Modern food biotechnology, human health and development: an evidence-based study

FOOD SAFETY DEPARTMENT*
WORLD HEALTH ORGANIZATION

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ACRONYMS AND ABBREVIATIONS

Bt	*Bacillus thuringiensis*
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
DNA	deoxyribonucleic acid
ERA	environmental risk assessment
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GEF	Global Environment Facility
GM	genetically modified
GMM	genetically modified microorganism
GMO	genetically modified organism
IPR	intellectual property right
MLS	multilateral system of facilitated access and benefit-sharing
NGO	nongovernmental organization
OECD	Organisation for Economic Co-operation and Development
PVP	plant variety protection
R&D	research and development
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
TRIPS	Agreement on trade-related aspects of intellectual property rights
UNCED	United Nations Conference on Environment and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
WHO	World Health Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

This study was commissioned by the World Health Organization (WHO) to establish a knowledge base for evaluating the application of modern biotechnology in food production. The study does not seek to address all issues and evidence in detail, but rather aims to place in context the overall impact of this technology on human health and development. The study reviews evidence in several broad areas related to the use of genetically modified (GM) organisms in the food supply (GM foods), including a review of GM food products currently available, the assessment of risks and benefits, the broader impact on societies, and the existing regulatory capacity in countries. The evidence was collected and collated by WHO with the support of a background group of external experts (list of experts - annex 1). Data for the study were gathered through traditional methodology as well as through an open questionnaire and an Internet-based electronic discussion process. Preliminary results were discussed at a broad stakeholder meeting held in 2003 (list of participants - annex 1), informing further data search and revision.

The first GM food (delayed-ripening tomato) was introduced on the US market in the mid-1990s. Since then, GM strains of maize, soybean, rape and cotton have been adopted by a number of countries and marketed internationally. In addition, GM varieties of papaya, potato, rice, squash and sugar beet have been trialed or released. It is estimated that GM crops cover almost 4% of total global arable land.

The development of GM organisms (GMOs) offers the potential for increased agricultural productivity or improved nutritional value that can contribute directly to enhancing human health and development. From a health perspective, there may also be indirect benefits, such as reduced agricultural chemical usage and enhanced farm income, and improved crop sustainability and food security, particularly in developing countries. Contradictory findings for such benefits sometimes reflect different regional or agricultural conditions.

The use of GMOs may also involve potential risks for human health and development. Many genes used in GMOs have not been in the food supply before. While new types of conventional food crops are not usually subject to safety assessment before marketing, assessments of GM foods were undertaken before the first crops were commercialized. To provide international consistency in the assessment of GM foods, principles developed by the Codex Alimentarius Commission (a joint programme of WHO and the Food and Agriculture Organization of the United Nations; FAO) now cover food safety, while the Cartagena Protocol on Biosafety covers environmental safety of GMOs. Many countries have established specific premarket regulatory systems in accordance with this international guidance that require a case-by-case risk assessment of each GM food. Risk assessment methodology undergoes continuous improvements, a fact that is recognized by the Codex principles, including the need for risk assessments to consider both the intended and unintended effects of such foods in the food supply. GM foods currently traded on the international market have passed risk assessments in several countries and are not likely, nor have been shown, to present risks for human health.

Although risk-assessment systems have been in use for some time, the perception of GM food among consumers has not always recognized these assessments. One explanation is that many national food-safety systems have had problems performing good risk communication in this area. In many countries, social and ethical considerations may cause also resistance to modifications which interfere with genes. These conflicts often reflect deeper issues related to the interaction of human society with nature — issues that should be taken seriously in any communication effort. However, while in many regions, food is clearly considered part of historical identity and societal life, scepticism towards GM food is not necessarily linked to traditionalism or to absence of knowledge about this new technology. Investigations of public perception indicate that the sceptical consumer will acknowledge arguments both for and against GM food and, in general, does not demand ‘zero risk’. Likewise, it has been seen that critical attitudes towards GM food are not necessarily linked to a negative attitude towards the use

of biotechnology as such, as demonstrated by a generally positive attitude towards the use of biotechnology in modern medicine. The issue of benefit to society therefore seems to constitute an important aspect related to acceptance of new technology.

Intellectual property rights are an important part of the GM food debate. Problems of assuring equal access to genetic resources, sharing benefits on a global level, and avoiding monopolization exist for GM food as for other uses of gene technology. Related to this are concerns about a growing influence of the chemical industry in seed markets. Sustainable agriculture and biodiversity are likely to benefit most when a rich variety of crops are planted, and a potential exclusive use of certain chemical-resistant GM crops could be seen to create dependency.

Conflicting assessments and incomplete substantiation of the benefits, risks and limitations of GM food have added to existing controversies. During a famine situation in southern Africa in 2002, the reluctance among several recipient countries to receive GM food aid was not primarily linked to health or environment issues, but to socioeconomic, ownership and ethical issues. Such controversies have not only highlighted the wide range of opinions within and between Member States, but also the existing diversity in regulatory frameworks and principles for assessing the benefits and risks of GM food. In addition, many developing countries cannot afford to build the separate capacities required for effective regulation of GM foods, which again underlines the benefits that could be derived from international work for broader evaluations of GM food applications.

At the international level, 15 legally binding instruments and non-binding codes of practice address some aspect of GMO regulation or trade. Such sector-based regulations increase the already overstretched capacity of developing countries, and present challenges to develop a fully coherent policy and regulatory framework for modern biotechnology. This study makes the case for the need for an evidence base to facilitate a more coherent evaluation of the application of modern food biotechnology and the use of GM foods. Such an evidence base should: deal with the assessment of human health and environmental risk as well as benefit; evaluate socioeconomic factors, including intellectual property rights; and consider ethical aspects. International harmonization in all these areas is a prerequisite for the prudent, safe and sustainable development of any new technology, including the use of biotechnology to produce food. Work towards such harmonization can only move forward through inter-sectoral collaboration and would therefore necessarily extend beyond the WHO mandate into the mandates of several other international organizations. This report should be seen as one possible starting point for further inter-sectoral discussions.

1. INTRODUCTION

1.1 Goals and terms of reference

The World Health Organization (WHO) commissioned this study to establish a broad knowledge base for Member States, international standard-setting bodies and other stakeholders, in order to achieve transparent and inclusive consensus on the evaluation and application of modern biotechnology in the production of food. The aim of this study is to determine the significance of the application of modern biotechnology to food production in terms of human health and development. The study does not seek to address all issues and evidence in detail, but rather to place in context the overall impact that modern food biotechnology may have on human health and development. It is intended to serve as a scientific basis for potential discussion by the governing bodies of WHO.

The study reviews evidence in five broad areas:

1. Current use, research and impending development of foods produced through modern biotechnology, and their significance for human health and development.
2. Risk assessments of present and future products of modern biotechnology in relation to food safety, human nutrition and environmental health.
3. The significance of modern food biotechnology for food security, and the impact of intellectual property rights on research.
4. National capacity for risk assessment and management.
5. The impact of modern food biotechnology on civil society, considering social and ethical concerns.

1.2 Methodology

A background group consisting of experts from various Member States (*Annex 1*) established the terms of reference of the study and a guidance document that directed a small team within WHO to gather the evidence. Members of the background group also assisted in data gathering.

Data were gathered using extensive literature and Internet searches, and through a questionnaire supported by approximately 120 responses which was circulated to a broad range of stakeholders in May 2002. The comments received from an electronic stakeholder discussion held between January and April 2003 have also been incorporated. The opinions of participants who attended a stakeholder meeting on 5–6 June 2003 in Geneva, comprising representatives from governments, consumers, industry, research and nongovernmental organizations (NGOs), from developed and developing countries, have also been included.

The focus on including a broad basis of scientific evidence as well as descriptions of opinions from a broad group of stakeholders has resulted in a list of references which includes documentation from many Internet sites. Documentation originating solely from Internet sites should not, in general, be treated or presented as documentation derived from peer-reviewed literature; however, it has been considered necessary in this study to include data and information presented from both sources, with a clear indication of when information is available solely from Internet sources.

1.3 Modern food biotechnology: definition and overview of potential benefits and risks

According to the definition of the Codex Alimentarius Commission (CAC 2001a) (adapted from the Cartagena Protocol on Biosafety — see *Section 3.3*), modern biotechnology is defined as the application of (i) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic

family, that overcome natural physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection.

This study focuses on the application of modern biotechnology (especially recombinant DNA technology) to organisms used to produce food.

The application of modern biotechnology to food production presents new opportunities and challenges for human health and development. Recombinant gene technology, the most well-known modern biotechnology, enables plants, animals and microorganisms to be genetically modified (GM) with novel traits beyond what is possible through traditional breeding and selection technologies. It is recognized that techniques such as cloning, tissue culture and marker-assisted breeding are often regarded as modern biotechnologies, in addition to genetic modification.

The inclusion of novel traits potentially offers increased agricultural productivity, or improved quality and nutritional and processing characteristics, which can contribute directly to enhancing human health and development. From a health perspective, there may also be indirect benefits, such as reduction in agricultural chemical usage, and enhanced farm income, crop sustainability and food security, particularly in developing countries.

The novel traits in genetically modified organisms (GMOs) may also, however, carry potential direct risks to human health and development. Many, but not all, genes and traits used in agricultural GMOs are novel and have no history of safe food use. Several countries have instituted guidelines or legislation for mandatory premarket risk assessment of GM food. At the international level, agreements and standards are available to address these concerns.

GMOs may also affect human health indirectly through detrimental impacts on the environment, or through unfavourable impacts on economic (including trade), social and ethical factors.

These impacts need to be assessed in relation to the benefits and risks that may also arise from foods that have not been genetically modified. For example, new, conventionally bred varieties of a crop plant may also have impacts — both positive and negative — on human health and the environment.

1.4 Recent international controversies and study initiative

Conflicting assessments and incomplete substantiation of the benefits, risks and limitations of GM food organisms by various scientific, commercial, consumer and public organizations have resulted in national and international controversy regarding their safe use as food and safe release into the environment. An example is the debate on food aid that contained GM material offered to countries in southern Africa in 2002, after 13 million people faced famine following failed harvests. This international debate highlighted several important issues, such as health, safety, development, ownership and international trade in GMOs.