

Biotechnology: Regulation, and Dialogue in achieving consensus

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Abstract

Biotechnology is the latest example of a scientific discipline creating enormous social, cultural, and public policy controversies. Review of some of dilemmas that have arisen as a result of the development of transgenic crop plants is given. Risks and benefits to the environment and the possible effects on human health are considered. An almost unprecedented amount of discussion has been stimulated on the merits and demands of genetic engineering of crop plants, that has divided both the public and scientific communities. The arguments for and against transgenics are discussed, and biotechnology's future is viewed as consensus of all participating institutions in debates; different approaches in legislative process are considered.

Given current political and public opinion realities about Biotechnology, the open debate of contrasting and even conflicting viewpoints and public representation in implementing policies maybe considered as one of the most appropriate forms in regulatory oversight in relation to agricultural biotechnology and in dealing with uncertainty, in general.

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The history is filled with numerous examples of revolutionary new technologies, many of which have changed the world, and we're glad to have benefited from them. History also knows that in significant number of cases many of these technologies turned out to have risks and cost-negative impacts on society, raising a variety of ecological and human health concerns - that were often unanticipated, or not understood until long after the inventions were implemented. In the most cases we didn't think of the risks associated with innovation and reaped the benefits of technological progress, trying to speed up the adoption of new technologies. But in some cases the risks were substantial enough to outweigh the benefits to say about any advantages and economic potential of implemented technologies, so that these initially seemed benefits were a costly mistake for society. In some cases the innovations were rejected, often after long scientific and political controversies and bitter experience.

Is the situation about food biotechnology different? Will it be rejected, yes or no? Can we manage all these associated uncertainties and risks, keeping them to an acceptable minimum and where is the social acceptable minimum? Or will we discount risk concerns and don't take advantages of lessons learned before and speed up the adoption of some applications of biotechnology driven by imaginable vision of future benefits, and only to learn later that it was wrong decision and our life-support system is irreparably threatened? There are some of the choices the biotechnology industry confront today. These problems can no longer be ignored; to do so might prove to be a costly mistake with serious ecological and human health consequences, and finally resulting in that society should pay an enormous price – politically, economically, and socially. Based on the lessons of history and recent trends, it would be useful to analyze the ways for solving controversies about biotechnology that may suggest a path toward consensus in the biotechnology debate. Dealing with technological risk under conditions of uncertainty demands the development of new forms of dialogue between researchers, experts, political decision-makers, industrialists and the public promoting greater public involvement in decision-making and achieving a sustainable society and formulating the strategies all over the world and of large European multinationals towards biotechnology, in particular, agricultural biotechnology. It's also important in the context of the most crucial central problems concerning globalization, localization and regulation for elaboration of approaches to unification, harmonization of different points of views and promoting innovative ways to make collective choices including alternative dispute resolution with public presentation, collaborative problem-solving, and negotiation process, including increasing need to establish communication process on risk aspects and to develop strategies of decision-making under conditions of ambiguity.

It would be relevant to mention that modern biotechnology is the result of massive surge of knowledge about the structure and functioning of living entities that has taken place over the past few decades. It's resulted in problems far beyond the science context of molecular biology and demonstrated that science become more tightly woven into the social fabric. The rising genetic paradigms is important reminder that issues around biotechnology research such as genome research, biodiversity, intellectual property, transgenics, animal protection and alternative methods are likely to affect all of us and have raised concern amongst of the public and led to controversies concerning ethical, social and legal aspects.

Public concern about biotechnology is related to such issues as trust, choice, need, and care of sustainable development and natural balance. These achievements in biological engineering and recent research have provoked controversy and to a large extent polarized society. It has become a battleground involving scientists, commerce, politicians, journalists, lobby groups and the public. This research area becomes new priority field and coincided with important changes in the national research policies and analyzing public perceptions in European countries and in world-wide international context.

One of the most recent, and perhaps the most contentious of the resulting controversies, has been the highly visible and ongoing debate on genetically modified (GM) agricultural products that's only one of the recent concerns related to the application of biotechnology but according to an often quoted phrase, 90 % controversy now is about agriculture biotechnology (Kershen D.L., 1999). According to (Kamaldeen S., Powell D.A., 2000), the major influences on acceptance seem to be knowledge level, awareness of benefits, confidence and trust. The subject of transgenic crops embraces many of the major issues in philosophy: the meaning of words, free will, the concepts of right and wrong justice, and ultimately the meaning of life itself.

Taking into consideration that the failure to provide basic needs and access to adequate food for 800 million people is real and one of the most urgent human problems today, it's commonly held view that transgenic crops might contribute to sustainable farming practices (FAO, 2001, p. 10). If biotechnology firms, some government agencies cite the potential contribution of biotechnology to resolve world hunger, nongovernmental organizations highlight the potential adverse impacts of biotechnology on farmers and ecosystems in developing countries (Persley G.J., 1999). While the impacts of most biotechnology products are relatively predictable, GM organisms present risk to human health and the environment and raise considerable uncertainties, in particular, regarding their environmental impact.

Whereas protests have targeted GM foods in Europe, Americans have been comparatively quiet and accepting of such new foods. According to some analysts, this difference emerges from greater regulatory transparency and ability to modulate agency decisions (often through courts, including limited suits against the government for damage caused by federal actions according to the Federal Tort Claims Act, etc). But in the USA biotech agriculture is becoming a hot issue and gathering steam now.

To analyze different aspects of biotechnology issues it should be mentioned that Americans and Europeans have differences in regulatory approaches. For example, European regulation of food deals with the entire food production system from farm to table, focusing its biotechnological regulatory policy not only on the product but also on the process, through adhering to the precautionary principle, at the same time as the U.S. system focuses primarily on the end product. It should be mentioned importance of this fact since the precautionary principle, as a risk management tool, helps to establish a view of the ways of assessing and managing risk and addressing issues where scientific facts are not able to provide full characteristics and assessment, this is a principle of how to act in the face of scientific uncertainty. According to European Union laws and regulation, biotechnology has special, separate regulatory schemes. It should be mentioned that in international discussion of biotechnological regulations a trade issue is considered as one of the most widely discussed topics and biotechnology issues are viewed as being commercial to a large extent in the USA, whereas the Europeans see trade as only one part of

a larger complex of related issues. Government, science, industry, NGOs and public on both continents should play important roles in solving controversies and achieving consensus in biotechnology debate concerning a wide spectrum of legal, social, ethical aspects, with increasing role of public in developing regulatory policy in dealing with uncertainty. Open debates should be encouraged to consider all aspects of the interrelations between science and public to create the pattern of great transparency and public involvement in decision-making process under uncertainties.

Recent public concerns against GM food are greatly in dependence on perceptions of risk and uncertainty of using GM organisms (Slovic P., 1991) and address issues far beyond defining risks in rather narrow, quantitative terms. The arguments are about values, which are neither absolute or universal; and the controversies surrounding transgenic crops to large extent polarized society into the proponents and opponents. Much of the arguments is emotive, with talk like of “Cashing in on Hunger”, “Demon Seeds”, “Terminator Technology”, “Mutant Food”, “Frankenstein Foods”, reflecting passions and sharpness of the problem. It should be mention the large number of the articles about biotechnology issues in the GB, as cited by Kamaldeen S. & Powell D., 2000, these issues are widely discussed in press, including representatives of king’s family (Prince Charles, 1998).

If proponents of biotechnology consider it as providing additional food, fiber, and medicines for human population, opponents hold the opposite vision and view biotechnology as having the potential to change fundamentally the ecology of the world and, through the food products of genetically modified plants and animals, the health risks of human beings. To opponents of biotechnology, each new genetically modified plant or animal is the introduction of an alien species into life, with completely unknown, unpredictable consequences and risks. One of the examples of these unknown consequences and risks was stated in Cornell University studies showing that pollen from insect-resistant Bt (*Bacillus thuringiensis*) maize is potentially toxic to monarch butterfly larvae (Sagar A, Daemmrich A., Ashiya M., 2000). In the wake of Cornell University studies, the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) stated it would tighten safety regulations on GM crops. Examples of unpredictable consequences may also include the transfer of herbicide tolerance to weeds, leading to more aggressive or more competitive weeds, the transfer of food allergenic compounds to products that didn’t contain them before, and numerous issues related to replacement of native populations with more uniform and aggressive genetically engineered varieties. It should be mentioned that these gene insertions may also lead to inappropriate inactivation or activation of genes (insertion mutagenesis), some of which may lead to cancer (insertion carcinogenesis). The obvious fear is that antibiotic marker genes could be inserted into humans (and domestic animals) rendering antibiotics ineffective in curing bacterial infections. Moreover, this technology has the power to break down genetic barriers between humans, animals, and plants altering genetic codes and creating heretofore unimaginable transgenic life forms which may pass these genetic changes onto their offspring through heredity. This introduction is done due to the arrogance of humans.

It should be mentioned that controversy about agricultural biotechnology has raged in the USA despite the United States government has implemented regulatory oversight regarding safety, efficacy and environmental impacts since biotechnology’s earliest stages. The debates over biotechnology issues have risen in the USA, and the speech now is about creation of a National Center for Biological Invasion, a new coordination body which would be essential to the success of nonindigenous species prevention and management efforts (Schmitz D.C., Simberloff D., 2001).

According to Cornell University biologists (Schmitz D.C., Simberloff D., 2001), nonindigenous species do more than \$ 130 billion a year in damage to agriculture, forests, rangelands and fisheries. There is no need to say that the most invasive species are artificially created and, moreover, long-term research is needed for studies of completely unknown, unpredictable consequences and risks of introduction of new genetically engineered varieties into life. The controversy erupted (November 2001) when it was stated that DNA from GM maize had been found in wild varieties of the crop in Mexico (Mantell K., 2002). As for further research, long-term studies are needed to explore the reasons, but the fact of presence of these transgenes in remote mountains in Oaxaca, Mexico was established.

According to Schmitz D.C., Simberloff D., 2001, there is no government-wide uniform procedure at the federal or at most state levels that identifies newly introduced species (proper species identification) and tracks existing invasions: nor is there a consistent system of reporting them or of deciding on control efforts and evaluating control success. Based on above-mentioned, no one regulatory system can not be considered complete and give answers without developing a risk assessment methodology, additional risk testing and regulatory requirements on biotechnology and without responsiveness to increasing demand of public for “socially precautionary” principles in regulatory oversight in dealing with uncertainty.

Opponents of biotechnology insist that regulation of biotechnology be a technology assessment, not only a product regulation.

According to Beck U. (1992), the shift from an industrial era to the information age has produced a “risk society” which is characterized by self-inflicted dangers, increasing independence of human decisions, worldwide implications even of seemingly local events, and controversies that undermine the basis for calculating risk and insurance. In such a society regulatory institutions, corporations, and even scientists who base decisions regarding field trials or widespread marketing of GM foods on risk/benefit calculations should take into account the deeper ethical and social bases that shape public opinion. A broader analysis indicates that the public participation and concerns about biotechnology applications include not only such issues as trust, choice, need, and care of sustainable development and natural balance but also globalization and stratification of power, ethics, equity and ultimately the meaning of life itself. According to Nelkin D. (1995, p. 445), “controversies over science and technology are struggles over meaning and morality, over the distribution of resources, and over the locus power and control”. The moral and ethical concerns are important factors in influencing on public (Callahan D., 1996) and future of the debate on transgenic crops and their products (Wadman M., 1996).

It should be noted that public risk perception is influenced as much by social and ethical relations, and the role of these factors is growing under condition of ambiguity, so that regulatory institutions, corporations and scientists who should take into account ethical, social and legal aspects while making decisions. Public attitude towards biotechnology is in dependence on factual judgments based on the scientific evidence and theories, and ethical judgments based on the best available moral principles and theories (Comstock G, 2000). It should be built a model risk analysis for genetically modified food and genetically modified organisms that incorporates the social dimensions, through the integration of risk analysis with a social impact (Barling D, de Vriend H., et al, 1999) including greater public involvement with accountable representation of all parties in the biotechnology debate.

Public policy-makers are faced with the need to maintain public confidence in biotechnology and credible regulations by guaranteeing that its risk is acceptable and the remaining question how much risk is tolerable and socially acceptable. The government officials in Europe respond to public concerns by instituting additional testing and regulatory requirements on biotechnology, one of these EU measures to protect European market from GM food was the decision of European Union's environment minister about a de facto three-year moratorium on new marketing approvals for the GM organisms in 1999 until adoption of legislative proposals that include requirements for traceability and labeling of GM products; measures that will take time to develop and that U.S. exporters will find difficult and costly to meet. Furthermore, ministers from several European countries independently insisted that they would block new applications to market GM seeds, plants, or foodstuffs until a new regulatory regime is put in place.

This may be illustration of how decision-makers should represent recent public concerns about biotechnology issues. It should be mentioned that EU has been "much more cautious, hesitant, and suspicious of biotechnology overall, and of agricultural biotechnology, in particular" (Kersh D.L., 1999, p. 6). This is different than a "food fight", as German foreign minister Joscha Fischer said: "Europeans do not want genetically modified food. It doesn't matter what research shows; they just do not want it and that has to be respected" (Moore J.A., 2001, p. 1-2). More Europeans are not willing to buy GM food, they want something they like and trust, and regulators should take it into account. Although a trade issue is one of the interrelated factors, EC and member states cannot enforce the consumers to buy GM food. By developing a strong and transparent regulatory framework, the EC authorities are seeking to create a market in which continued safe information is encouraged.

One of troublesome areas is labeling of genetically engineered foodstuffs. Careful labeling of products would be informative for those averse to buying a product derived from a transgenic crop. Recognition of consumer's right to have information and make a choice, and in response to demands from opponents, grocery processors and other organizations are supporting the development of biotechnology labeling criteria for food production (Optima, 1999, Pollara and Earncliffe, 1999). The usual justification is to enable for consumers an informed choice in the market, ability to choose or avoid particular food. In this connection, it would be interesting this information given in a government-commissioned survey (Pollara and Earncliffe, 1999) related to Canada, of 1,515 Canadians, it was found that more respondents were startled to hear that up to 75 % of the ingredients were genetically modified and felt that this was allowed without their consent or knowledge. As a result, 93 % of respondents wanted the government to demand companies to voluntarily label products so that they could make an informed choice (Pollara and Earncliffe, 1999). The results also point out that Canadians are dissatisfied with the government's efforts at informing the public and want the government to toughen up the regulation of biotechnology. As for European consumers response, surveys constantly show that 97 % European consumers want labeling of all genetically engineered foods and 80 % do not want genetically engineered food at all. Biotechnology industry and government agencies recognize well that billions of dollars in agrobiotechnology sector mean nothing without consumer acceptance.

More broadly, critical reactions to emerging applications of biotechnology are based on control of research agendas, access to useful technologies, influence in decision-making forums, and debates over who will benefit from new technologies. Public attitude to genetically modified food is driven by uncertainty about possible negative health and environmental effects and a widespread

perception that producers and farmers are the primary and the main beneficiaries of agricultural biotechnology (Kamaldeen S., Powell D.A., 2000).

Biotechnology where the top five biotechnology firms control more than 95% of green transfer patents (UN Development Programs, 1999) is expected to give further impetus to the current process of globalization. It would be interesting to mention that two large biotechnology companies DuPont (already the world's largest seed company and fifth largest agro-chemical company) and Monsanto (already the world's second largest seed company and the second largest agro-chemical company) will control 41 % of GM crop patents and 93 % of the global GM seed market after pooling their resources in April and creation of DuPont-Monsanto alliance in April 2002 (ETC group, 2002), demonstrating concentration of capabilities and power in the hands of a small number of global players. So it addresses humanitarian, environmental and business ethic issues simultaneously.

The regulation actions on biotechnology issues should be built on trust in nondiscriminatory, science based principles and reflective of the judgments made by elected bodies with representative of public regarding risks and benefits to the environment and possible effects on human health. It should be mentioned that Europeans are more cautious and hesitant about some biotechnology applications and according to several surveys the European public expresses most trust in consumer and environmental groups than in government regulatory system. One of the main reasons of "trust crisis" (but not only one) is related to the recent events about the bovine spongiform encephalopathy (BSE better known as mad cow disease) and dioxin crisis which have delivered a huge blow to the credibility of science and authorities (Braun R., 1999). The BSE outbreak has cast "a crisis of confidence" in science and government and ability of the regulatory system to ensure food safety (Powell D.A., Leiss W., 1998, pp. 176-178) resulted finally in the slaughter of millions of animals and in economic losses totaling an estimated \$5.5 billion as a result implemented later by the U.K. government of stringent control measures (Moore J.A., 2001). The dioxin crisis was yet another food safety scare that questioned the competency of the regulatory system to manage risks and hinge on public attitude towards science in general and public confidence in government science, in particular.

The discussion and controversies surrounding some biotechnology applications highlight two fundamental issues: the scope for and need to reach agreement on a certain number of rules and principles while taking into account cultural and political differences, and the role that public authorities have to play in defining these rules and principles. The process for seeking consensus would be productive if it includes all parties representation, defining confronting issues such as acceptability of risks and ethical values, and willingness to listen, so this dialogue should be a two-way process including listening to others' perspectives and being willing to change one's own point of view.

There should be all conditions for improving the public's knowledge of science including television programs providing information on science, internet databases and editions, permanent or temporary exhibitions and events organized around these issues with efforts made to reach more cooperative links at national level and to strengthen cooperation at international scale. In view of this point, holding all these efforts could have positive effect with hope to solve debates in a manner satisfactory to all parties and lead to the process in which decision-makers should consider how they have represented the public and its concerns when making decisions. But this process is not straightforward because these issues are far more complex than generally portrayed and the

ways for conflict resolution should be found since it's obviously too late to keep the genie in the bottle (Mayer S, 1996, p.51), it's already out of the bottle and to some extent, unfortunately, it's out of control, and this is reality. The basic ways to solving these controversies may be viewed in responsiveness of authorities to public concerns and providing public participation and representation in decision-making process in the construction of new forms of governance, and providing greater public access to information, the opportunity to comment on proposed actions, the right to receive reasoned explanation and awareness in reaching compromising decision. The new interactive model should be developed with response to concerns raised by scientific experts, other organizations, and citizens for achieving consensus. The models of engaging the public before problems arise would lead to informed debates and increasing public trust in regulatory authorities to manage risks and ensure the safety of the food supply.

Given the substantial social and economic consequences of biotechnology, many perspectives are inserted into discussion and decision-making about biotechnology through participating institutions. The issue of accountable representation is central to the biotechnology debate, in which stakeholders' interests should be given priority, not only for reasons of justice and fairness but also because sustainable development of biotechnology will require widespread acceptance by the public of its goods and services. It's not related to European attitude to science. Sure Europe is not against science because of their sometimes questioning of the safety of biotech techniques and products. Although there has been determined opposition to some biotech applications, in particular, to GM food, Europeans are supportive of science and its benefits in areas where biotechnology might contribute. It's related to the solution of urgent problems, e.g. bioremediation, clean and sustainable products, e.g. renewable raw materials, save and sufficient novel vaccines and other pharmaceuticals for somatic gene therapy extending beyond heredity disease to the threatening of cancer and infectious disease like AIDS. And European investments in biotechnology research is comparable to that in the United States: over \$2 billion per year (Laget P., Cantley M., 2001).

Conclusions

As for agricultural biotechnology, public response concerns focus not only on the narrow scientific issues but also broader social, and ethical aspects creating enormous controversies, and one of the main factors in the emergence of these controversies has been neglect of the public needs, interests, and concerns in the biotechnology arena (Sagar A., Daemmrich A., Ashiya M., 2000). Biotechnology has become the contested battleground between contending historical forces and cultural values at this stage, resulting in firestorm of public debate, scientific discussion, and media coverage. I can't foresee the future of some biotechnological applications but this situation will be in dependence on the new forms proposed for solving controversies and cultural values adopted by individual human beings who, in turn, shape societal beliefs and values. Sure nobody would like that this situation with biotechnology (including long-term impact of GM modified agricultural products on human and animal health and environment, and recent research on cloning) would look situation with "Golen Science" (Collins H., Pinch T., 1993) which might destroy its masters with its cruel vigor. Or it should work by producing agreement among experts? But "scientists are nether Gods nor charlatans, they are merely experts, like every other expert on the political stage"

(Collins H., Pinch T., 1993, p. 148). And the future of biotechnology is viewed only in consensus of all participating institutions in this dialogue. But, unfortunately, the price for these decisions is too expensive for all society, and in extreme scenario biotechnology might be used for “bioterrorism” actions as well (FAO, p.10). But I would not like to be pessimistic in my perspectives on future of biotechnology applications. It’s only reminder for all of us about our own responsibility in this process.

Given current political and public opinion realities about Biotechnology, this open debate of contrasting and even conflicting viewpoints and public representation in implementing policies should promote convergence of policy and lead to reconciliation of rulemaking approaches with benefits to all parties.

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