Public policy responses to Biotechnology

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Glossary:
APHIS (the Animal Plant and Health Inspection Service)
CBD (Convention on Biological Diversity)
CGIAR (Consultative Group for International Agricultural Research)
EPA (US Environmental Protection Agency)
FAO (Food and Agriculture Organization)
FDA (US Federal Drug Administration)
FIFRA (the Federal Insecticide, Fungicide and Rodenticide Act)
GURTS (Genetic Use Restriction Technology)
IPM (Intellectual Property Rights Management)
NEPA (US National Environmental Policy Act)
OECD (Organization for Economic Cooperation and Development)
OTSP (the White House Office of Science and Technology Policy)
PP (Precautionary Principle)
SE (Substantial Equivalence)
TRIPS (Trade related aspects of intellectual property rights)
UNCED (United Nations Conference on Environment and Development)
USDA (US Department of Agriculture)
WHO (World Health Organization)
WTO (World Trade Organization)
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Summary:

The rapid evolution of the biotechnology industry in the last two decades is associated with hopes and fears regarding its impact on health and environment. In the face of a new and controversial technology, such as genetic engineering, public policy is confronted with different world views and scientific uncertainty. An appropriate regulatory system must consider scientific expertise regarding the risks and benefits involved as well as the public risk perception. The public perceives products derived from modern biotechnology to be very risky compared to conventional products. Scientists, in general, cannot find evidence for this assumption and emphasize the potential benefits of this technology for agriculture, health and environment. Public confidence is necessary to improve communication between experts and the lay public in order to narrow this perception gap and to ensure a cost-effective and sustainable regulatory system. However, in the last few years, in particular in Europe, this confidence in regulatory agencies has been undermined because of several food scandals and the release of controversial publications regarding health risks. The lack of public confidence led to more polarization in the public biotechnology debate and hinders effective risk management and risk communication regarding biotechnology. This article investigates the reasons, which led to the increasing public opposition towards agricultural biotechnology in developed and developing countries, shows how public policy and the market are responding to the increasing opposition, and presents ways for policy-makers to handle the increasing difficulties.
Introduction

The revolution in the biological sciences in the last 25 years led to a huge industrial transformation in the fields of agriculture, foodstuffs, chemicals, medicine and pharmaceuticals and the resulting new products promise to have tremendous benefits for agriculture, human health and the environment. But there is also considerable concern about the scientific uncertainty of potential health and environmental hazards in the long-term.

Since the mid 90s, the increasing public opposition against modern biotechnology in food and agriculture had significant effects on national public policies and international relations. Decision-makers in charge of trade, foreign affairs, agriculture, environment, health and science and technology are all concerned with issues related to biotechnology and their decisions are not always in harmony.

Public policy on the national level is supposed to promote this new technology with regard to the potential benefits for the economy, the people and the environment but at the same time it has to protect the public from potential health and environmental hazards. However, policy decision-makers cannot just rely on scientific expertise and decide what is best for the public but they find themselves in a political arena, which is dominated by corporate and public interest groups, all seeking to influence public policy through lobbying or the mobilization of the public opinion. Important political stakeholders apart from the government and the legislative bodies are the academy, the industry, farmer organizations, consumer organizations and environmental protest groups. The general public support, networking capacity, appearance in the mass media, the financial endowment for lobbying and the economic importance are factors, which determine the influence of political stakeholders on the political decision making process.

Risk assessment of bioengineered products comprises economic, environmental, epidemiological and toxicological components. It estimates the form, dimension and characteristics of a risk. However, risk assessment in itself cannot guarantee robust political decisions on regulatory issues. It has to go along with an effective risk management that chooses among the range of policy options available for reducing risk. This includes also an intellectual property management (IPM) that addresses mainly the socioeconomic risks. An effective IPM rewards innovation and enables access to technology developed by others. The last component within an effective regulatory system is risk communication that seeks the dialog with the lay public. Risk communication is a two-way process where the experts not only explain the risks involved in an understandable way but also try to consider the major public concerns in their risk management strategy. Effective risk communication, however, requires that the public believes that experts are telling them the truth about the potential risks involved. However, this trust in experts representing science and government has been undermined by the environmental crisis in the 80s, the food scandals in Europe in the 90s, the public uneasiness with economic globalization and the increasingly radical activism of the anti-biotech movement. The lack of public confidence increases the importance of risk
perception in risk policy and helps explaining the preventive national risk policies adopted, in particular in Europe, Japan and some developing countries.

Biotechnology is above all a global issue. Multinational biotech-companies are no more attached to a certain country, the anti-biotech movement is essentially a global movement and the potential benefits of biotechnology are expected to be largest in developing countries. Therefore, a national policy decision on the regulation of biotechnology not only receives domestic but also international attention. Depending on the size and economic power of a nation its biotechnology policy might have a large influence on international trade, public and private investment in biotechnology research and international development. Thus, a rich country’s decision to ban biotechnology indirectly might affect the destiny of biotechnology in other countries.

National regulatory regimes differ largely from country to country, some countries prefer to use a precautionary principle and tend to have a more preventive risk policy, others rely more on the industry’s risk assessment (which is expected to be profound due to strict liability laws) and learning by doing. The different cultures in risk assessment produce tensions and render political decisions concerning international trade unpredictable. The purpose of several international agreements is therefore to improve predictability of national political decisions through international harmonization.

However, harmonization efforts on the international level again tend to increase public opposition on the national level. Therefore, international agreements leave in general space for unilateral actions. In the context of biotechnology, the outcome of Cartagena Protocol on Biosafety settled in Montreal, January 2000, has clearly shown that negotiators cannot neglect public opinion in their home countries: a consensus on the use of precaution in case of scientific uncertainty has been achieved only because those countries, which were previously opposing it, had to respect the increasing public opposition in their home countries [1]. This again, indicates that environmental and health regulations remain a truly national issue.

National public policy related to biotechnology comprises issues such as the import of genetically modified organisms, the patenting of living organisms, the public demand for mandatory labeling, food safety and biosafety regulations, public investment in biotech-research, education, public awareness, public risk dialog, technology transfer to development countries and economic competitiveness. Political-decision makers in all these fields face internal pressure from both sides: concerned consumers organizations and environmental protest groups prefer a precautionary approach because of potential health and environmental risks, while universities and the life science industry prefer a supportive policy which would increase competitiveness and stimulate innovation in research and development. Often there is not much space for a far-sighted public policy but only for defensive short-term reactions as a panacea to mitigate public emotions.

This article begins with an overview of the evolution of the life science industry during the last two decades and presents the future challenges of this industry in the face of public opposition. Section 2 deals with the question why biotechnology faces a lack of public acceptance and points out the importance of trust in institutions for public
consensus and more public participation in policy-decision making processes. Section 3 presents some theoretical considerations regarding public confidence as a prerequisite for communication in an increasingly complex society. Section 4 shows how public policy has responded to public opposition to date. The last section finally presents the future challenges and public policy options in dealing with scientific uncertainty in risk assessment, global market concentration in the life science industry and the danger for developing countries of being unable to profit from this new technology.

Challenges for the Biotech-Industry

In the early 1950s, Watson and Crick described the structure of DNA as a double helix. This pioneering work triggered a new biotech-industry, which expanded in particular in the 80s and 90s. The range of applications of this new technology comprises agriculture, medicine, chemicals, pharmaceuticals, energy, warfare and bioremediation.

Geographically, this new industry emerged in the United States. The early success of US start-ups after the mid 70s is explained by the geographic proximity (which enabled a rapid translation of academic results into competitive enterprises), the flexible American academic system, the high mobility of the scientific labor market, and, in general, the social, institutional, and legal context that encourages leading academic scientists to become deeply involved with commercial firms [2]. This includes a favorable financial climate (through financial collaboration with big pharmaceutical companies rather than venture capital), a competitive environment, strong intellectual property rights and a regulatory climate that does not restrict genetic experimentation [3].

The new biotechnology firms in the U.S. acted as ‘middlemen’ in the transfer of technology between universities and established pharmaceutical or agrochemical firms. While universities had the technical expertise in new field of genetic engineering, the big firms had the downstream capabilities needed for commercialization [4]. Historically, process development and research had been managed as highly separate manufacturing activities. Since genetic engineering is, as its roots, a process technology, it inherently involves a far higher degree of integration between these activities. Therefore, one of the critical institutional roles played by the small U.S. start-ups was to develop an entirely new set of ‘architectural’ competencies that enabled them to act as effective integrators across research, manufacturing, and process development ⁵.

Over the 1980s, strategic alliances increased significantly and contributed to a reduction in the investment costs needed to achieve optimal production size, accelerated the R&D process and limited the risks faced by firms under existing conditions of uncertainty. Consequently, the industrial organization changed from one structured mainly by large integrated groups into one in which growth takes place increasingly through a shifting pattern of alliances between firms. This has two consequences: industries can no longer easily be described in terms of particular products and the ranking of principal producers in a stable hierarchy has become difficult. This erosion of frontiers between industries and the discontinuities in technological progress undermined the traditional oligopolistic
structure in this field. This new competitive environment gave a significant impetus to strategic partnerships in R&D, production and marketing and the development of knowledge-based networked oligopolies on a global scale. During the 90s the concentration process moved into a higher gear with spectacular in- and cross-country mergers and acquisitions and more intensive strategic partnerships among companies and universities [5].

In analogy to the digital revolution in information technology, which gave a common basis to all the industries dealing with text, sound and video, the genetic code produced a common language to all industries dealing with living organisms or organic compounds [6]. In the field of agricultural biotechnology, genetically modified seeds were of immediate interest for agricultural conglomerates since they promised to be easier to grow, process, and ship. Chemical companies saw genetic engineering in agriculture as a direct threat to their pesticide and herbicide business and decided for an offensive strategy in buying seed companies. And big pharmaceutical companies joined the ramble for seed companies with regard to the potential of combining health with food. This new life-science industry faces, however, a lot of challenges: Agribusiness not only faces lower margins than pharmaceuticals but it is also more cyclical. Nevertheless, until 1999 the new strategy looked very promising: the total area cultivated with GM crops increased in the US from 1.5 million hectares in 1996 to 72 million hectares in 1999. On the global scale, 72% of all GM crops are cultivated in the US, 17% in Argentina, 10% in Canada and another 1% in other countries such as China, Australia, and South Africa. Today, herbicide-tolerant soybean is the most cultivated GM crop: 90% of Argentina’s soybeans and roughly half of the US soybean crop came from genetically modified varieties. Other important GM crops are insecticide resistant (Bt) maize, cotton and canola [7].

However, the growing public opposition towards genetic engineering in agriculture, especially in Europe makes corporate leaders of big life science companies feel the market forces from the bottom-up. Extensive consumer surveys revealed that a majority of the consumers in Europe do not want to eat genetically modified (GM) food and would prefer to pay a premium price for non-GM food [8]. This sent signals to the retailers, which are closest to the consumer and they passed them on to wholesalers, food and food processing companies. As a consequence, food companies are increasingly reluctant to use ingredients such as genetically modified soybean for their ready-made products and food processing companies are asking farmers to separate GM and non-GM food for giving consumers a choice through labeling. Finally, this has an impact on the farmers’ decision to adopt the GM crops. Although, farmers in the United States made very good experiences with the herbicide tolerant soybean capturing around half of the total economic benefits derived from this technology [9], they are know increasingly doubtful about the future development of the export markets in Europe and Japan. As a result, the previously steep adoption rate of transgenic varieties in the US slowed for the first time in 2000. This again has an impact on the insurance industry, which does not know if and how it should insure a biotech-company’s loss due to the public risk perception rather than real risks. Since there is no clear conception of the risks accepted, the risk profile of genetic engineering is extremely diversified and very difficult to anticipate for an insurance company. The reverse trend in the burden of proof and the resulting strict
liability emerging in European legal systems, the increasing demand for mandatory labeling worldwide and the lawsuits against regulatory agencies and the life science-industry in the US [10] show that the risk potential and the risk profile are subject to the influence of changing social values and acceptance [11].

This increasing costs resulting from the lack of market and public acceptance help explaining why the big life science companies start selling their agribusiness and concentrate on pharmaceutical products [6]. However, the splitting up of pharma and agro most probably won’t lessen the concentration of knowledge and power in the life science industry. On the contrary, the increasing delays for approval of patents, field testing and commercial use as well as the increasing number lawsuits against biotech-companies raise the entry costs of small biotech-companies considerably. In this context, the fight of the protest movement against the growing market concentration in the life science industry might have the opposite effect.

**Reasons for the lack of public acceptance**

Public opposition against biotechnology in food and agriculture is not a unique phenomenon in history. The introduction of new technologies is mostly accompanied by the uncertainty regarding long-term hazards and its potential of abuse and therefore, raises considerable concern in the public sphere. There was always public opposition to innovation that appeared to threaten a certain life-style, economic sector or value system. In particular, innovations in food and agriculture produced fierce opposition movements since it is related not only to a change in life styles, but raises questions about the value of nature and life in itself.

There is indeed an undeniable danger that unexpected negative side effects might come along with a new technology. The past negative experiences with agricultural technologies and pharmaceutical products showed that it is often not the new technology itself but the inappropriate use of a new technology that can have serious consequences for people and the environment (e.g. loss of biodiversity, water contamination, antibiotic resistance etc.), in particular in developing countries. Public opposition in developing countries, therefore, points on these negative experiences and is concerned about the capacity of regulatory agencies to ensure proper implementation of biosafety guidelines. In turn, regulatory agencies in developed countries are criticized for not being transparent regarding risk assessment and product approval procedures. Moreover, the approach used in risk assessment is criticized for being reductionist. As a consequence, more participatory approaches on the political as well as on the user’s level are developed. The industry also starts responding to public pressure by showing more willingness to share more knowledge with the public sector.

But, nevertheless, a major part of the public still perceives the potential risks to be unacceptable, even in the face of the potential benefits of agricultural biotechnology in food and agriculture [8]. The answer to this phenomenon is very complex since there are various factors that might play a role. Public opposition is related to world views,
emotions of fear, values of integrity, individual cost/benefit analysis and perceived health, environmental and socioeconomic risks [12].

In particular, in the case of agricultural biotechnology, public opposition is more pronounced because of the consumers’ individual cost/benefit analysis of GM food. The first GM crops are designed to improve farmers productivity through better pest management (e.g. pest resistant Bt corn, herbicide-tolerant soybeans) but don’t offer consumers any additional benefits. Unlike genetic engineering in drug development, and medicine where the risks are more accepted because of the expected benefits [13].

Cognitive research demonstrated that risks are socially constructed [14]. Public risk perception of new technologies is influenced by media coverage, trust in the private and public institutions involved, socially conveyed cultural values and accumulated individual experience. That does not mean, however, that the lay public’s perception is irrational, but unlike the scientific risk assessment, a lay person also considers social issues. In particular, she wants to know who will be the potential winners and losers with the introduction of this new technology, and to which extent she and her environment might be affected by the potential accident resulting from the use of the technology.

Extensive research has been conducted in the field of public risk perception: Modern biotechnology, especially in the fields of food and agriculture, seems to face a public opposition unseen since the protest movement against the nuclear industry in the 70s. Although the technical risks of these technologies are very different [15], many surveys in cognitive risk research revealed that the risks of these two technologies are perceived both to be involuntary, unobservable, uncontrollable and catastrophic consequences are expected in case of an accident [16, 17].

It is crucial that experts, who represent public and private institutions involved in agricultural biotechnology research and regulation, are able to communicate the nature of potential risks effectively in the public arena. The aim of such communication is to provide the consumer with sufficient knowledge about the risks and benefits of this technology in order to enable them to make informed choices about whether or not to buy genetically modified food [18]. However, an expert cannot communicate risks effectively if the public does not trust the institution he or she represents. It is the increasing intensity of conflict and the high degree of complexity of biotechnology that often shifts the public debate from a factual, to an institutional and finally to a world view level [19]. On the world view level, the discussion is value-based and highly emotional. On this level, the experts’ factual knowledge does no more matter. What matters is for whom he is working for and what kind of world view he represents.

In Europe, several scandals in the 80s and 90s (Anti-freeze agent in Austrian wine, HIV contaminated blood in France, mad cow disease in the UK, Dioxin in Belgian eggs and meat products, and contaminated Coke in Belgium and France) undermined trust in regulatory institutions significantly. This also explains why there is strong public opposition all over Europe, in spite of the different social, cultural and political backgrounds.
Public Resistance against GM food in Japan is also related to decreasing trust in the government’s capacity to control risks (e.g., accidents in nuclear plants, financial crisis) but is also strongly attached to the traditional importance of food, in particular rice. No country has a more protective agricultural policy than Japan and Japanese consumers are ready to pay very high subsidies in order to maintain family-based farming and ‘multifunctionality’ in agriculture. Unlike the European Union which has increasing problems to maintain and justify its highly expensive agricultural policy (due to overproduction and resulting expensive export subsidies), Japan does still not face these problems, therefore, continues to maintain a highly protectionist policy [20].

In the USA, the situation is somehow different. Food scandals such as in Europe did not occur in the US and as a consequence, the federal agencies regulating food (FDA) and environmental risks (EPA and USDA) still enjoy more public confidence. Furthermore, the agricultural policy is less protective and gives farmers more incentives to adopt new technologies. Nevertheless, there are some spillover-effects of the public opposition in Europe that also start affecting the American public, which proved to be very little informed about the introduction and commercialization of GM food. This lack of prior public involvement in the policy decision-making process regarding biotechnology in the US bears also the danger of increasing public mistrust towards its regulatory agencies.

In developing countries, the perception of the risks and benefits of biotechnology differs from the one in developed countries. A case study conducted in the Philippines [21] showed that the political stakeholders involved in the biotechnology debate are not so much worried about health risks but very concerned about socioeconomic and environmental risks. While consumer organizations and professional multinational protest organizations are dominating opposition towards biotechnology in developed countries, farmer organizations and a wide range of national non-governmental organizations (NGOs) with different worldviews are relevant in developing countries. Their main socioeconomic concerns are related to WTO/TRIPS agreement, which seeks to establish international minimal standards for patent protection of new crop varieties. Opponents in developing countries fear that the international enforcement of patent protection will increase the dependence of smallholders on multinational companies or even prevent access to this new technology. They also fear that the lack of legal protection of local knowledge and natural resources in developing countries will promote bioprospecting of big pharmaceutical companies without seeking prior informed consent and benefit sharing with local communities [22].

The dominance of international agricultural research centers (CGIAR) in the development and distribution of seeds is associated with the concern that the gene revolution will use the same technical top-down approach in rural development and food security like the former Green Revolution. This is also considered to be a serious socioeconomic concern. Environmental concerns are related to the very different ecological conditions in developing countries, the lack of financial resources to conduct ecosystem specific risk assessments of GM crops and the fear that the established biosafety guidelines cannot be implemented properly due to the lack of institutional capacity. The study in the Philippines showed furthermore that there is also an increasing polarization between opposing public interest groups and the proponents from the fields
of business and government. The different social, political and cultural backgrounds in
developing countries can affect the public attitude significantly. Bad experiences with
different Western powers in the past produce different anti-Western feelings. Anti-
Western feelings are often related to the dominance of Western countries in international
trade and politics. In this context, biotechnology is conceived as another import from the
West that threatens the existence of native technologies and knowledge developed in
local communities and might create further dependence of developing countries on
Western technologies. This consciousness of cultural heritage and history of resistance
against western powers often imbues the public debates on new technologies [23] with a
nationalistic jargon and explains why the Anti-biotech movement has a strong link to the
Anti-WTO movement.

Mistrust related to modern biotechnology in developing countries is therefore not
directed against science in general but mainly against the government, which is often
seen as a henchman of Western and Corporate interests [21]. This mistrust is to somehow
comprehensible. Western efforts to promote economic development and improve living
standards in developing countries proved to be very ambiguous during the Cold War
period. The fact that the state budgets for foreign aid were cut back significantly in the
90s indicates that public investments in developing countries were influenced by the fight
against communism rather than designed for the real needs of the poor population in
developing countries.

The impact of previous introductions of agricultural technologies in developing countries
is also perceived to be ambiguous. The introduction of modern plant varieties had,
without any doubt, boosted world food production, improved the economic conditions of
farmers in favorable cultivation areas, and lowered food prices for the growing urban
population. But at the same time those who introduced the technology did not consider
the importance of good governance in order to bring the benefits to the poorest of the
poor. Often the resource poor farmer’s social, cultural, political and economic conditions
were not taken into account [24]. The consequences were that these farmers could not
afford the technology, or in the case of adoption became indebted due to too many
economic and political risks. Moreover, lack of extension service led to inappropriate use
of pesticides and fungicides and deteriorated human health and the environment [25].

The ambiguous record of Western behavior and the shortcomings of the first Green
Revolution might slow or even impede the diffusion of modern agricultural
biotechnology in some developing countries. This is in particular a matter of regret, since
modern biotechnology definitely has a high potential for improving the situation for the
poorest of the poor provided that structural problems are also addressed and efforts are
made to establish private-public research partnerships with the purpose to develop
products that are financially accessible for everyone and need-oriented. The development
of stress-tolerant varieties, food with higher nutritional content and ‘agroceuticals’ (e.g.
built-in vaccines against diarrhea, tetanus, diphtheria, hepatitis B and colera) are examples
which indicate biotechnology’s huge potential to improve the living of the poor
significantly without exposing them to any additional socioeconomic risks.
However, in response to the domestic opposition to biotechnology, development agencies in industrialized countries tend to regard public research in agricultural biotechnology as a poor contribution to development and cut funds. In turn, public opposition in Europe tends to spillover its apocalyptic fears to developing countries.

**Some theoretical considerations regarding public confidence**

Psychology regards trust as a prerequisite for social orientation. Interaction among individuals relies on a minimum of trust between those involved. Thus, confidence is a prerequisite for any social interaction and, at the same time, is a major mechanism for providing orientation in uncertain situations. It also renders the outcome of communication more predictable.

In this sense Luhmann [26] sees trust as a media, which reduces complexity in society by limiting the scope of behavioral responses; at the same time, he recognizes that trust is also an essential mechanism to increase complexity in society by means of functional differentiation and networking. Different social systems such as business, science, politics and judiciary administer different social issues like money, truth, power, justice, etc. and they are all based on a system-specific rationality. Society is willing to transfer the authority regarding these issues (or media of communication) as long as they have confidence in the respective institutions. In this context, modern society is based on a trade-off: increasing complexity at the cost of increasing transference of trust in the institutions that manage the complexity.

Therefore, each form of rational behavior is firmly based on trust. Any system that loses public confidence completely would immediately break down and dissolve into chaos. Entropy is the constant threat to complex systems.

The phenomenon of loss of confidence shows that, indirectly, we always assume that technology functions flawlessly, commodities are safe, laws are respected, money possesses a value, property is tradable, broadcast/published information is true and that the other person says what he or she means, etc. If we did not believe in these assumptions we would not dare to leave our houses.

As mentioned earlier, the failure of risk communication with regard to new controversial technologies is often explained by lack of confidence in institutions that develop, manage and regulate the technology. The mass media’s affinity to cover scandals produced by protest groups is often held responsible for this situation [27]. But the business community has also learned from the protest groups’s use of the mass media and also increased started creating more media events in form of PR conferences, inaugurations and presentations. Such PR events are intended to inform the public about the companies activities and create a public image of transparency and good will [28].

Many radical opponents and proponents consider the current biotechnology debate as a war carried out in the mass media rather than a risk dialog. In fact, in their fight to influence public opinion political actors don’t even shy away to spread false information
and constantly ignore new findings in risk research if it doesn’t fit their worldview. This is certainly a matter of concern for public policy and it makes the search for public consensus through risk communication looking like a rather naïve approach.

According to numerous risk researchers [15, 29, 30] the main origin of the confidence crisis in science and technology lies in the perceived ambivalence of progress itself. Science and technology managed to reduce many dangers posed by nature and converted them into risks which can be attributed to certain man-made decisions. However, technological progress also produced environmental problems, such as the greenhouse effect and the ozone hole, or social problems such as overpopulation in developing and the increasing percentage of elderly people in developed countries. These problems are considered to be unintended side-effects that are not the result of incorrect calculations or irrational behavior, but arose due to the respective system rationalities (e.g. western medicine managed to extend life expectancy and minimize child mortality but it can not solve the resulting social problems such as overpopulation and increased percentage of elderly people). The fact that there are no scapegoats to blame and no tangible solutions available, has led to the public’s doubt that science and its institutions are able to control such side-effects and to impede them in future. It also makes people more receptive for alternative views that are often found in esotericism and conspiracy theories and make protest groups more appealing to the public.

Business, science and other social systems have an inherent preference of growth, which means that new options must be recognized and risks have to be taken into account [29]. But this also applies to protest groups: Their internal growth through donations and their political influence depends on media attention and social networking. Protest groups are forming global networks and modern information technology enables them to act fast, flexible and effective. The protest movement recruits its own followers and creates its own myth, which provides members with their ideological orientation. By their very nature, it is indeed not possible for protest groups to show great interest in seeking public consensus, since by agreeing to this consensus they would sacrifice their role as a protest group on the respective issue. The main purpose of protest groups is not the search for a common, political solution for specific shortcomings and abuses of power, but rather to detect and disclose such flaws [29].

In general, the political influence of public opinion in politics has increased significantly since the end of the cold war. The actual transition from ‘state secret’ to ‘public’ as media of communication, transformed the risk situation in two respects: in the degree of attention accorded to risks which might have a social impact (rejection of situations where one may be a victim of the risky behavior of others), and in the self-risk inherent in politics [29] that means politics is increasingly kept busy by those who do not actually participate in political decisions but could be affected by a possible damage.

However, broader public participation in political decision making processes had also very positive impacts: politics is forced to become more transparent and public concerns are taken into account more seriously. In developing countries, the emerging strength of the NGO-led civil society movement in the 90s achieved that inequality, corruption, environmental problems, fair trade, equal access to resources and human rights have
become important political issues on the national and the global level. Moreover, the grassroots movement helped introducing valuable bottom-up approaches in development co-operation. Even the anti-biotech movement had the positive effect of making the big life sciences corporations less arrogant towards the public concerns, more willing to co-operate in drug development for tropical diseases and to provide knowledge and funding for public agricultural research in developing countries [31].

But there are also a lot of tensions within the so-called civil society movement: diversity of ideologies within the movement is increasingly perceived as a weakness [32]. After having failed to create an international network in accordance to grassroots principles, a number of large NGOs decided to transnationalize their structures and operating mainly as global players. In this context, the global protest organization Greenpeace represents the most prominent case of ‘global players’. Whereas other big international NGOs such as Friends of Earth and Oxfam created rather loose worldwide networks, Greenpeace established branches controlled by a central office that provides necessary financial means and build a homogeneous ‘corporate identity’ worldwide. In this aspect, it is argued that Greenpeace practices a kind of franchising not dissimilar to McDonalds [33].

Public Policy Issues related to Biotechnology

Today, public policy just acts in a reactive way to public opposition against biotechnology. The regulatory regime often tends to become more restrictive or even preventive not as a result of scientifically confirmed risks but just in response to increasing public concerns. The development of European policy and regulation regarding biotechnology in recent years confirms this argument to some extent.

EU directives and regulations governing field testing, commercial release, and marketing of GM products require that EU member countries and advisory committees assess and register GMOs at each stage in the development. Either a license or a consent must be obtained by a member government before a crop can be field tested, released or marketed. Such a regulatory approval can only be granted after officials and advisors have a chance to review a risk assessment of the product. The assessment must show that negative effects do not significantly differ from conventional crops. All long-term effects on the environment and ecology need to be monitored and precaution must be applied in case of scientific uncertainty. Due to this rather preventive regulatory policy and the increasing public opposition, the EU stopped approving new GM crops for use in or import into the EU since April 1998 [10]. Moreover, the EU Novel Food Regulation (Directive 97/258/EC) requires then that mandatory labeling of processed foods which may contain DNA or a new protein that is no longer equivalent to conventional foods or food ingredients that are outside the accepted limits of natural variations for such characteristics. The last EU council regulation (Council Regulation 1139/98) even asks companies to ensure that all foods on store shelves containing GMOs are labeled [10].

The approach chosen in the US differs largely from the one of the EU. Politically, the risks associated with genetic engineering were addressed already in mid 70s. During the Asimolar Conference in February 1975, scientists were concerned about the
epidemiological risks of modern biotechnology. A consensus among scientists was tried to be achieved about how to self-regulate research involving rDNA technology until its safety could be assured. The National Health Institutes became involved in 1976 when it first published research guidelines using rDNA techniques. In 1986 the White House Office of Science and Technology Policy (OSTP) stated in its Coordinated Framework for Regulation of Biotechnology [34] that bioengineered products would continue to be regulated according to characteristics and novel features and not by their method of production. Moreover, it proposed to regulate biotechnology under the existing web of federal statutory authority and regulation. This meant that the Federal Food and Drug Administration (FDA) is responsible for regulating transgenic food and feeds, the US Department of Agriculture (USDA) and the Animal Plant and Health Inspection Service (APHIS) regulate importation, interstate movement and environmental release of transgenic crops and the Environmental Protection Agency (EPA) deals with the registration of certain plant pesticides produced in transgenic plants. In general, this kind of regulation proved to be less bureaucratic and more efficient and flexible than EU regulatory regime. But it was also criticized for relying too much on the industry’s risk assessment and neglecting risks related to the novelty of the technology.

This rather preventive public policy in the EU causes high costs for the industry due to mandatory labeling and huge delays in the approval process. In this context, the US as the major exporter of biotechnology products started complaining before the World Trade Organization on Technical Barriers to Trade and elsewhere [10]. However, unlike in the previous case of the EU’s ban on imports of US hormone treated beef, the USA cannot formally protest under the WTO rules in this case because the EU has not yet taken any official action against these imports.

In 1999, the public fear regarding alleged health risks of GM food spread all over the world and induced governments in Japan, South Korea, Australia and New Zealand to prepare the enforcement of mandatory labeling for some transgenic food if it is intended for human consumption. Even developing countries, previously in favor of biotechnology such as Thailand, the Philippines, India, Brazil, Sri Lanka and Kenya are delaying the approval for commercial release [35]. Although many developing countries set up biosafety guidelines and committees in the 90s that are designed to regulate biotechnology and enable decisions to decide about the approval of certain GMO imports, institutional capacity and financial resources necessary for evaluating applications are lacking.

Most recently the public opposition against biotechnology in the US, the cradle of the biotechnology-industry, induced even the US government to respond to the public concern. Since 1999, the US environmental protection agency (EPA) takes action to impede the development of pest resistance by making the planting of Bt corn conditional to a certain percentage area of minimum structured refuge of non-Bt corn depending on the geographical location. Moreover, the National Research Council criticizes in its recent research report on agricultural biotechnology [36] that genetically modified pest-protected plants are not subject to regulation as pesticides. It encourages therefore the EPA to promptly complete the process for issuing regulations, policies and guidance that set out the review and regulatory parameters for pesticidal substances in transgenic pest-
protected plants. Also in response to increasing public concern, the US federal food and drug administration (FDA) announced in May 2000 plans to refine its regulatory approach regarding foods derived through the use of modern biotechnology. Developers of genetically engineered foods are to notify and consult with the agency before marketing to ensure that all safety and regulatory questions have been fully addressed. It includes efforts to provide more information for consumers and guidance to assist voluntary labeling. In this context, the FDA emphasizes that these initiatives have not been started because the existing approval process is considered as inadequate but to provide the public with continued confidence in the safety of these foods [37]. This means that FDA will stick with the concept of substantial equivalence, which means that a GM food product, which is not qualitatively different from a non-GM food product does not require additional risk assessment or labeling. Basically the product is tested independent from the way it has been processed (genetically engineered or not). This concept was first developed on the international level by the Organization for Economic Development and Cooperation (OECD) and then adopted by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) in the Codex Alimentarius. Since then, it was also adopted in the national laws and practices in many countries around the world.

However, the concept of substantial equivalence (SE) is often misunderstood and, therefore, contentious. Opponents attacked the principle of substantial equivalence as being a ‘pseudo-scientific’ approach because it would ignore many special aspects related to genetic engineering and would have been created primarily to provide excuse for not requiring biochemical and toxicological tests [38]. In response to this reproach, the OECD published a rectification which points out that SE is not considered to be a substitute for safety assessment but is only a guiding principle and important starting point in a safety assessment that compares a new product and its traditional counterpart with a view to demonstrating that it is as safe as its traditional counterpart. In case that a new product is considered to be substantial equivalent, except for the novel trait, safety assessment should focus on the novel trait [39]. In this context, the concept of SE just means that previous knowledge and familiarity as well as comparative analysis are considered to be useful in risk assessment.

The precautionary principle (PP) is another important and contentious legal concept in public risk management. The essence of the principle is that once a risk has been identified the lack of scientific proof of cause and effect shall not be used as a reason for not taking action to protect the environment.

Many countries incorporated the Precautionary Principle in response to the environmental crisis in the 80s. In the Maastricht Treaty of the European Union the Precautionary Principle (PP) is included as the legal obligation and required aim for environmental policy [40]. However, despite a growing body in case law, the concept has never been defined and its meaning and applicability remain unclear.

In consequence, the European Union recently issued a communication paper of what it understands as the Precautionary Principle [41] and how it intends to apply it. Although this document provides some important guidelines for the application of the PP, it is still
unclear about how much scientific evidence is required to ensure that a new technology is safe and to what extent social concerns associated with the new technology can influence this level of scientific evidence required to grant market approval of a new technology.

The PP has gained prominence in international law with its adoption in the 1992 Rio Declaration at the United Nations Conference on Environment and Development (UNCED) as Principle 15\(^1\). Since then it has been included in virtually every recent treaty and policy document related to the protection and preservation of the environment. In January 2000, the Precautionary Principle has also been adopted in the Convention on Biological Diversity (CBD) as Articles 10.6 and 11.8\(^2\) of the finalized Cartagena Protocol on Biosafety (2000) ‘taking also into account risks to human health’. Many opponents claim now that the Protocols’ inclusion of human health issues into the precautionary concept in international law would question the Codex Alimentarius’ principle of substantial equivalence. However, proponents argue that the juxtaposition of the SE and the PP does not seem to be justified since one is a tool in risk assessment and the other one a tool in risk management. Hence, applying the SE approach would not contradict the PP but rather provide a practical basis for the implementation of the PP.

Whereas Article 5.7 in the WTO’s Sanitary and Phytosanitary Agreement\(^3\) considers precautionary to be a temporarily, the Biosafety protocol does not define the PP in a provisional sense. These changes and the growing importance of the precautionary principle as a guideline for public policy related to biotechnology starts worrying the United States. It is feared that countries start rejecting the importation of genetically modified products not because of scientific uncertainty related to health and environmental risks but because of political reasons - be it to protect the domestic farmers, be it to address consumer concerns. Moreover, environmentalists can use the Precautionary Principle in an absolutist sense (the radical approach as opposed to the proportional approach) using it as a legal tool to block the approval of any kind biotechnology products, since, scientifically, it can never be proven that a new technology is entirely safe.

Although the US National Environmental Policy Act (NEPA) in 1969 does not address the problem of scientific uncertainty, decisions made by the Council on Environmental Quality (which assists the implementation of NEPA) required first that a worst case scenario has to be elaborated in case of scientific uncertainty (1978). This can be seen as

\(^1\) Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation (Principle 15 in the UNCED Rio Declaration, 1992).

\(^2\) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a LMO on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent the Party from taking a decision, as appropriate, with regard to the import of the living modified organism…, in order to avoid or minimize such adverse effects (Article 10.6 and 11.8 of the finalized Cartagena Protocol on Biosafety, 2000).

\(^3\) In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt…measures on the basis of available pertinent information…in such circumstances, Members will seek to obtain the additional information necessary for a more objective assessment of risk and review the…measure accordingly within a reasonable period of time (Article 5.7 of the WTO/SPS Agreement, 1993).
a way to take precaution into account. Later on the expression ‘worst case’ was replaced with ‘rule of reason threshold’ (1986) [42]. Furthermore, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires registration of pesticides with the EPA. If doubts about safety arise later, the registration can be first suspended and then canceled if the doubts are confirmed. As in the case of the Precautionary Principle, this can shift the burden of proof from the potential victim to the polluter. However, it does not necessarily mean reversing the burden of proof, but adjusting the threshold at which we are willing to take action [43].

Precaution is also applied in US environmental litigation: to establish tort liability, it is usually enough to prove that it is more likely than not that the defendant caused the plaintiff’s injury [42]. In general, the US regulations on biosafety and food safety rely more on the industry’s proper risk assessment for they assume the industry to act precautionary because of the strong liability rules.

Preventive public policies are certainly a matter of concern for the young biotech-industry. However, as mentioned previously, the market itself probably poses even a more serious threat to this new economic sector. To avoid consumer boycotts and lawsuits food companies, retail stores, and fast-food chains (including Burger King and McDonald’s) in Europe announced the intention to stop using GM ingredients. Even in the US many food companies such as Frito Lay, the nation’s major snack food provider and baby-food companies such as Gerber and H.J. Heinz intend to switch to non-GM ingredients. These decisions force food processing and export firms increasingly to ask US farmers to separate GM from non-GM crops in order to provide the consumers with ‘GM-free’ products35. The separation of GM from non-GM crops from the farmer’s field to the food shelf in the super-market will produce additional costs that will probably result in an increase of the food price. This might make GM food less competitive and less affordable for the poor. In turn, organic farming, which has the image of being close to nature, enjoys an increasing market demand, as a potential substitute of the GM food. However, organic farming will most probably remain a niche market where producers have lower yields, which are, in turn, compensated by a price premium the consumer is willing to pay.

**Some reflections on future public policy towards biotechnology**

The current biotechnology debate is mainly focused on the potential long-term risks for human health and environment. The fact, that there is scientific uncertainty regarding these potential risks gave radical opponents the opportunity to accuse scientists, policy-makers and the business community for abusing the public as ‘Guinea Pigs’. However, to date, there is no evidence that genetic engineering in food and agriculture poses a bigger threat to health and environment than conventional breeding. Moreover, new tools are developed in order to ensure safety for humans and the environment. Considering also the expected benefits of biotechnology for agriculture, health and the environment, the ‘Guinea pigs’- reproach does not seem to be justified. It might well turn out that the benefits of biotechnology will outweigh the risks significantly. In that case, a
very preventive public policy today might be more risky than a supportive one for the coming generations. In turn, an extremely supportive policy that does not give due consideration to the novelty of GMOs in environmental and health impact assessments increases the probability of a future health hazard, which would make biotechnology definitely unacceptable for the public. But also socioeconomic risks have to be addressed carefully since they might turn out to be the main reason for the public concern. The increasing importance of the private sector in research and risk assessment, the power and knowledge concentration in the life science industry and the lack of transparency and public involvement in decisions on regulatory issues is producing increasing concerns regarding the equal distribution of risks and benefits of modern biotechnology.

Therefore, public policy must, first of all, try to find measures to retrieve public confidence. Such measures may include better risk management and risk communication in addition to a serious risk assessment. Such a risk policy must consider value judgments and social acceptability. But policy should not just take social acceptability as fact but as a dynamic component. Public policy has to focus on risk perception of biotechnology, which forms its social acceptability. By means of more public participation and transparency in the political decision making processes on regulatory issues and more information for citizens about current research and policy efforts aiming to reduce potential risks and increase potential benefits of genetic engineering, policy-makers can increase public confidence and improve risk communication. In this context, the government needs to gather information and monitor all frontiers of biotechnology research and communicate it to the public in an understandable way. It should also search for more dialog with the public interest groups and, in this context, not shy away from discussions about values. In the public arena it is very important that the government presents experts that have enough social competence for not being judged as an emotionless scientist without social values.

Since the public increasingly doubts the reliability and validity of findings obtained through risk assessments conducted by the private industry, more risk assessment studies conducted by independent public institutions have to be sponsored by the state. This also raises the question to what extent the industry should be involved in the public dialog. Since the biotech-industry is currently linked more to conspiracy theories than critical judgment in public and any kind of communication is simply interpreted as a PR action designed to improve the image but not the facts, it has a very hard stance in the public. A way out of the dilemma for the industry is to listen carefully to the fears expressed by the consumers and environmentalists and try to develop technologies or mechanisms that will lessen the fear associated with certain risks. For example, if consumers are afraid that antibiotic markers pose a threat to human health because of the possibility of antibiotic resistance, the industry focus its research efforts on the replacement of these markers genes even if there is no scientific evidence for such a risk. If environmentalists point on the possibility that GM plant varieties can outcross into the wild varieties nearby, the industry should concentrate its research efforts to eliminate this risk (e.g. chloroplast expression instead of nuclear expression).

The industry should directly seek the contact to important and moderate opposing public interest groups (which enjoy public confidence), and try to address all the concerns
expressed by these interest groups. Once some of these critical interest groups get the
impression that the industry is not just an evil power put really takes public concerns
serious, it might improve its public image more than bold PR campaigns.

In the context of socioeconomic risks (or technology-transcending risks as opposed to
technology-inherent risks) [44], NGOs concerned with international trade and
development are afraid that resource poor farmers won’t have access to this technology
and biosafety cannot be guaranteed in these countries in case of the release of biotech-
crops due to the lack of knowledge, infrastructure and enforcement mechanisms.
Therefore, the industry should invest more in public-private research partnerships, joint-
ventures and institutional capacity building in agricultural biotechnology in developing
countries. To date, the big multi-national Life science companies profit most from
globalization and have a higher GDP than most of the developing countries but they still
expect that public policy (with its ever diminishing budget) is able to monitor
biotechnology and impede its negative social and environmental side effects. If multi-
national companies want their products to be adopted by farmers and consumers they
have to help creating the appropriate conditions that would insure the safe use of this
technology.

The biotech-industry is currently learning that the research, development and regulatory
approval of a new transgenic product does not only imply private costs but also social
costs, which bounce back on the returns of the product and the image of the industry as a
whole. The Genetic Use Restriction Technology (GURT) also known as the Terminator
Technology proved how unanticipated social costs due to a lack of social acceptance can
affect a company and the industry as a whole. The importance of taking social costs into
account is currently also reflected in the industries general willingness to accept more
strict regulation in the hope that this will increase public confidence and decrease social
costs.

Apart from that, it is also important to create a more robust and cost-effective regulatory
regime. Such a regime would consist of a national regulatory agency with extensive
autonomy in decision making. To make sure that the institutions’ autonomy is not abused
advisory committees should constantly monitor and report the work done by the
regulatory agency. The agency’s decision to approve a new product should be based on a
comprehensive risk assessment, cost/benefit analyses and precaution as long as adequate
information is not available (or the product does not seem to be socially acceptable). It
can be expected that increasing knowledge about the positive and negative impacts of the
new technology and increasing experience will also affect its social acceptability.

The application of precaution in regulatory decisions regarding biotechnology is more
complex than just adopting the previously used toxic waste model. Unforseen potential
health and environmental risks of bioengineered products have to be compared with the
potential benefits that this technology provides in terms of economic wealth, health and
the environment. In particular in developing countries, where biotechnology might have
an enormous positive impact on agricultural productivity, improved nutrition of the poor,
and better environmental conditions, the risk not to adopt the technology might, in some
cases, turn out to be bigger than in case of adoption. In this case, precaution might be
applied in favor of biotechnology. Regulatory agencies in industrialized countries must take into account this aspect as well since biotechnology is considered to be a global public good.

A robust and flexible regulatory regime must consider the concerns raised by the public but should also be constantly aware of the moving knowledge frontiers and have the authority to change its regulation in case of increasing scientific certainty of the real existence (or non-existence) of a certain risk. Developing new information is critical to this dynamic approach. Therefore, regulatory agencies must be allowed to use an experimental approach, trying a lot of different things and attempting to learn from the results. Field tests are necessary in particular to gather information about the impact of GM crops on the ecosystem.

Regulatory agencies should also seek the constant dialog with the different political actors involved and in particular with public interest groups opposing biotechnology. Agencies must welcome their efforts to monitor the development at all frontiers. However, radical opponents who even oppose officially approved field testing cannot be taken serious in a risk dialog since they prove not to be interested in more information about the risks involved but just don’t want this technology as a whole.

According to the OECD, the environmental risks involved in field testing should be addressed by investigating six safety issues: gene transfer, weediness, trait effects, genetic and phenotypic variability, expression of genetic material from pathogens, and worker safety [45]. The risk assessment regarding the safe consumption of GM food products requires comparative data on molecular, nutritional, biochemical, toxicological and immunological characteristics.

Supposed that all the tests done (including the investigation of the novel trait) indicate that the new product is substantially equivalent to its traditional counterpart, it can be assumed that there is a familiarity between the products. Although familiarity cannot be equated to safety, it is a useful basis for applying existing management practices to new products and is premised upon case-be-case and step-by-step risk assessment and management of new products [46].

The OECD and the US regulatory system propose to address the safe use of biotechnology by means of science based, case-by-case, hazard identification and risk assessment, regulating the end product rather than the production process itself, developing a regulatory framework that builds on existing rather than establishing new ones, and on flexibility to reduce regulation of products after they have been demonstrated to be of low risk [46].

This approach proved to be quite successful, although the heavy reliance on the industry’s proper risk assessment might have been quite risky in some cases. Recent steps undertaken by EPA and FDA to strengthen their regulatory policy indicate that consumer and environmentalist concerns will be addressed more seriously by providing more information and more attention to the particularities of genetic engineering in risk assessment. The fact that both agencies did not take much effort to previously inform the
public about risks and benefits of genetic engineering and the reasons for applying a
certain approach in safety regulations can be considered as a shortcoming.

A science-based, efficient and transparent regulatory system that enjoys the confidence of
the public and the business and farming communities, is essential for the effective use of
biotechnology. In this context, the European Union faces a much more difficult situation
in its regulatory policy. Confidence in regulatory agencies has been widely undermined
by the several food scandals, the regulatory regime lacks accountability and the highly
bureaucratic approval process is not very efficient and transparent. The rather radical use
of the precautionary principle regarding food safety may be seen also as a public policy
response to this lack of public confidence in the regulatory regime.

As mentioned, many developing countries already established a regulatory regime for the
safe use of biotechnology. However, because of the lack of human and financial
resources the regulatory agencies are hardly able to apply the existing principles and
practices for a proper safety assessment. Therefore, they are also inclined to apply the
precautionary principle in a more radical sense because this prevents that they can be held
liable for any kind of risky decisions. In this context, it is crucial to support institutional
capacity building and the accommodation of new knowledge and experience in the
regulatory decision making processes.

It is important that all the new information obtained in these risk assessments are made
publicly available in an understandable way. In case that a new product turns out to be
not substantially equivalent, agencies must conduct additional safety tests, make sure that
the hazardous product will not enter into the food chain, and inform the public what kind
of additional risks impeded market approval.

Labeling of GM products will probably become inevitable in market-driven and
democratic countries where consumers want to have free choice between GM and non
GM food. In this context, regulatory agencies should just assist companies in their
intention to label their food products.

The constant acquisition of more information about risks will help to ‘raise our regulatory
IQ’ [43]. In spite of international efforts to harmonize regulation on biosafety, each
country will probably design its own regulatory approach. Public policy towards
biotechnology will always be largely influenced by the public attitude. In this context, a
country with a rather preventive public policy can learn from the positive and negative
experiences in countries with a more supportive policy. Increasing information about
long-term risks and benefits might also help to narrow the gap between the different
public attitudes in different countries and help to decrease the national differences in risk
management.

In future, more public financial resources will probably have to be invested again in an
effective and responsible risk policy. This will be in the interest of politicians who want
to be re-elected, the concerned public and the industry who wants to sell its products.
In conclusion, a more extensive and robust regulatory regime and a stronger commitment of the industry to help reducing socioeconomic risks in developing countries can help to reduce the social costs triggered by the increasing public opposition towards biotechnology.

References


   http://papers.nber.org/papers/w5341


