

PUBLIC POLICY RESPONSES TO BIOTECHNOLOGY

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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 worldviews 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 the 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 for the increasing public opposition towards agricultural biotechnology in developed and developing countries, shows how public policy and the market are responding to this increasing opposition, and presents ways for policymakers to handle the increasing difficulties.

1. Introduction

The revolution in the biological sciences in the last 25 years has 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 has 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; 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 public opinion. Important political stakeholders apart from the government and the legislative bodies are academia, industry, farmer organizations, consumer organizations, and environmental protest groups (see also chapter *The Economics of Agrobiotechnology*). General public support, networking capacity, coverage in the mass media, financial resources for lobbying, and economic importance, are factors that 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 alongside 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. 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 dialogue 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 to explain 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 receives not only 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, and public and private investment in biotechnology research and international development. Thus, a rich country's decision to ban biotechnology might indirectly 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, while 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, in general, international agreements leave space for unilateral actions. In the context of biotechnology, the outcome of the Cartagena Protocol on Biosafety settled in Montreal, in 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 previously opposing it had to respect the increasing public opposition in their home countries. 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 consumer 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 of why biotechnology faces a lack of

public acceptance and points out the importance of trust in institutions for public consensus and of 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.

2. Challenges for the Biotechnology 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 1980s and 1990s. 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 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, a social, institutional, and legal context that encourages leading academic scientists to become deeply involved with commercial firms. 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.

The new biotechnology firms in the US acted as “middlemen” in the transfer of technology between universities and established pharmaceutical or agrochemical firms. While universities had the technical expertise in the new field of genetic engineering, the big firms had the downstream capabilities needed for commercialization. Historically, process development and research had been managed as highly separate manufacturing activities. Since genetic engineering is, at 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 US. 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.

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 has undermined the traditional

oligopolistic structure in this field. This new competitive environment has given 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 1990s 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.

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. In the field of agricultural biotechnology (see also chapter *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 on an offensive strategy in buying seed companies. Big pharmaceutical companies joined the scramble 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 has 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 percent of all GM crops are cultivated in the US, 17 percent in Argentina, 10 percent in Canada and another 1 percent in other countries such as China, Australia, and South Africa. Today, herbicide-tolerant soybean is the most cultivated GM crop: 90 percent of Argentina's soybeans and roughly half of the US soybean crop comes from genetically modified varieties. Other important GM crops are insecticide resistant (Bt) maize, cotton, and canola (see also chapter *Crop Protection through Pest Resistance Genes*).

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. 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 in order to give consumers a choice through labeling. Finally, this has an impact on the farmers' decision to adopt the GM crops (see also chapter *Plant Breeding and Molecular Farming*). Although, farmers in the United States have had very good experiences with the herbicide tolerant soybean, capturing around half of the total economic benefits derived from this technology, they are now 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 show that the risk potential and the risk profile are subject to the influence of changing social values and acceptance.

The increasing costs resulting from the lack of market and public acceptance help to explain why the big life science companies have started selling their agribusiness and concentrating on pharmaceutical products. However, the splitting up of pharma and agro most probably will not lessen the concentration of knowledge and power in the life science industry (see also chapter *Integration of Biotechnology into Lifesciences - Future Development of Global Lifescience Industries*). On the contrary, the increasing delays for approval of patents, field–testing and commercial use as well as the increasing number of 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.

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