APŽVALGINIS STRAIPSNIS

Genetically modified organisms: do the benefits outweigh the risks?

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Key words: *genetically modified organisms; risks and benefits; international and European legal and ethical requirements.*

Summary. *The objective of this literature review is to analyze the implications of using genetically modified organisms (GMOs) as well as international and European position regarding such organisms.*

Method. Review of international and European legal requirements and ethical guidelines and relevant publications, found and accessed with the help of PubMed and Lund University Library databases.

Results. The article discusses the main application areas of GMOs, the expansion of using GMOs in the world as well as the advantages and disadvantages of the implications of their usage. It further provides an overview of the suggested ways to tackle or avoid the GMO-related risks. The international and European positions regarding the application of GMOs are discussed and European Directives, Regulations, and ethical guidelines are overviewed. The article further presents the public attitudes towards GMOs in Europe as well as overviews surveys conducted at the national level.

Conclusion. Suggested steps to tackle the challenge of developing and managing biotechnology for the benefit of public health and the environment are presented.

Introduction

In its broadest sense, genetic engineering includes uncontroversial techniques, like selective breeding. In its narrower sense, used in this article, genetic engineering refers to gene splicing-inserting DNA fragments from one organism's genes into the chromosomes of another, thereby changing its genetic makeup (1). Article 2 (2) of the European Directive 2001/18/EC defines a genetically modified organism (GMO) as an organism (with the exception of human beings) in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination (2). Similarly, a genetically modified microorganism (GMM) according to Article 2(1b) of the European Directive 98/81/EC is a microorganism in which the genetic material has been alter ed in a way that does not occur by mating and/or natural recombination (3).

In the field of animal and plant biotechnology, there are three main application areas of genetic engineering:

1. ***Improving the quantity and quality of agricultural production*** for the benefit of consumers and producers. Genetic engineering is often performed to make the crops herbicide resistant rather than to make them disease-resistant. For example, until 2002 no commercially used genetically engineered crops increased drought tolerance (4, 5) in part because such engineering is more difficult than designing pesticide resistance (1). Examples of other modifications are changed flower color, delayed senescence of fruits and flowers, male sterility as an aid to crossbreeding, and modification of lipid biosynthesis for specialized oil production (6).

2. ***Pharmaceutical production in more sustainable ways or facilitated drug delivery*** for developing countries, e.g. through plants or milk (6).

3. ***Applications of environmental relevance***, as alternatives to industrial polymer production or used for innovative decontamination of polluted sites (6).

However, there is still the lack of knowledge about many important characters of plants and animals, and

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this is one of the main causes delaying the fulfillment of the most interesting applications of GMOs (6). Only a few of the potential applications have been actually realized and have reached the stage of GMO production, and even less GMOs have reached commercial application (6). So far only genetically modified micro-organisms and plants have been commercially applied – for example, genetically modified plants are utilized for seed production, as animal feed, or for production of food ingredients, such as soy lecithin and maize starch (6).

The global level of consumption of foods derived from GMOs is increasing rapidly. For example, between 1996 and 2003, the land planted with GM crops increased approximately from 3 million to 70 million hectares globally (7). Argentina and the United States are the countries that have extensively adopted biotechnologies, mainly applied soy-bean and corn, and about 80% of land in these countries have been planted with GM crops (7). A dramatic increase in GM-planted land has also been recorded in Brazil (7). It has been estimated that more than 30 000 food products will contain soybean or maize ingredients, and approximately 32 millions tons of feed will be derived from GMOs (6).

In 2004, three-quarters of GM crops, which were grown worldwide, were cultivated in developed countries, predominantly on large-scale industrial farms in the United States, Argentina, and Canada (8). Of approximately six million farmers who grew GM crops legally worldwide in 2002, more than three-quarters were resource-poor, small-scale farmers, mainly in China and South Africa (8). While the number of farmers using GM crops was the highest in developing countries, they only accounted for 27% of the total area (8).

In Europe, one of the main obstacles to the success of GMOs is the inadequacy of existing GMOs to the needs of European agro-ecosystems. Comparatively, North American and South American agricultural systems are more suited for the application of existing GMOs (6). In Europe, the food production system overall is strongly influenced by the need for raw materials for animal nutrition. Out of approximately 30 million tons of soy-bean cakes used in 2001, only 2.5% were produced with soy-bean grown and processed within the EU, which means a wide use of imports from third countries that have already been using GM crops for some time (7).

Seeing such an increasing use of GMOs, one starts to wonder what the advantages and disadvantages of using them are, and whether the benefits outweigh the risks. The implications of genetic engineering are both complex and contradictory, since genetic engineering uses new technologies and brings up very different opinions and conflicting viewpoints (9). This article will discuss the benefits and risks of the use of GMOs and present the European policy and public opinions regarding this issue.

The implications of using GMOs: advantages and disadvantages

Benefits of using GMOs. It has been argued that public health could benefit from using GMOs and that there are some issues, which could be solved with current biotechnological instruments, for example:

1. ***Producing edible vaccines or medicines*** in milk, eggs, or fruit to facilitate distribution of therapeutic or preventive molecules (6). The ability to genetically modify animals in order to produce pharmaceuticals in their milk has been one of the most innovative applications of genetic modification techniques. Medicines or vaccines produced in milk could be manufactured and distributed cheaply, and made more accessible to people around the world (10). It has been argued that the advantages of edible vaccines are manifold. Injected vaccines are expensive, require trained medical staff for their administration, and usually require constant cooling during transport and storage, which creates difficulties in many developing countries. The use of needles also brings the risks of spreading infections (8). Edible vaccines would help to avoid these inconveniences and dangers. There are examples of transgenic plants that have been developed to immunize against the hepatitis B and Norwalk viruses, both of which are of substantial concern for individuals living in developing countries (10). Researchers have also produced a variety of transgenic potatoes that contain a small portion of the cholera toxin and immunize against the disease upon ingestion (10). In 2004, the European Union Sixth Framework Programme awarded the Pharma-Planta Programme a grant of € 12 million to genetically modify plants to grow vaccines against rabies and tuberculosis, and eventually, diabetes and HIV (10). It has to be mentioned, however, that development of GM crops that can produce biopharmaceuticals is at a very early stage (8). Concerns have also been expressed that introduction of edible vaccines would not only pose the problem of appropriate dose control (10) but also raise concerns about the effect of such crops on insects and other animals, which might feed on it (8).

2. ***Producing functional food or nutraceuticals with added traits*** that could make them beneficial for

health or for preventing diseases, and ***producing food for disadvantaged consumers***, affected by food allergies or intolerances (11) as well as biofortification of the micronutrient content of food crops (6, 10). An example of nutraceuticals can be tomatoes with increased lycopene (an antioxidant, which is a useful agent in the prevention and treatment of prostate cancer and heart disease (12, 13)) content (14) or a soybean protein (alpha-glycinin) mutated to exhibit antihypertensive properties – the mutated protein has been purified from the soybeans and was able to lower blood pressure in hypertensive laboratory animals (15). Another example is a GM rice variety that supplements the vitamin A synthesis pathway (10). Vitamin A deficiency is a serious burden on the health of millions of children living in developing countries who cannot afford alternative sources of the vitamin, and it causes up to 500 000 cases of childhood blindness and 2–3 million deaths annually (10). The most famous of such crops is Golden Rice, which was developed to contain a beta-carotene supplement (a precursor to vitamin A) (10). It has been reported that in the next generation of genetically modified plants, scientists will select plants more balanced in their chemical composition to better satisfy the nutritional requirements of humans and farm animals (16). Nutritionists expect higher nutrient content and a better availability of these nutrients (proteins, amino acids, fatty acids, minerals, trace elements, and vitamins) as well as less antinutritional factors from such plants (16).

3. ***Improving the qualities of certain crops and producing safer food.*** It has been reported that the use of some conventional varieties of crops can have grave health consequences (8). For example, most varieties of *Lathyrus sativus*, a lentil formerly grown widely in North India and now spreading in Ethiopia, are known to cause the crippling disease of lathyrism, and traditional varieties of cassava in Nigeria also have dangerously high levels of hydrocyanic acid (8). Research on GM crops could create safer varieties of these and other crops that could replace harmful traditional varieties by reducing the levels of undesirable substances including mycotoxins, alkaloids, and glucosinolates (8).

4. ***Breeding with increased yield while reducing the use of pesticides***, ***improving plant adaptation to unfavorable environments*** (16). In order to achieve this advantage, herbicide-tolerant and pest-resistant GM varieties as well as virus- and fungus-resistant crops have been developed (17). GM technology has also been used to generate crops that are tailored to particular environments, *e.g.*, drought resistant varieties or crops that are tolerant of high soil salinity (17). GM crops may offer solutions to very specific climatic conditions prevalent in developing countries and allow for more effective control of pests and fungal infections (8). For example, African climates vary so considerably that it is a real challenge to breed varieties that will grow from region to region, and the ability to design crops suited to particular regional climatic and environmental conditions could be beneficial to developing countries (10). Some GM improvements may offer additional benefits, for example, GM rice in China requires less pesticide spraying in addition to increasing crop yields (18). Cultivating such rice may reduce incidences of pesticide poisoning and environmental pollution. Criticism has been expressed, however, that GM pest-resistant strategies may lead to the evolution of pest resistance in the long term, which could have an impact on both GM and conventional agriculture (10). Yet, another important fact is that labor and energy consumption are reduced, as farmers reduce the number of treatments and the use of fuel (8), and such reduction affects the environment positively. When smaller amounts of pesticides are used on GM crops, this reduces pesticide exposure to farm workers, to the communities surrounding farms, and ultimately to consumers, as well as decreases the impact of agricultural pesticides on nontarget insects (8).

5. ***Using GMOs in scientific and medical research.*** It has been reported that genetically modified virus has had some success in targeting and destroying cancer cells, while leaving healthy cells undamaged (19). Cancer Research UK scientists have examined the effect of the genetically modified virus on pancreatic, lung, ovarian, liver, and colorectal cancers *in vitro* as well as in tumor bearing mice; the modified virus replicated vigorously within the cancer cells and spread through the tumor tissue, causing the cells to die (10). Genetically modified bacteria may also be able to serve as a barrier by secreting proteins protecting women against HIV infection (20). For example, a natural component of the vaginal microbial flora *Lactobacillus jensenii* has been genetically modified to secrete soluble CD4 (a protein that HIV specifically binds in order to gain access to cells and infect them) and has been shown to block laboratory strains of HIV from infecting human cells (20).

6. ***Using GMOs for bioremediation*** – the use of organisms to degrade waste materials into less toxic or nontoxic material in the environment (10). Naturally occurring organisms (*e.g.*, bacteria, yeast, fungi)

can be used as bioremeditors to clean up industrial or general waste such as sewage, pesticides, heavy metals, and nuclear waste. It has been suggested that genetic modification of such organisms can increase the effectiveness of bioremediation (10). Techniques of phytoremediation, the use of living plants to absorb toxic waste, also show substantial promise (21). For example, the yellow poplar *(Liriodendron tulipifer*a) has been genetically modified to express bacterial mercuric reductase, which allows the poplar to grow in normally toxic levels of ionic mercury, which the modified poplar converts to the much less toxic elemental form of mercury up to 12 times faster than poplars that have not been genetically modified (21).

Risks of using GMOs. Bearing in mind all the possible benefits of GMO applications, the risks of application of biotechnology in agriculture and medicine should also be discussed. The following risks have been identified:

1. ***Health risks.*** Potential health risks associated with the use of GMOs are the following:

a) ***Unexpected gene interactions****,* different from the foreseen effects of the transferred gene construct (*e.g.* with synthesis of some toxic compounds) (16). For example, some feeding studies have shown minor effects on the weight of animals fed on GM diets (11). It is likely that these unexpected results are linked to either the specific gene added to the GM crop tested or to the particular side effects of a genetic transformation event, which can potentially disturb metabolism (10).

b) ***Cancer risks***, which may appear because GM crops have higher pesticide residues than non-GM ones and the main ingredient of some pesticides, glyphosate, has been linked to increases in non-Hodgkin's lymphoma (22).For example, in 1996, the US National Academy of Sciences concluded that allowable pesticide residues, on US foods would cause a million premature, fatal cancers in the next 75 years (23). Other GMO effects are illustrated by deaths and disabilities caused by food-supplement DL-tryptophan, produced by a genetically engineered bacterium (24).

c) ***Allergenic potential.*** Allergenicity may be caused directly by the new proteins or by their interaction with usual proteins, producing a new allergen (16). Assessing the allergenic potential of novel foods presents major problems, since there are no reliable tests for predicting allergenicity (25). The possibility of creating new allergens has been identified as a risk that does not relate directly to the use of GM technology, but depends on the particular gene that has been added to a GM crop (10). Allergies develop when an individual is repeatedly exposed to a particular protein allergen (10).

d) ***Horizontal gene transfer (HGT)*** – the transfer of genetic material directly to a living cell or an organism followed by its expression (26). HGT has been shown to engage members of the same species, of different species, or even of different domains of life (26). In contrast to vertical gene transfer, where DNA is spread from a parent to an offspring, HGT is the transfer of DNA between cells of the same generation (26). In various ways, humans and animals have been in touch with "foreign DNA" for millions of years. In humans, the amount of DNA absorbed with food varies between 0.1 and 1 g per day and includes fragments of plant and animal genes, degraded to varying degrees, as well as bacterial DNA (27). Because diseases like Ebola, AIDS, Lyme, and mad cow appear to have moved genetically from animals to humans, it has been argued that about 20% of GMOs with engineered genes from viral pathogens might create new viral strains having unknown properties (28). HGT is considered more important in the adaptation of bacteria to new environments than the alteration of gene function through mutations (26).

e) ***Antibiotic resistance***, which can occur because of the use of antibiotics in the early stages of the process of genetic modification to select for the gene construct including resistance to antibiotics (26). Antibiotic resistance may be transferred by means of HGT from genetically modified plants to human gut bacteria due to the transformation of bacteria in the food chain (16) as well as to soil and plant-related microorganisms (26). In the gastrointestinal tract, DNA may remain stable for some time, particularly in the colon (26). However, the breakdown of DNA in the gut, combined with the breakdown of the DNA due to food processing, reduces the risk of HGT because of DNA degradation, which begins before it arrives at the critical sites for HGT (26).The HGT of an entire and functional antibiotic resistance gene from ingested GM food to the bacteria in our guts is a possibility, but has never been reported. The World Health Organization and the Food and Agricultural Organization of the United Nations expert panels have concluded that this event cannot be completely ruled out and should be considered by risk assessors (29).

2. ***Environmental risks.*** Other controversial issue in this area relates to the potential risks posed by the technical manipulation of genetic material, since the effect of such manipulation on animal welfare is still difficult to evaluate (9). Toxicity of gene products may have a negative influence on feed composition, which in its turn may cause negative performance of fed animals (16). GMO-related environmental threats also include problems like pesticide plant-and-animal toxicity (30), and this use of GM crops will require the provision of special agronomic facilities that restrict the spread of seed and pollen (8).

3. ***Threat to biodiversity.*** Convention on Biological Diversity defines biological diversity as the variability among living organisms from all sources including terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part, including diversity within species, between species, and of ecosystems (31). In the evolutionary history of species, spontaneous mutations that give rise to new allelic forms submit the organism to a period of adaptation to a new gene. The transformation of a single element reflects on the group as a whole (32). In the case of GMOs, where an exogenous gene has been inserted into a receptive organism, this network of genes is disturbed by the integration and expression of the exogenous gene (32). This disturbance modifies the orchestration of the network, resulting in the breakdown of epistatic relations, in provoking alterations in feedback mechanisms that regulate gene expression, in the occurrence of mutations by inactivating other genes, and other interactions that may turn genes in the host genome on or off (32). One example of adaptation to a new gene among transgenic plants is the genetically modified soybean. Inserting the gene CP4-EPSPS from *Agrobacterium* destroyed the harmony between gene networks and changed the metabolism and production of lignin, a substance that physically sustains the plant (32). When this genetically modified soybean is planted in soils where temperatures go over 45°C, the stem cannot withstand the heat and breaks down (32). When the integrated functioning of the genes in an organism is changed, this alteration may be more disadvantageous than advantageous, since it involves the modification of a biological model that was the result of a long evolutionary process (32). The consequence of genetic modification is an increase in the plant's genetic load, and there is an inverse correlation between the genetic load and the adaptive value, which means that GMOs tend to have less adaptability in proportion to their increased genetic load (32). The introduction of genetically modified plants into native ecosystems may also result in the flow of DNA from crops to wild relatives, which may impact on the genetic identity and integrity of wild populations and could affect local genetic diversity (10). While the possibility for gene flow exists for both non-GM and GM crops some fear that gene flow from GM crops could endanger biodiversity in a new way (8). The diversity of wild species of plants can be seen as a reflection of the process of natural selection and other evolutionary mechanisms, and genetic modification is thought to interfere with these processes (8).

However, the arguments about the GMO threat to biodiversity also cause some criticism. It has been argued that crop varieties which are used in agriculture already frequently interbreed with their wild relatives, and, given that the systematic cultivation of plants had begun by 6000 BC, humans have been influencing natural selection for a long time (8). For example, we may question whether the rhododendron, which originated in Spain and Portugal, should ever have been introduced into the UK, where it became invasive and adversely affected the environment (8). Changes in nature cannot be undertaken only if there can be absolute certainty that no risks are implied, since we do not apply this requirement consistently in other cases where human intervention affects biological and ecological systems (8).

4. ***Increase in social differences.*** It has been argued that genetic engineering policies are unfavorable for the developing countries for the following reasons:

a) ***Many innovations would remain unreachable for most of the citizens of developing countries*** even after the monopoly on patents have finished because of the differences in income when compared to the developed countries (33). Developing countries might also be reluctant to approve GM crop varieties because of fears of jeopardizing their current and future export markets, and they may also not be able to provide the necessary infrastructure to enable compliance with EU requirements for traceability and labeling (8).

b) ***Genetically engineered seeds may cause food shortages, unemployment, resistant weeds, and extinction of native cultures in the developing countries*** (1). A founding principle of natural selection is that submitting an organism to pressure will increase its probability of evolutionary adaptation – this is how bacteria developed antibiotic resistance (10). For example, a wide-scale application of herbicide-resistant crops could eventually lead to the emergence of weed varieties that resist

the particular herbicide, and target insects may become resistant to an insect-resistant GM crop through mutation and natural selection (10). The centers of diversity of modern crops such as cotton or maize are primarily in developing countries, and there are concerns that cultivated crops and their wild relatives, growing in these regions, might be irreversibly altered by the transfer of genetic material from GM crops (8). It has also been argued that current global food production is sufficient to provide food for the world's population, if only inequalities in access to food were eliminated, and GM crops are seen as a "technological fix," proposed instead of undertaking economic, political, and social changes (8). However, most cattle and poultry consume maize or soybean, and the conversion of fodder into meat and milk requires three to six times the amount of these crops than would be needed if people ate them directly (8). It has therefore been argued that providing farmers with pest- or virus-resistant crops is a more appropriate solution than the alternative of leaving them to rely on food donations if their harvest is destroyed by pests or viruses (8).

c) ***Labor costs would be decreased by letting farmers use more chemicals, since 80% of commercial GM seeds are designed only to resist herbicides*** (1). Using GM crops could be to the detriment of agricultural workers if the use of herbicide-resistant GM crops leads to a considerable reduction in the demand for labor for weeding (8). However, the use of genetically modified crops that reduce labor could help rural communities lacking labor force as a result of the AIDS pandemic (8). In Kenya, for example, the losses in agricultural production from AIDS at household level range 10–50%, and shortage of farm laborers means that children are increasingly involved in agriculture, impacting their education and quality of life (8). It has also been argued that encouraging developing countries to adopt GM crops demonstrates a lack of sensitivity to their vulnerable position, as they may be tempted to adopt in haste a technology that could pose severe risks (8).

d) ***Focusing on GM-related applications may detract from efforts to explore other ways of enhancing agriculture***, such as fostering more relevant national and international policies, improving systems of seed production and distribution, and promoting better development of markets and improved agricultural practices (8).

For all the above-mentioned reasons, before introducing GMOs into developing countries, policy makers and scientists should consider whether the distribution of benefits and burdens between rich and poor countries is affected and whether these effects differ between production and use (34). For example, Sweden has a special rule that with every proposed use of GMOs ethical evaluation must be performed (35). Every GMO application should bring sufficient benefit for humankind, and not just a benefit, and besides that animals should not be exposed to unnecessary suffering (35). It should also be taken into consideration whether the proposed method of GMO application means that other harmful applications, which would be used instead, can be avoided (35).

5. ***Scientific concerns***, which include inadequate genetically modified seed (GES) testing, driven partly by companies' unwillingness to share proprietary information as well as GES research priorities (1). GES biotechnology has been mostly used for profitable but risky pesticide-resistant products instead of increasing drought tolerance or increasing yields (1). For example, by 1999, 12 companies, many with the US Department of Agriculture funding, had more than 25 patents to make GES either sterile or chemically dependent, while annually a million children die from nutritional deficiencies and another 350 000 become blind from vitamin A deficiencies (1).

6. ***Potential threat to the autonomy and welfare of farmers who wish to produce non-GM products***. The risk of gene flow from fields planted with GM crops to conventional and organic farms could potentially pose a threat to autonomy of organic farmers (10). For example, a field study conducted in Australia examined the transmission of herbicide tolerance from GM canola and found that the highest level of contamination in neighboring fields was 0.07% (36). This contamination level is well below the 0.9% threshold set by the EU as the limit above which labeling is required (36). However, organic farmers have established a zero-tolerance rule for GM and their autonomy could be compromised if cooperation is not established within farming communities (36). The question of respect of farmers' autonomy also raises the issue of liability in cases where compensations may be sought (10).

Suggested ways to tackle or avoid the GMO-related risks

It has been argued that from the available experimental data, currently utilized GM plants appear safe and show no effects on animals or animal products (16). It has also been stated that risks caused by the

use of GM plants appear to be so low that they should be negligible in comparison with their potential benefits (16). However, long-term risks for most conventional foods have never been analyzed (8). GM crops are novel foods, and the assessment of their safety is essential to protect the environment, as well as the health of humans and livestock (16). It is also important to try to tackle the risks related to the application of GMOs. The following proposals have been made:

The risk of unexpected gene interactions could be tackled as follows: to predict gene interactions, the insertion of a gene coupled with a promoter into a GMO chromosome could trigger the expression of a neighboring gene for a toxin or allergen that was previously present but not expressed (25).

The risk of allergenicity could be tackled by assessing the stability of the novel protein(s) to the processing of food and to digestive processes, since many allergenic proteins are resistant to degradation (25). It is also advisable to avoid using plants containing known allergens, such as peanuts and Brazil nuts, as sources of genes for GM plants (25).

The risk of HGT in the organisms fed with GM could be tackled by using kanamycin, an unusual antibiotic as antimicrobial resistance marker (16). However, antibiotic marker genes should be excised after the initial multiplication step, according to the measure endorsed by EU since 2005 (EU directive 2001/18) (37). It has been estimated that the likelihood of transfer of DNA from ingested food by gut microflora and/or human cells is minimal (37) and thus the likelihood that a GMO's gene construct resistant to antibiotics may be transferred to gut bacteria is also small (16). It has been stated that after consumption, DNA and DNA fragments are rapidly degraded by gastric acid and various enzymes in the digestive tract, but this process may leave some fragment intact, which may be absorbed in the intestinal epithelia (27).

Perturbation of the long-established systems caused by genetic manipulation could be tackled by manipulation techniques, which involve precise and predictable manipulations, with minimum perturbation of the long-established systems (32). One of these new techniques of DNA insertion is called transposon movement – it allows plants to relocate their DNA, reducing the disruption caused by genetic manipulation (32).

Extinction of native cultures could be avoided by preventing the seeds of GM varieties from food aid donations from being planted in the soil of countries objecting to introducing GM crops into their territory (8, 10). This could be achieved by providing food aid in milled form (8, 10). The establishment and maintenance of ***seed banks to conserve genetic resources of crop plants*** is also important (8).

Pollen-mediated transmission of transgenes could be avoided by establishing appropriate separation distances between fields containing GM and non-GM crops (8). Also, many GM crops are male sterile varieties which means that pollination cannot occur (38). There are farming practices that can be deployed to minimize what has been referred to as "genetic contamination" (10).

It has been argued that thanks to scientific research, a better understanding of technologies and to recent provisions, most of the parties participating in the discussion on GMOs agree on the fact that foodstuffs and ingredients originating from the current GM crops do not seem to pose a hazard to public health (7). According to the judgment of the Nuffield Council of Bioethics, there is no empirical or theoretical evidence that GM crops pose greater hazards to health than plants resulting from conventional plant breeding (8). The Nuffield Council of Bioethics has argued that the potential benefits of contemporary plant breeding, including those arising from the use of genetic modification of crops, have been empirically demonstrated in some instances, and have considerable potential in others, to improve agricultural practice and the livelihood of poor people in developing countries while reducing environmental degradation (8). According to this Council, there is an ethical obligation to explore these benefits responsibly, in order to improve food security, profitable agriculture, and the protection of the environment in developing countries (8).

It has been argued that there is currently not enough evidence of actual or potential harm to justify a moratorium on research, field trials, or the controlled release of GM crops into the environment (10). Research on the use of GM crops in developing countries should therefore be sustained and governed by a reasonable application of the precautionary approach (10), and the views of farmers and other relevant stakeholders must also be taken into account (8). It is equally important that governments and citizens of developing nations are involved in the decision-making process on the use of GM crops in their countries (10).

If the technique of genetic modification is deemed acceptable in principle, then more specific moral questions arise. How should GM technologies be used? What sorts of organisms should be developed, for what purposes, and how should they be used?

International and European positions regarding the application of GMOs

International requirements regarding the usage of GMOs. The concerns about the evaluation of the risk-benefit balance are reflected in the requirements of the international documents on biosafety and biodiversity. Articles 16(5a) and 23 of the Protocol of Cartagena on Biosafety require that states parties to the Protocol should:

- Cooperate in identifying living modified organisms or their specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;
- Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of such living modified organisms;
- Consult the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public (39).

Articles 14(1a) and 19 of the Convention on Biological Diversity also require that as far as possible and appropriate, contracting parties shall introduce environmental impact assessment of proposed projects that are likely to have significant adverse effects on biological diversity and, where appropriate, allow for public participation in such procedures (31). Moreover, contracting parties should:

- Take legislative, administrative or policy measures to provide effective participation in biotechnological research (especially in developing countries, which provide the genetic resources for such research);
- Take all practicable measures to promote and advance priority access on a fair and equitable basis (especially for developing countries) to the results and benefits of biotechnologies (31).

Position of the European Community regarding the usage of GMOs. The current EU legislation on GMOs is regarded as the strictest in the world (8). Genetically modified plants are widely grown all over the world, but many constraints still tend to discourage their use in Europe considering potential risks of their use (16). European legislation does not allow unapproved material derived from a GMO in the human food chain and increased monitoring capacity is required of all countries, especially with the adoption of the Cartagena Protocol on Biosafety, as international law (40). The European Community has not yet authorized production of genetically modified crops, excluding experimental ones. In the European legal framework for GMOs and genetically modified micro-organisms (GMMs) the primary goals are the safeguard of human and animal health as well as the environment (7). Table presents this European position.

It has been argued that policies with the aim to awaken public opinion and the media towards understanding of the biotechnological progress and limit emotional responses. The social community should take part to the decision processes and it ought to share responsibility (9). The gap between institutional and/or academic knowledge and the social community should be removed. Correct, transparent, and accessible knowledge and information are needed to make responsible choices and keep the debate out of generalized schemes, which are due to inadequate information and prejudiced viewpoints. Aside from delays in disseminating necessary and dutiful information, there is just as much danger due to anxiety about the use of transgenic food and organisms. This anxiety, based on not yet scientifically proven grounds, might induce the political world to take excessive and arbitrary measures (9).

Public attitudes towards GMOs in Europe

Eurobarometer polls conducted in the twenty-five Member States of the European Union by way of face-to-face interviews in peoples' homes in their national language between September 2 and October 6, 2005, indicate that more than 40% of people think that their health could be damaged by the food they eat or by other consumer goods (46). However, the spontaneous association of food with health is only made by one person in five (46). There are as many Europeans who spontaneously cite GMOs and food additives as possible sources of risk as there are of people who consider food to be safe (46).

In this Eurobarometer study, respondents were asked what worried them most regarding food, and GMOs were mentioned only in the mid-range of the "worry" scale. At the top end of the "worry" scale, consumers express concern regarding external factors that are clearly identified as dangerous (pesticides residues, new viruses such as avian influenza, residues in meats, contamination of food by bacteria, unhygienic conditions outside home), and in the mid-range, one finds other external factors such as environmental pollutants (e.g. mercury), GMOs, food additives, animal welfare and "mad cow disease" or BSE (bovine spongiform encephalopathy) (46). Consumers appear to be less concerned about personal factors (such as individual susceptibility to food allergies) or other factors linked to their own behavior (e.g. food preparation, food hygiene at home and putting on weight) (46). When asked to what extent they were worried

Table. **European position on genetically modified organisms (GMOs) and genetically modifiedmicroorganisms**

Requirement	Document
All appropriate measures must be taken to avoid adverse effects on human health and the environment which might arise from the contained use of GMMs (3) and their deliberate release or the placing on the market of GMOs (2). Potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, must be accurately assessed on a case-by-case basis (2).	***Directive 98/81/EC*** (amending directive 90/219/EEC) Art. 5(1) (3) ***Directive 2001/18/EC*** (repealing directive 90/220/EEC) Art. 4(1,3) (2)
GMOs containing genes expressing resistance to antibiotics in use for medical or veterinary treatment must be taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment (2).	***Directive 2001/18/EC*** (repealing directive 90/220/EEC) Art. 4 (2) (2)
Food /feed must not: (a) have adverse effects on human health, animal health or the environment; (b) mislead the consumer /the user, and in case of feed – harm or mislead the consumer by impairing the distinctive features of the animal products; (c) differ from the food/feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer (in case of feed – for animals or humans) (41).	***Regulation 1829/2003 (EC)*** Articles 4 and 16 (41)
Member States shall: a) consult the public on the proposed deliberate release of GMOs; b) make available to the public information on releases of GMOs in their territory (2) or on unintended transboundary movement of GMOs (42).	***Directive 2001/18/EC*** (repealing directive 90/220/EEC) Art.9(1,2) (2) ***Regulation 1946/2003 (EC)*** Art. 14 (42)
The labeling shall clearly state that a GMO is present (2, 41). In case such product is placed on market, the unique identifier(s) assigned to those GMOs must also be stated (42, 43) Requirement does not apply to products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing (42). These uses must be clearly indicated on the product (as well as that it is not intended for deliberate release into the environment) and contact details for further information must be given (42). The unique identifier for each GMO must be recorded in the Commission registers (44) thus enabling their traceability. Consumers have a right to make informed choices about what they eat, and receive a clear indication of where additional information can be obtained (*e.g.* from databases, free telephone help lines, information networks), especially when their choices include cultural (45) ethical or religious considerations (41, 45) and in cases where the food differs from its conventional counterpart in nutritional value, composition, use, or health implications (41). Labeling is appropriate when modern biotechnology causes a substantial change in composition, nutritional value or the use for which the food is intended. Information should be: a) useful, adequate and informative; b) clear, understandable, non technical; c) honest, not confusing, and aiming to prevent fraud; d) enforceable, *i.e.* possible to verify (45).	***Directive 2001/18/EC*** (repealing directive 90/220/EEC) Art. 19(3e) (2) ***Regulation 1830/2003 (EC)*** Art. 4(1b) (43) ***Regulation 1946/2003 (EC)*** Art. 12 (42) ***Regulation 65/2004 (EC)*** Art. 4 (44) ***European Group on Ethics in Science and New Technologies.*** Opinion n° 5 05/05/1995. Ethical aspects of the labeling of foods derived from modern biotechnology (45) ***Regulation 1829/2003 (EC)*** Articles 4, 13 and 16 (41)
For products where adventitious or technically unavoidable traces of authorized GMOs cannot be excluded, a minimum threshold may be established below which these products shall not have to be labeled. (2) Art. 21(2) (2)	***Directive 2001/18/EC*** (repealing directive 90/220/EEC)

about genetically modified productsin food or drinks, 25% of EU citizens answered "very worried" and 37% answered "fairly worried" (46). The survey shows that consumer groups, physicians, and scientists are the most trusted sources when it comes to providing information about food risks (46). Public authorities are also trusted in this regard (46). However, media generate a fairly low level of trust, and manufacturers, farmers and retailers are cited as being amongst the least trusted sources (46).

Citizens were also asked whether they would approve of developing genetically modified crops in

order to increase the variety of regionally grown food. Less that half (37%) declared that they would never approve of this while 31% would approve of this provided it was highly regulated and controlled (46). The national results show that in six of the countries surveyed a majority responded "never": Croatia (60%), Switzerland (58%), Cyprus (56%), Greece (54%), Slovenia (53%), and France (52%) (47). Looking at the environment, a comparatively low proportion of EU citizens (19%) declare that they would "never" approve of developing genetically modified bacteria that could clean up the environment after environmental catastrophes (47). An equal proportion, 20%, responds that they would approve of this "in all circumstances" while 37% say that they would approve of this "only if it is highly regulated and controlled" (47). Respondents who believe that we have a right to exploit nature for the sake of human well-being are more inclined to state that they would approve of developing genetically modified crops to increase the variety of regionally grown food "in all circumstances" or "only if it is highly regulated and controlled" compared to those who, on the contrary, disagree with this statement (47).

Surveys have also been conducted at the national levels. For example, the survey administered by the Irish Council of Bioethics (analyzing 560 replies) shows that the respondents are greatly opposed to the introduction of GM crops and are largely of the view that GM foods currently on sale are not safe for human consumption (10). Concerns were also expressed about the unknown future implications of GM technology. Some respondents noted that all testing should be independent and the results published. Many also expressed concerns that organic farming would be undermined as a consequence of crop contamination from GM crops grown nearby. Several respondents urged support for an organic farming industry as an alternative to GM crops. Calls were also made for a debate on the topic of GM crops/foods and a suggestion was made that an information pamphlet should go to all households to be able to make a fully informed choice (10).

Conclusions

It has been argued that biotechnology as such is neither good nor bad, and it has the potential to alleviate or aggravate the impact of agriculture on the environment, to improve human and animal nutrition or to pose danger to human or animal health (48). The challenge is thus to develop, supply, and manage biotechnology for the benefit of humankind and the environment (48). The following suggestions have been proposed to tackle this challenge:

1. It is important that countries have appropriate mechanisms to determine whether it is desirable to introduce any new genetically modified crop into the environment, and to monitor its impact (8). In most developing countries, it will be a major financial challenge to provide the capacity and resources to undertake such evaluations; therefore, particular attention should be given to measures that will enable the sharing of methodologies and results, e.g. environmental risk assessments for countries, which have similar ecological environments (8).

2. It is important to monitor the food chain and promote labeling of genetically engineered food, as required by the European Directive 2001/18/EC. Monitoring is important for the following reasons:
   a) For detection and elimination of organisms or genes of potential threat and for prevention of environmental harm;
   b) For achieving detection limits relevant to the proportion of contamination that might cause harm;
   c) For maintenance of public confidence in science, since confident public often means supporting public, and accountable and transparent science creates public confidence and support (40).

3. Although it is difficult to determine how much GMO is enough to cause harm, GMO monitoring must be focused on both – detecting signs of unknown or undesirable organisms and genes and on monitoring known but prohibited commercial GMOs (40).

4. It is important to maintain a system of rewards that encourages invention while at the same time providing more people with the benefits of innovations (33). It has been suggested that genetically engineered seed patent-holders could:
   a) Develop and donate biotechnologies for third world use as well as sell genetically modified seed-related herbicides there at lower price;
   b) Help train third world scientists and attorneys in biotechnology, public health, and intellectual property;
   c) Have limited "use rights" (not exclusive patent rights) to genetically modified seeds;
   d) Share profits from special varieties of genetically modified seeds (such as basmati rice or jasmine rice) with their countries of origin;
   e) Compensate stakeholders for genetically modified seed-related harms, especially in developing nations (1).

5. Interdisciplinary approach is necessary in this field of research. Such approach would help defend environmental safety, preserve genetic resources as well as agricultural and alimentary traditions and respect the human rights (9).

6. The use and application of innovative technology should be subject to social and economic rationalization through the balance cost-benefit principle as well as ethical screening to prevent damage to the environment and all living beings (9). However, it is usually scientists and scientific facts that dominate the societal debates about agricultural biotechnology, and in order to deal with the ethical issues of this technology, these societal debates need to be broadened, and as the technology has societal impacts, lay perspectives need to be taken into account (49).

9. Safety measures and monitoring should have their foundations not in ideological reasoning, but on a firm scientific basis, because emotional and pessimistic approaches towards innovative technologies can induce us to miss important opportunities, modify the evaluation of real risks, and thus prevent efficient measures against current risks (9). Every restriction should therefore be proportional to the real risk (9).

10. A possibility should not be underestimated that in some cases the use of a GM crop variety may pose fewer risks than are implied by non-GM alternatives (8). Therefore, in applying the precautionary approach, risks implied by the option of inaction (or by alternative actions) must also be considered (8). It is important to focus on the specific situations in particular countries and to ask the question how the use of a GM crop compares to other alternatives. In order to improve human health, nutrition and the ability to afford an adequate diet in a cost-effective and environmentally sustainable way, all possible paths of action must be compared, including inaction (8). It could mean that GM crops might have attractive benefits in particular cases (8). Cost-benefit analysis could be supplemented with developing a precautionary approach that could recognize the multidimensional nature of environmental qualities and risks, such as irreplaceability, irreversibility, uncertainty, and complexity (50).

It is difficult to argue that using our knowledge of genetics to improve natural resources with GM technology is immoral, while selective breeding, which may equally be guided by genetic knowledge and aimed at results that would never occur without human intervention, is not (10). However, it must also be recognized that GM technology offers more choice than selecting genetic modifications through conventional breeding practices. This calls for an ethical examination of the goals sought out through GM technology, as well as of its potential consequences (10). However, as long as the individual autonomy of consumers and farmers is protected through adequate labeling and coexistence strategies, and a real choice provided for all parties, the potential benefits of GM crop technology can be made accessible to those who wish to avail of them (10).

Genetiškai modifikuoti organizmai. Ar nauda nusveria riziką?

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Raktažodžiai: genetiškai modifikuoti organizmai, rizika ir nauda, tarptautiniai ir Europos teisiniai bei etiniai reikalavimai.

Santrauka. Šios literatūros apžvalgos *tikslas* – išanalizuoti genetiškai modifikuotų organizmų vartojimo padarinius, taip pat tarptautinę bei Europos poziciją šių organizmų vartojimo atžvilgiu.

Metodai. Tarptautinių ir Europos teisinių bei etinių reikalavimų, taip pat aktualių publikacijų, rastų „PubMed“ bei Lundo universiteto bibliotekos duomenų bazėse, apžvalga.

Rezultatai. Straipsnyje aptariamos pagrindinės genetiškai modifikuotų organizmų pritaikymo sferos, genetiškai modifikuotų organizmų panaudojimo plėtra pasaulyje, taip pat teigiami bei neigiami genetiškai modifikuotų organizmų vartojimo padariniai. Taip pat apžvelgiami rekomenduojami būdai siekiant sumažinti genetiškai modifikuotų organizmų vartojimo padarinių riziką ar užkirsti jai kelią. Aptariama ir tarptautinė bei Europos pozicija genetiškai modifikuotų organizmų pritaikymo klausimu, pateikiama Europos direktyvų, nurodymų bei etinių gairių apžvalga. Straipsnyje pateikiama ir Europos visuomenės nuomonė genetiškai modifikuotų organizmų vartojimo atžvilgiu bei nacionalinio lygio nuomonių vertinimų apžvalgos.

Išvados. Pateikiami rekomenduotini būdai plėtoti biotechnologiją ir reguliuoti jos pritaikymą taip, kad ji teiktų naudą tiek visuomenės sveikatai, tiek ir aplinkai.

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