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Scientific Debate on Genetically Modified Organisms in the Food Chain

by
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Abstract. The issue of genetically modified organisms generated a wide range of views, more or less extreme: on the one hand are those who say that we are dealing with what is undoubtedly the most important and promising agricultural technology of the moment, on the other hand are those who argue that genetic modification has been released into the environment and handled with almost no risk assessments.
Without a doubt, the usage of GMOs has been in the center of political, economic and social debates both in Europe and around the globe, because GMO products have entered all the parts of the public food supply.
The introduction of new, modified, transformed products on the market involved legislative changes designed to ensure product safety and coding of correct information for consumers, toxicological studies on the potential risks to public health, nutritional assessments.
Another point of disagreement is consumer information and the effects of GMOs on human health. In theory, gene transfer is done either to increase resistance to various harmful factors or to increase productivity, but there was no scientific consensus on health issues.
The European Union regulates the traceability and labeling of GM products so the choice to consume such products belongs to the consumer. But the regulations do not apply to products derived from animals fed with genetically modified feed or treated with genetically modified medicinal products, as these are exempted from the requirements for approval and labeling. Therefore, there are such products of animal origin (milk, eggs, meat) that enter the food chain without public knowledge.

Key words: ethics, food product, GMO, legislation, protection of consumer
JEL classification: K29, O33, Q55

1 Introduction

The evolution of the concept of food product began in the 1940s, with intensive use of pesticides and food additives.
Enrichment of food products in some of their natural components, as well as reducing some components from their content, is another step to extend this concept, which made the transition to the idea of new food product. The challenge launched, new concepts have emerged, succeeding as follows in Figure 1.

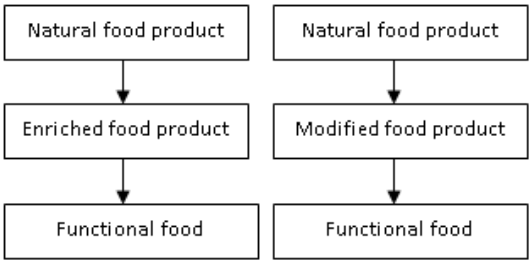

Figure 1. Evolution of foods

Gradually, from "natural food product" emerged "modified food product" or food product that contains modified ingredients; from the "natural source" of the food to "genetically modified source".

Pros & Cons of GMO Foods

Selection and use of raw material resources relates to their superior capitalization and the opportunities for improvement are quantitative and qualitative, but also cover new directions for use.
Traditional food resources are subject to a priority concern, yet at the same time, new unconventional resources are identified, collected, or reproduced, their biological, technological and commodity potential rapidly explored. These "new sources" also include genetically modified organisms (GMOs) and are used on an increasingly large scale, by selection and association, in order to increase and diversify food products.

At the present, an analysis of food supply according to the compositional nature of the raw materials, the basic types of raw materials incorporated, shows movements that occurred over time, but also the coexistence of some types of food: organic food, traditional food, natural foods, conventional foods, unconventional foods, foods with synthetic constituents and genetically modified food.

One controversial issue remains the ratio between them, from a quantitative and structural- assortment point of view.

Solving this problem depends, to a decisive extent, on highlighting the health impact of new products, on studying their hygienic value, on rethinking the notion of innocuity, involving restrictions in the use of certain raw materials and (bio) technology.

Biotechnology opens new horizons and multiple opportunities for the food industry.

GM products are obtained by direct external intervention on DNA to obtain organisms with improved characteristics, through the technology known as genetic engineering; new varieties can be done in less time and greater diversity.

The respective organisms are modified using DNA recombinant technology (Thompson, 2011), which allows individual genes to be transferred from one organism to another, either from the same species or different species (Mann, Truswell, 2002). This procedure is not done by mating or conventional genetic recombination (Eastwood, 2003).

GMOs first appeared in the 1960s, in agriculture, and their creation was met with skepticism; but areas cultivated with GMOs registered an explosive growth in recent years, particularly in the U.S.A. and South America. However, European countries have been more reluctant to the issue of GMOs, positioning themselves against cultivation and even imports of such organisms.

In agriculture, genetic engineering is used for:

- Increasing resistance to herbicides and pesticides in plants (soybean, corn and potatoes);
- Increasing the nutritional value of plants (genetically modified soybean and canola containing increased levels of monounsaturated fatty acids (Thompson, 2011), genetically modified rapeseed oil high in vitamin A, reduced saturated fat content in oilseeds (Eastwood, 2003), rice with increased content of beta-carotene, peanut with low levels of allergens (Mann, Truswell, 2002), potatoes that absorb less oil during frying (Mann, Truswell, 2002) etc.);
- Increased salt tolerance as to allow GM crops to be grown in soils rich in sodium. Also, GM plants extract salt from the soil making it suitable for common crops (Thompson, 2011);
- The introduction of growth hormones (bovine somatotrophin) to increase milk production in cattle (Eastwood, 2003);
- Modifying fruits to contain vaccines (Eastwood, 2003);
- Turning off certain genes, e.g. the gene that controls fruit softening can be disabled for tomatoes used in tomato paste to maintain a high pulp content (Mann, Truswell, 2002);
- The use of hormones to improve the nutritional quality of pig meat.

These are just some examples of possible transformations as in practice the potential transformations can be far more numerous.

Despite all these advantages, there is a strong current of opinion against genetically modified organisms, especially in Europe (Denault, 2007).

Consumer reluctance regarding consumption of GM food can be observed in the results of a study: if they had information on the origin of their food printed on food labels, 57% of U.S. consumers and 82% of Germans and 78% of the French said that they would be "less likely to buy products containing genetically modified organisms" (Phillips , 2000).

Thus, while in the European Union, in order for genetically modified organisms to be approved many tests, analysis and compliance with special labeling are required, in the U.S. the system for approval of GM food is based on a principle that if a new food can be found that is equivalent in composition to an existing food then this one is assumed to be safe for

consumption. This approach focuses on the finished products rather than the production process (Denault, 2007).

The future development of genetically modified organisms will probably continue to come up against consumers' reluctance regarding the intervention of technology in products for human consumption. Among objections already expressed is the need to know the long term effects of GMOs on plants, insects and animals they eat or use them as habitat.

Despite the consumers' reluctance, statistical data on production of genetically modified organisms in the world shows that the cultivated areas are increasing.

According to the 2010 annual report of the non-profit organization ISAAA (International Service for the Acquisition of Agri-Biotech Applications) on the production of GM crops worldwide, there were 25 countries in the world where GM plants were sold in 2009, their number increasing in 2010 to 29, while 14 million farmers were working with GM plants at world level.

Developing crops with GM plants in Europe has evolved contrary to the rest of the world.

Thus, in 2009 the area cultivated with genetically modified Bt maize (MON810, GM maize variety that produces a toxin against an pest insects) decreased by 15,000 ha from 2008, reaching 94,000 ha in France and Germany due to the adoption of a decision prohibiting the cultivation of this variety. In Spain, the largest European cultivator of genetically modified corn, the area has decreased slightly, a trend also observed in Slovakia and Romania.

Romania also had a harp increasingly in the surface cultivated MON810 maize in 2007 but after joining the EU the area diminished constantly.

The areas planted by Romanian farmers with genetically modified maize MON810 in 2009, represented only 0.15% of the total area cultivated with maize in Romania (2.3 – 2.6 million ha), because the legislation authorizing the GMO is done for all EU countries and for a limited period.

Therefore, in the EU, only MON810 maize produced by US giant Monsanto remained cultivable today. And this on a tiny area of only 132 000 ha in 2012, which represented 0.07% of EU agricultural area. States are cultivating MON 810: Spain (116 000 ha), Portugal (9000 ha) and several hundred hectares in Slovakia, Romania and the Czech Republic.

Restrictive policy of the EU in the field has led many companies specializing in biotechnology to withdraw its interests in Europe, a good example being the German company Bayer.

Although hardly cultivate GMOs, European countries import huge amounts of transgenic agricultural commodities. According to some organizations, EU imports are not less than 51 GMO: corn, cotton, sugar beet, potatoes and especially, soybeans. A greater paradox is that there is no EU statistical of national expenditure on imports of GMOs.

Based on a new draft Directive in Luxembourg on 12 June 2014, EU Member States are left free to decide whether the cultivation of GMOs authorized in advance by the EC is permitted. In these conditions, there are states that can accept GM crops, Romania case, for example, or to impose interdictions (France, Hungary, Austria) but in conditions to reach to legal disputes with the regulations of Organization World Trade. At the gate of Brussels there are applications for authorization of GMO crops; a favorable opinion will get the TC 1507 maize produced by DuPont Pioneer, for example.

Unlike the first generation of genetically modified organisms, where the focus was on insect resistance and herbicide tolerance, the next generation (which has already started to be used in the U.S.) allows the development of selected features of the organism. Currently, genetic modifications are becoming increasingly sophisticated, allowing for changes in the food quality and nutritional value (Eastwood, 2003). Future generations of genetically modified organisms will be used to produce genetic material with uses in medicine, pharmaceuticals and nutrition (Vaclavik , 2009).

A future development that must be considered is the fact that requirements regarding food products will increase, approaching those for pharmaceuticals, at least in terms of scale of the information related to the specific usage value,

of the methods of storage and use, for the simple reason that the question of dose and the way of administering is equally valid in both cases.

In these circumstances it can be concluded that the emergence and development of substitute foods on the market, parallel to the natural products they replace, are designed to enrich the variety of food products, to satisfy the increasingly diverse needs of consumers, thereby adding new values to the food industry.

Legal implications on the use of genetically modified organisms in the food chain

Considering the perspective that changes the conception of food, several issues were raised about the safety and protection of the consumers, as well as about providing them with accurate information about the products they buy. On the other hand, producers of genetically modified organisms are trying to protect their "professional secret".

We consider that this situation can be solved only by adapting the legislation to the socio-economic reality, by introducing a stricter control on production and marketing of products containing genetically modified organisms along the entire food chain. The food chain generally covers all participants and processes involved in food production, from primary producers (farmers), processors (food factories), merchants (companies and supply chains) to the final consumer. The quality and safety of novel foods is based on the efforts of all those involved in the food chain, involving agricultural production, processing, transportation and consumption.

The possibility of such products entering the market of should alert the authorities in charge of consumer protection, since the issue regards new plants and substances, results of laboratory research, whose effects on human health must be well tested.

Obtaining, testing, using and marketing of genetically modified organisms - plants, animals or microorganisms - are subject, in all countries, to a special regime of regulation, licensing and management, which establishes legal and institutional framework designed to eliminate or reduce risks of producing negative effects on human and animal health or the environment.

In the U.S.A., the introduction in the environment and on the market of transgenic plants is done only after obtaining special approvals from government agencies responsible for environmental protection and human and animal health: The U.S. Department of Agriculture (USDA), The Environmental Protection Agency (EPA), The Food and Drug Administration (FDA).

In the U.S.A., Canada and other countries, transgenic plants are grown and used in human and animal nutrition, the separate storage and labeling of products containing GMOs not being mandatory.

In the European Union, beginning in 1990, specific legislation was developed, which was later improved and expanded, aiming to protect the environment and human health and create a single market in the field of biotechnology. Table 1 shows the evolution of the legislation concerning GMOs beginning on 1990.

Table 1. Legislation regarding GMOs in the European Union

Regulation	Modifications	Regulated topic
EEC Council Directive no.219/1990 of 23 April 1990	amended by Directive no.81/1998	The contained use of genetically modified micro-organisms, for research and industrialization purposes.
EEC Council Directive no.220/1990 of 23 April 1990	completed by several Commission decisions (623, 811, 812, and 813/2003)	The deliberate release into the environment of genetically modified organisms
Regulation (EC) no.258/1997 of the European Parliament and of the Council of 27 January 1997		Initially governed the introduction on the Community market of novel foods and novel food ingredients. Among the categories of novel foods covered by this Regulation are: a) food and food ingredients containing or consisting of GMOs under Directive 90/220/EEC; b) food and food ingredients produced from GMOs but not containing such organisms;
Council Regulation (EC) no.1139/1998 of 26 May 1998		Introduced a compulsory food labelling model for food products derived from GMOs.
Commission Regulation (EC) No 49/2000 of 10 January 2000 (also called "the threshold regulation")	amended Council Regulation (EC) no.1139/1998	Addressed the issue of accidental contamination and made mandatory the labelling of GM food whose GM content reached more than 1%, at ingredient level. To strengthen the accidental character of GMOs presence, operators also had the obligation to present evidence of adopting measures to avoid contamination.
EC Directive no.18/2001 of the European Parliament and of the Council of 12 March 2001	Repealed EEC Council Directive no.220/1990	The deliberate release into the environment of genetically modified organisms; updating and strengthening existing regulations regarding risk assessment and decision-making process of introduction into the environment of GMOs. It also introduces the obligations to inform the public, to monitor long-term effects, to label and trace genetically modified organisms at all stages of their marketing.
Regulation no.1829/2003 of the European Parliament and the Council of 22 September 2003 on GM food and feed		The objective of this Regulation is to: a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market; (b) lay down Community procedures for the authorization and supervision of genetically modified food and feed; (c) lay down provisions for the labelling of genetically modified food and feed.
Regulation no.1830/2003 of the European Parliament and the Council of 22 September 2003 concerning the traceability and labelling of GMOs and traceability of foodstuffs for food and feed produced from GMOs and amending Directive 2001/18/EC	amending Directive 2001/18/EC	This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.

Gradually, the adoption of legislation that was comprehensive, unified and updated was needed.

Thus, since October 2003, Regulation no. 258/1997 was no longer applied to GMOs, since the need for legislation specifically designed for this problem was imposed.

Two new regulations were issued, amending or replacing the existing legislation in this field:

- **Regulation no.1829/2003** of the European Parliament and the Council of 22 September 2003 on GM food and feed;
- **Regulation no.1830/2003** of the European Parliament and the Council of 22 September 2003 concerning the traceability and labeling of GMOs and traceability of foodstuffs for food and feed produced from GMOs and amending Directive 2001/18/EC.

The main change was the transfer of responsibilities from specialized national authorities to the European Food Safety Authority.

The two regulations introduced, as main elements, rules for labeling, traceability and authorization of transformation processes for marketing.

Regulation no.1829/2003 and Regulation no.1830/2003:

- establish a harmonized EU system for tracing genetically modified organisms,
- introduce labeling of genetically modified feed,
- establish a continuous procedure for introducing into the environment or authorizing, as food or feed, of genetically modified organisms,
- and
- strengthen labeling regulations for GM food, setting a new threshold, which entails mandatory labeling of GM content which, at the ingredient level, exceeds 0.9%.

In terms of labeling, without prejudice to other requirements of Community legislation on food labeling, foods with GM contents of more than 0.9%, at ingredient level, are subject to special labeling requirements detailed in Article 13 (1) Regulation no.1829/2003 and Article 4.B of Regulation no.1830/2003.

Just as intensive are the international concerns for constantly updating the legislation in the field. Starting with the main purpose to implement the Joint FAO/WHO Food Standards Programme, to protect the health of consumers and to ensure fair practices in the food trade, the Codex Alimentarius Commission adopted, in 2003, ***Principles and Guidelines on foods derived from biotechnology.*** These are primary principles on the risk analysis of foods derived from modern biotechnology and guidelines for food safety evaluation of foods derived by various modified and combined plants and microorganisms DNA, hoping that this compact format "*will allow a wide use and encourage the governments, regulatory authorities, food industries, all food handlers and consumers to use with confidence". (FAO, 2003)*

In many cases in order to manage the risks associated with foods the information gathered along their history of use was required. Risk analysis has been used since many years to address chemical hazards (traces of pesticides, heavy metals or other contaminants, additives etc.), nowadays being more and more used to address also microbiological hazards and nutritional factors. **These principles were not designed for all categories of foods. As such, t**hese documents do not into consideration the food for animals or the food processed from the animals fed with it. Accordingly, *risk assessment requires a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present. Also, it should include a comparison between modern biotechnology based food and its conventional correspondent, focusing on identification of their similarities and differences. If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be documented to determine its impact upon the human health.*

Scientific data for risk assessment are generally obtained from a variety of sources, such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties and should

be assessed using appropriate science-based risk assessment methods. Risk assessment should take into account all available scientific data and information derived from different testing procedures, provided that the procedures are scientifically sound and the parameters being measured are comparable.

Risk management measures for foods derived from modern biotechnology should be proportional to the risk and based on the outcome of the risk assessment.

Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods, reference materials and tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified.

Ethical controversies on the use of genetically modified organisms in the food chain

Faced with the avalanche of GM products, specialists from various fields of expertise studied this issue:

- toxicologists - to evaluate potential health risks to consumers;
- legislators - to ensure product safety through proper labeling and traceability;
- manufacturers as producing these products involves significant technological changes;
- traders who need to rethink the assortment structure and adjust exposure areas;
- consumers that request to be properly informed and protected.

The development of GMOs has led to debates about the **environmental impact** and in relation to **food safety**, especially considering allergens, the toxicity and possible transfer of antibiotic resistance.

Food safety, the environment and GMOs are linked in the minds of consumers who, through their purchasing, will play a pivotal role in influencing decisions regarding the future of this technology. A number of consumers' concerns can be classified according to the following issues:

- The foundation of consumers' concern about GMOs is **food safety**. Because of experiences with non- GMO food problems such as allergens, pesticide residues, microbiological contaminants and, most recently, bovine spongiform encephalopathy ("mad cow" disease), consumers are sometimes worried about the safety of foods produced with new technologies.
- The potential of GMOs to perturb the balance of nature and ***environmental impact*** is another concern of the public. GMOs are "novel" products which, when released, may cause ecosystems to adjust, perhaps in unintended ways; a pre-launch testing of GMOs is considered appropriate as well as a post-release monitoring to protect ecosystems.
- In forming their views about GMOs, consumers weigh the ***perceived benefits*** of accepting a new technology against the ***perceived risks***. It is said that consumers take the risks while the producers (or the suppliers or companies) reap the benefits. The science-based methods used to assess risks, together with their relationships with risk management and risk communication must be carefully analyzed and stated.
- ***Transparency.*** This begins with rules for ***the transparent sharing of relevant information*** and the communication of associated risks. Science-based risk analysis seeks to enable experts to make decisions that minimize the probability of hazards in the food supply system and the environment. Consumers, however, may also wish for more transparency to protect their right to exercise informed consent on their own. An often-discussed set of means intended to protect these rights is the labeling of products, whether or not they are derived from GMOs.
- Involving consumers in local, national and international debates can lead to greater responsibility for issues related to GMOs.
- A related issue is how to bring the private sector transparently into public fora and, subsequently, how to hold public and private sector agencies accountable.
- Societies have ***ethical standards*** that acknowledge the importance of ensuring

that those who cannot satisfy their basic food needs receive adequate means to do so. When appropriately integrated with other technologies for the production of food, other agricultural products and services, GMOs may, among other biotechnologies, offer significant potential for assisting in meeting the human population's needs in the future. An ethically salient issue that then emerges is how the development and use of GMOs in agriculture can be oriented towards improving the nutrition and health of economically poor consumers, especially in developing countries.

Food security, environmental safety and the GMOs issue are closely linked in consumers' minds, which, through the demand they will express on the market will significantly influence decisions about the future of this technology.

Conclusions

The ratio between conventional and unconventional food products, including GMOs, is influenced by the **availability of food resources**, but their existence in different proportions is dictated by **economic and biological considerations as well as the need for consumer protection**.

The development of enriched, modified, transformed, new products determined increased measures for checking their quality and their effects on consumer health, taking into account:

- To ensure the innocuity of products, accurately informing consumers, involving new regulations and quality standards;
- To evaluate potential risks to public health through toxicological studies;
- To determine their nutritional value in nutritional studies.

Experience so far has shown that the acceptability of foods containing unconventional raw materials over a certain margin encounters some reluctance on the part of several categories of consumers concerned about the safety of the products.

Introduction of GMOs into the food production chain and the entire food network should take account of:

- increasing consumer demands regarding the development of innovative products and services,
- the influence of informative and communication technologies on transactions between companies and their logistics,
- new organizational and technical mechanisms for feedback and communication,
- conversion systems, systems for traceability and quality supervision,
- integration of food production management systems,
- market demand for efficient food chain management in what regards the process and product innovation and the attracted side effects.

The supervision of food quality in order to prevent damage to health or human life or even the quality of the environment should be treated with utmost responsibility. The consumer should remain the focus of specialized authorities, as well as for all other stakeholders.

The countries that produce genetically modified organisms must have clear and responsible rules and have authorized bodies to ensure that the risks are analyzed in a scientific manner and that all possible safety measures are adopted, based on tests conducted before the dissemination of products resulting from the application of biotechnology. A close monitoring once these products were disseminated is also required.

Although it could not be proved that food produced from genetically modified organisms is the best solution to the food problem, these products tend to occupy a growing space on the markets of many countries, especially those in which a high-productivity intensive agriculture is pervasive.

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