 60 countries. It is a voluntary, non-profit association of national food science organisations linking the world's food scientists and technologists.

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