ROLE OF PUBLIC PERCEPTION AND REGULATIONS IN THE ACCEPTANCE OF GENETICALLY ENGINEERED FOODS

by

Ravinder K Goyal

FOOD REGULATION IN THE UNITED STATES

Professor Neal Fortin

[December 4, 2008]

ROLE OF PUBLIC PERCEPTION AND REGULATIONS IN THE ACCEPTANCE OF GENETICALLY ENGINEERED FOODS

TABLE OF CONTENTS

ROLE OF PUBLIC PERCEPTION AND REGULATIONS IN THE ACCEPTANCE OF GENETICALLY ENGINEERED FOODS

Ravinder K Goyal

I. Introduction

In the era of modern agriculture, genetic engineering occupies an important place. Also, known as recombinant DNA (rDNA) technology or gene technology, it has capability of making alterations in the cellular DNA, which is a blueprint of life. As our understanding increased on the DNA function and mechanism, it widened the scope of using organisms in the benefit of mankind. The technology has revolutionized almost every field of biology including those that have direct relevance to human welfare i.e., biomedicine, diagnostics agricultural products and environment. In agriculture, the application of rDNA technology has brought about a tremendous increase in the novelty of foods. The foods are termed as genetically engineered (GE) foods when they are obtained from the plants, animals or other organisms with their DNA engineered. GE foods with tailor-made qualities promise benefits to producers, processors, operators and consumers. Nevertheless, like any other technology, which has certain risks associated with it, the production and consumption of GE foods are not completely free from the risks. The accrual of advantages of rDNA technology to its full potential, therefore, depends on how readily it is adopted by the public. The trust and perceptions of risks and benefits of gene technology weigh

significantly on the attitude of public towards its acceptance[1, 2], which indeed has shown a strong impact on the progress of GE foods[3]. Numerous factors account for in the process of trust building. Knowledge and awareness on the biology of GE foods and its implications is one of the components, which can play a substantial role in creating the public trust in GE foods. Not everyone can understand the complexities of GE but those who are trusted should be transparent on all facets of GE foods. For a continued trust, it is equally important to have a credible regulatory system, which is capable of preventing unsafe foods to land on a consumer's table. Otherwise, the fear of GE foods safety to consumer as well as to the environment will outweigh these foods' beneficial characteristics. This paper in brief will describe the GE foods, the regulatory framework and concerns associated with these foods. The last two sections will review, how the public perception and trust on gene technology influences the acceptance of GE foods and how confidence in regulatory system affects the trust in GE foods.

II. What are genetically engineered foods?

GE foods result from the genetic modifications of the organism employing rDNA technology. In rDNA technology, a recombinant DNA is prepared *in vitro* by cutting and splicing of DNA fragments from more than one organism. The

[1] Siegrist M (2000). The influence of trust and perceptions of risks and benefits on the acceptance of gene technology. *Risk Analysis*, **20**, 195-203.

[2] Bronfman NC, Vzquez EL, Gutirrez VV and Cifuentes LA (2008). Trust, acceptance and knowledge of technological and environmental hazards in Chile. *J. Risk Res.* **11**, 755-773.

[3] Rabino I (1994). How European and U.S. Genetic Engineering Scientists View the Impact of Public Attention on Their Field: A Comparison, *Science, Technology, & Human Values* **19**, 23–46.

insertion of rDNA into host produces a new genetic combination with valuable traits. The genetic modification is also a natural process where gene arrangements or transfer of genes takes place between closely related species. This property of plants or animals has been exploited in traditional breeding to improve the traits of an inbred organism. The use of rDNA technology allows the alteration and transfer of genes beyond closely related species to practically any organism. It is capable of transferring genes from a microorganism to plants and animals or from animals to plants or vice versa. There are surmounting evidences to believe that in the evolutionary process gene transfer was not restricted to closely related species. However, through rDNA technology it can be accomplished much faster than what Nature did in the past. Use of this technique can create different types of scenarios in the organisms that are source of GE foods.

a) An organism that has same genetic makeup but was manipulated to enhance or suppress one or more of its genes for a gainful purpose. For example, Flavr Savr™ tomato was produced by Calgene Inc. through suppression of one of the genes (encoding for polygalacturonase) that makes it soft during ripening[4].

b) Modification of a plant or an animal's genome by directly transferring a gene(s) from outside the closely related species but within the kingdom. Expression of human lactoferrin (an iron binding protein) in transgenic cow is an example of this type of GE food.

[4] First fruit: The creation of the Flavr Savr Tomato and the Birth of Biotech Foods' by Martineau, B., 2001, McGraw-Hill

c) A genetic makeup of a plant or an animal can be altered by introducing a gene(s) from a completely unrelated source. For example, the expression of a bacterial gene in plants or animals. Even the genes from insects, amphibians or animals have been expressed in edible food crops[5].

Genetic engineering is a powerful tool with wide range of applications to modify the foods or the organisms. The technology not only promises to feed the hungry through increased yield, but also can pack nutrients to alleviate the nutrient deficiency[6]. Notwithstanding benefits, there are concerns on the safety of GE foods the magnitude of which may depend on the manipulations carried out. Besides the safety, GE foods may have environmental and ethical considerations. These are discussed in a separate section.

III Regulation of genetically engineered foods in United States

The section briefly describes the framework of GE food regulation in United States. What are the different regulatory agencies and how they regulate various aspects of GE foods? What are the current regulatory guidelines being followed? The objective is to get an overview to make an assessment on their effectiveness to meet safety concerns without laying focus on the law details. More details can

[5] Osusky M, Zhou G, Osuska L, Hancock RE, Kay WW and Misra S (2000). Transgenic plants expressing cationic peptide chimeras exhibit broad-spectrum resistance to phytopathogens. *Nat. Biotech.* **18**, 1162-1166.

[6] Falk MC, Chassy BM, Harlander SK, Hoban IV TJ, McGloughlin MN and Akhlaghi AR (2002). Food biotechnology: benefits and concerns. *J Nutr*. **132**, 1384-1390.

be found elsewhere[7].

A. Regulatory agencies

In United States, the GE foods are regulated by three government agencies: Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the US Department of Agriculture (USDA). The FDA is responsible for the safety of food, feed and food additives. The Agency's Centre for Veterinary Medicine (CVM) oversees the regulatory procedure of genetically engineered (GE) animals. The USDA determines the safety issues of GE crops. The agency's Animal and Plant Health Inspection Service (USDA-APHIS) has the authority to monitor field-testing, interstate movement and importation of GE organisms. It can also deregulate commercial cultivation of GE crops based on the Federal Plant Pest Act (1957) and the Plant Protection Act (2000). APHIS ensures that GE crop is as safe as its traditionally bred counterpart so it can be freely used in agriculture. The EPA under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) regulates transgenic plants that have been modified to produce a pesticide substance. It ensures the safety of a pesticidal substance to the environment and establishes its permissible levels in food supply. The agency also evaluates pest resistant and herbicide resistant GE crops for their influence on the environment.

B. Regulatory guidelines

Genetically engineered plants, animals and animal clones are regulated

[7] Food Regulation: Law, science, policy and practice, by Neal D. Fortin, 2008 Willey.

by a different set of guidelines[8]. In brief, these are outlined here to give an overview to the consumer who can analyze the risks of GE foods.

Plants: To make a regulatory policy on GE foods, a newly established body, the Office of Science and Technology Policy (OSTP) after deliberations recommend that rDNA technology was not inherently risky and the regulations should focus on the risks of products, not the process used to develop them. The OSTP (1986) concluded that the products of rDNA technology do not require a special regulatory system and can be regulated by the current legislations and regulations. Following OSTP's recommendations, US National Academy of Sciences (NAS) prepared a report in which rDNA was not perceived with additional risks than that arise from the organisms with non-engineered DNA[9]. With this philosophy, GE plants are regulated through a coordinated mechanism of federal agencies - USDA, FDA and EPA.

The USDA regulates the import, interstate movement and cultivation of GE plants. Each type of GE plant is considered as "regulated article" under Plant Protection Act (2000)[10]. The plants with regulated status cannot be cultivated like other crops but have to follow certain guidelines. There exists a provision for GE plant developers to petition for "non-regulated" status. USDA's APHIS makes 'environment assessment' to determine the environmental safety under National

[8] Council on Environmental Quality and the Office of Science of Technology Policy. Case Studies of Environmental Regulation for Biotechnology, January 2001. (http://www.ostp.gov/html/02201.html)

[9] US National Academy of Sciences, 1987. *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues*. Washington DC: National Academic Press.

[10] Genetically modified pest-protected plants: science and regulations –report on US biotech regulatory system, National Academy of Sciences, National Academy Press, 2000, Washington DC. (http://www.nap.edu/books/0309069300/html)

Environment Policy Act (1970). After 'Finding of No Significant Impact' to the environment, 'non-regulated' status to a GE plant is granted, which enables its commercial release.

FDA under FD&C Act USC 301 regulates new food and feed regardless of method of production. FDA ensures the safety of GE foods through a concept of 'substantial equivalence' i.e., by comparing them with genetically unmodified counterparts. It takes into consideration the presence of allergens, toxins, anti-nutritional substances and the level of nutrients. FDA's 1992 policy statement granted GE foods presumptive 'generally recognized as safe' (GRAS)[11]. Foods containing hazardous or unexpected substances are labeled as 'adulterated' and are regulated thereof. FD&C Act does not give authority to FDA to seek pre-market approval of GE whole foods rather its approach to safety relies on post-market enforcement against unsafe foods. In case, the GE event intends to add a new substance to the food then it would be regulated under the regulatory laws on additives. More details on regulations can be found in review articles[12, 13].

Animals: The regulatory authority on transgenic and cloned food animals is vested with FDA's Centre for Veterinary Medicine (CVM). The Agency regulates GE animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), and FDA's regulations for new animal drugs. For the purpose of regulations FDA considers the progeny of transgenic animals to be

[11] Pelletier DL (2005). Science, law and politics in FDA's genetically engineered food policy: scientific concerns and uncertainties. *Nut. Rev*. **63**, 210-223.

[12] Pelletier DL (2005). Science, law and politics in FDA's genetically engineered food policy: scientific concerns and uncertainties. *Nut. Rev*. **63**, 210-223.

[13] McHughen A and Smyth S (2008). US regulatory system for genetically modified [genetically modified organism (GMO), rDNA or transgenic] crop cultivars. *Plant Biotech. J.* **6**, 2-12

transgenic regardless of the presence of a transgene. There are procedures to request for the approval of transgenic animal food for human use. Recently (September 18, 2008), CVM released draft Guidance for industry to clarify the Agency's regulation of GE animals[14]. However, FDA has yet to grant permission to any GE animal for food supply.

Cloned animals: The regulatory agencies view cloned animals differently than the GE animals as these are not produced by applying rDNA technology. Consequently, cloned animals undergo less stringent regulatory guidelines as source of foods. On the separate regulatory guidelines for GE animals and animal clones, the Agency's response is reproduced below:

> In the case of clones, the agency first needed to determine whether food from clones posed any additional risks compared with food from more conventionally bred animals. Following the completion of a comprehensive risk assessment, the agency was able to determine that cloning fell on the continuum of assisted reproductive technologies, and that cloning poses no new risks to the health of animals involved in the cloning process or to food from cattle, swine, or goat clones or the progeny of clones of any species traditionally consumed as food. Additionally, clones are not different from non-clones with respect to their DNA; only the method by which they are produced is different. Therefore, FDA determined that no additional regulatory oversight was necessary.

Based on the comprehensive risk assessment, the agency in its notification on January 15, 2008 allowed the cloned animal as food source[15].

IV. Concerns associated with genetically engineered foods

The GE foods raise a specter of concerns in their all-possible forms. Many

[14] http://www.fda.gov/cvm/GEgeneralQA.htm

[15] http://www.usda.gov/wps/portal

of these concerns are born out of ignorance on GE foods and do not have any scientific basis. Nevertheless, there are legitimate concerns associated with the development and consumption of these foods. A brief review of the concerns is presented here.

A. Food safety

In rDNA technology, a part of DNA is inserted into the existing DNA of an organism. The product of inserted DNA is either known or can be anticipated, which is easy to evaluate for its toxicity to the human system and livestock. Insertion of DNA is an uncontrolled event, which can change the genetic makeup of the organism in many ways giving rise to the potential of creating unintended effects. It may arrest, lower or enhance the expression of certain genes whose products may exert control over allergenic -, toxic -, nutrient - or anti-nutrient - substances. It is practically impossible to search for every possible effect of the integrated gene in the organism. Moreover, the effects would be unique to every insertional event. To circumvent the difficulties and to ensure food safety the concept of 'substantial equivalence' was developed. It says that if it can be demonstrated that the novel food is essentially similar to its counterpart in terms of nutritional and anti-nutritional components then it is likely not to be more toxic than the latter. Application of the concept is not a complete safety assessment but provides a starting point of the assessment[16].

B. Environmental concerns

Introduction of GE organisms into the agriculture system can indirectly affect

[16] Kuiper HA, Kleter GA, Noteborn HPJM and Kok EJ (2001). Assessment of the food safety issues related to genetically modified foods. *Plant J.* **27**, 503-528.

human health through their impact on the environment by gene flow[17]. There is a possibility that pollens or seeds escape to the environment and spread the introduced gene to unrelated recipients. Another type of environmental concern is linked to planting of GE plants with resistance against insects. An insect specific toxin produced by *Bacillus thuringiensis* (Bt) is widely used to engineer insect resistance in plants. The fear is that cultivation of these crops on large scale would threaten beneficial insects of ecosystem because of the Bt crops' potential non-specificity to the targeted insect(s). The threat to biodiversity gained momentum when the Bt cotton showing resistant to European corn borer also showed a certain degree of toxicity to Monarch butterfly. The opponents of GE crops raised the pitch questioning the safety of GE plants. Subsequent investigations by conducting more research on the safety of Bt toxin alleviated the safety concerns but absolute safety could not be guaranteed[18]. Environmental concerns also arise from herbicide tolerance of GE plants. It is speculated that growing these plants would encourage application of pesticides in higher doses leaving more amount of the residues in the environment. EPA guidelines, however, strictly regulates the pesticide usage. The horizontal gene flow from herbicide resistant crops to natural weeds is feared to create "superweeds". The scientific data suggests that genes conventionally flow between related species but the possibility cannot be ruled out[19, 20]. More

[17] Haslberger AG (2006). Need for an "Integrated safety assessment" of GMOs, linking food safety and environmental considerations. *J. Agric. Food Chem.* **54**, 3173-3180.

[18] Pew Initiatives on Food and Biotechnology – Three Years Later: Genetically Engineered Corn and the Monarch Butterfly Controversy, June 10, 2002. (www.pewtrusts.org/our_work_detail.aspx?id=442

[19] Ellstrand NC (2001). When transgenes wander, should we worry? *Plant Physiol*. **125**, 1543-

information on the environmental impact of GE crops and comprehensive regulations can be found elsewhere[21] [22].

C. Social and ethical issues

The range of social and ethical concerns linked with the consumption and development of GE foods is exceedingly broad[23]. The group who supports animal welfare does not want the animals be experimented with because manipulations at some stage inflict sufferings to them. There are religious concerns with GE foods when the genes are transferred from prohibited animals to foods. While others find it unacceptable to have animal genes in plant foods. Yet others consider it unethical to disrupt the ecosystem. The patenting of new genetically modified organisms (GMOs) implies that life has become a commercial property.

The term 'ethics' is a broad and vaguely defined term. Something unethical for one segment of population does not appear un-ethical to the other segment of population. This presents a difficult challenge to regulatory authorities to frame guidelines for the use and development of GE foods. Therefore, it is not surprising that there are no laws to regulate GE foods based on ethical issues. The existing laws require regulators to review genetically modified animals using scientific risk assessment protocols; they do not make provisions for regulators to take ethical or moral issues into consideration in decision making.

1545.

[20] Snow A (2002). Transgenic crops –why gene flow matter. *Nat. Biotechnol*. **20**, 542-543.

[21] Haslberger AG (2006). Need for an "Integrated safety assessment" of GMOs, linking food safety and environmental considerations. *J. Agric. Food Chem.* **54**, 3173-3180

[22] US National Academy of Sciences, 1987. *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues*. Washington DC: National Academic Press.

[23] Thompson PB and Hannah W (2008). Food and agricultural biotechnology: a summary and analysis of ethical concerns. *Adv. Biochem. Eng. Biotechnol.* **111**, 229-264.

V. Public perception and acceptance of genetically engineered foods

To realize the benefits of any technology to its full scope, it is fundamental to have public trust in the technology. A combination of factors with varying degree of impact contributes to the process of a trust build-up. Some of these factors cut across scientific lines and cannot be reasoned out. The trust is a driving force for a positive public perception or opinion, which governs the acceptance or non-acceptance. Without trust and willingness of acceptance there will not be anything to offer as reflected by the following quote.

> With all that biotechnology has to offer, it is nothing if it's not accepted. This boils down to a matter of trust—trust in the science behind the process, but particularly trust in the regulatory process that ensures thorough review—including complete and open public involvement.
>
> Dan Glickman
> (Former US Secretary of Agriculture)

How is trust placed in the context of GE food acceptance will be discussed in this section. The role of more complex issues of society and politics is beyond the scope of present discussion.

A. Knowledge and perception

Knowledge and awareness on all aspects of a technology, genetic engineering and foods in the present case, play a decisive role in shaping the perception. The absence of a reliable knowledge along with emotive factors

results in low degrees of public acceptance of agricultural biotechnology[24]. The public perception of risk with lack of knowledge may be different than the knowledge-based perceptions of experts[25]. This makes one ponder what type of knowledge is necessary to create trust in GE foods? Public in general may not be interested in the fine details of GE process. More relevant to people is the perceived outcome. How is it going to benefit an individual and mankind on whole? What would be the cost borne by the society in terms of human health, protection to environment, and freedom to choose. Even if we ignore benefit and cost (risk) temporarily the morality of the act needs to be socially justified.

The benefits and risks of GE foods have opposing effects on public perception of GE foods. The benefits of GE foods are virtually unlimited ranging from better sensory and processing qualities to nutritive or therapeutic values. The types of risk include a direct risk to health, to the environment and perceived risk to the next generations. If something is stigmatized out of risk possibilities, even overwhelming benefits may not be able to undo the fear. In the age of rapidly advancing technologies sometimes it is difficult for the public to make their own risk analysis on the pros and cons. Under the given circumstances the public rely on the different institutions that include scientific as well as non-scientific[26]. Although the report suggested that the evaluators – scientists, universities, and medical professionals are trusted the most but it may only hold true as long as

[24] Peterson RKD (2000). Public perceptions of agricultural biotechnology and pesticides: Recent understandings and implications for risk communication. *American Entomology* **46**, 8-16.

[25] Slovic P (1987). Perception of risk. *Science* **236**, 280-285.

[26] Lang JT and Hallman WK (2005). Who does the public trust? The case study of genetically modified food in the United States. *Risk Analysis* **25**, 1241-1252.

they are not perceived working for their self goals. The accuracy of assessment that is tested with time is crucial for maintaining the trust in the scientific bodies. Also, important is that scientists, regulators and industry take account of actual public concerns[27]. Trust in these institutions promotes a positive perception about biotechnology and as a consequence, gene technology is assessed as beneficial and not laden with dangers to our society[28]. Otherwise, people may misperceive the risks and uncertainties and be swayed by the exaggerated claims of those opposing the technology[29]. For instance, Bt corn and Monarch butterfly provided a perfect recipe to the opponents of GE technology to claim serious imminent dangers of pursuing GE foods. They managed to create headlines from around the country that emphasized the risk to the beloved butterflies[30].

> The *San Francisco Chronicle* warned "Gene Spliced Corn Imperils Butterflies." In Boston, the *Globe* headline read, "Butterfly Deaths Linked to Altered Corn." And, the *Los Angeles Times* maintained "Genetically Engineered Corn May Have Adverse Effects on Monarch Butterflies."

The incidents, which are a part of the associated risks, when exaggerated, make a severe dent in the trust in scientific institutions and as well as in GE foods. Public polls on the GE foods showed highest opposition (58%) in 2001 after

---

[27] Frewer L, Lassen J, Kettlitz B, Scholderer J, Beekman V and Berdal KG (2004). Societal aspects of genetically modified foods. *Food Chem. Toxicol.* **42,** 1181-1193.

[28] Siegrist M (2000). The influence of trust and perceptions of risks and benefits on the acceptance of gene technology. *Risk Analysis*, **20**, 195-203.

[29] Freudenberg WR (1993). Risk and recreancy: Weber, the division of labor, and the rationality of risk perceptions. *Social Forces* **71**, 909-932.

[30] Pew Initiatives on Food and Biotechnology – Three Years Later: Genetically Engineered Corn and the Monarch Butterfly Controversy, June 10, 2002. (www.pewtrusts.org/our_work_detail.aspx?id=442)

another incident of StarLink corn in September 2000. Enormous benefits without reoccurrence of biological accidents provide a healing touch and help in the restoration of trust. It was reflected in softening of the public opposition to GE foods from 58% to 46% in 2006, though the support remained study at 27%[31]. The report further suggested that the advantages led to increase in popularity of GE or genetically modified crops that showed a significant expansion in GM corn plantation from 26% in 2001 to 61% in 2006. Today, more than 100 million acres of GE crops are grown in US covering a wide range of crops including corn, cotton, canola, soybean and squash.

B. Bioethics and public attitude

Food safety may be of the primary concern but bioethics has a substantial influence on the public perception of GE foods. The ethical sentiments are complex and vary in different parts of the world. Several factors including personal belief, religion, and concept of life form the basis of ethical sentiments. When viewed through the prism of ethics the manipulation of genes, which are messengers of life, gives a sense of immorality as the action is perceived against God's will. It amounts to defying His order on worldly lives thereby creating a fear of being punished in the form of natural disasters. The stem cell research and its application is a controversial issue for the same reasons. Similarly, the religious beliefs act as a strong factor in the selection of foods. For those who are vegetarian and are forbidden to eat meat or others who cannot consume certain type of animal meats, the transfer of animal genes into plants creates a negative

[31] Pew Initiatives on Food and Biotechnology – Public Sentiment About Genetically Modified Food. Dec. 01, 2006. (www.pewtrusts.org/our_work_detail.aspx?id=442)

perception vis-à-vis unacceptability. To find the extent of opposition to certain GE foods, I conducted a small survey in Victoria, Canada on 20 consumers who were vegetarians by religion. The results showed (Table 1) a high degree of discomfort to accept GE food with animal genes. Although the number of people surveyed was small to draw a valid conclusion but it reflected a trend that religion and ethical concerns weigh heavily in making perception on certain type of GE foods. Also, it showed that with education the extent of opposition was reduced.

Table 1. Acceptability of GE plants with animal genes among vegetarians by religion

Question	**Response**			
Acceptability of plant food when,	Strongly opposed	Moderately opposed	Doesn't affect	Supported
Animal gene(s) transferred	12	6	2	0
Told that transfer of a few genes doesn't impart animal taste and characteristics and hundreds of genes are common in plants and animals	8	4	6	2

In Pew Initiative workshop on moral and ethical aspects on GE and cloned animals it was acknowledged that ethical and welfare concerns are factors in whether consumers will accept or reject transgenic animals and the products of animal cloning in the marketplace[32]. Subsequently, it was found that Americans

[32] Pew Initiatives on Food and Biotechnology - Workshop Proceedings on Moral and Ethical

with strong religious attendance are also more likely to be uncomfortable with animal cloning. And among these people 'religion and ethical concerns' was the biggest factor for their negative attitude. In general, the public is more concerned with the use of animals rather than plants or microorganisms[33]. From the studies, it is apparent that for wider acceptance of GE and the foods the religious and ethical concerns needs to be appropriately addressed. In this context, sociologists argue for greater public involvement in the early stages of policy information and scientific agenda setting[34].

VI. Confidence in regulatory framework

As discussed earlier, GE and the foods produced through this technology have certain inherent risks. To introduce these foods for their beneficial effects there must be a credible mechanism to contain the risks. The latter creates the sense of safety, which is directly correlated with the consumer confidence and acceptability[35]. With fearful mind and imminent danger one is unlikely to embrace the gene technology. The safe application of gene technology depends on the effectiveness of a regulatory framework. Public confidence in a regulatory framework corresponds to the level of assurance it can provide. More it is able to guarantee the safety higher will be the confidence. This principle was applied in the concluding comments of the General Accounting Office report on genetically

Aspects of Genetically Engineered and Cloned Animals. Oct. 28, 2005. (http://www.pewtrusts.org/news_room_detail.aspx?id=20052)

[33] Frewer LJ, Howard C, and Shepherd R (1997). "Public Concerns in the United Kingdom about General and Specific Applications of Genetic Engineering: Risk, Benefit, and Ethics," *Science,Technology, & Human Values* **22**, 98–124.

[34] Cunningham-Burley S (2006). Public knowledge and public trust. *Community Genetics* **9**, 210-214.

[35] Ryuichi T (2004). Food safety and consumer confidence: Prospects for food product distribution reform on traceability. *Agric. Information Res.* **13**, 1-17.

modified foods to enhance confidence in the regulatory procedures[36].

What makes people believe that the regulatory framework is robust and effective? A few aspects deserve attention in this context. First, how appropriately consumer concerns are addressed in the formulation of regulatory policy on the development and consumption of GE food? A priority to a consumer rather than to the developers or merchants reinforces the consumer confidence in regulatory process[37]. However, it is important to keep in mind that very tight regulations slow down the flow of benefits to the consumers. It may even deprive them of the potential advantages due to prohibitory cost of unreasonable and impractical regulations. Therefore, it needs a delicate balancing act and absolute consumer confidence would not come, if absolutely there were nothing on the table. Another related factor in the formulation of regulatory policy is the consensus among the scientific fraternity. A lack of consensus on safety assessment of any issue on biotechnology may negatively affect the consumer confidence in regulatory procedures. For example, inconsistency in food safety standards among European Union and United States may provide reasons to a consumer to question the lenient approach on GE food safety. It is not unreasonable to believe that human physiology is similar across the globe. And if something were unsafe for people in one part of the world, it is unlikely that it would be safe in the other part of the world.

The implementation of regulatory guidelines and maintaining a proper

[36] GAO Report submitted to the Congress on genetically modified foods. GAO-02-566 Washington DC. (http://www.gao.gov/new.items/d02566.pdf)

[37] De Jonge J, Trijp H, Renes RJ and Frewer L (2007). Understanding consumer confidence in the safety of food: Two-dimensional structure and determinants. *Risk Analysis* **27**, 729-740.

discipline are the basic components of any technology to deliver benefits with minimal risks. The regulatory guidelines serve as an important tool to reduce the risks under given circumstances. Although in long-term they help keep the industry, merchants and even the technology itself afloat but the actors in the food chain do not always consider them as friendly. To gain a competitive edge by the developers and merchants or the quest for rapid accumulation of wealth, the regulations and risk management practices are in danger of being pushed to the back. On other occasions there may be an unintentional compromise on the safety of GE foods. The watchdogs –FDA, USDA and EPA have the fundamental responsibility to ensure that regulatory guidelines are followed in a true letter and spirit. How effectively these agencies discharge their responsibility relates to public trust in the regulatory framework. Therefore, trust in the regulatory institutions positively influence consumer confidence in the safety of foods[38]. The case of StarLink corn that contained a Bt protein Cry9c severely tested the efficacy of regulatory agencies. EPA only approved the Bt corn due to its potential allergenicity in humans for animal feed. During summer 2000 StarLink corn was detected in trace amounts in human food chain. Even though the allergenic reactions in humans were never proved, it rattled the confidence in regulatory agencies. Not only it inflicted huge financial losses to the companies but also shook the public confidence in GE foods. To boost the confidence in regulatory agencies and GE foods, the General Accounting Office[39] reviewed the

[38] Grunert, KG (2002). Current issues in the understanding of consumer food choice. *Trends in Food Science and Technology*, ***13***, 275–285.

[39] GAO Report submitted to the Congress on genetically modified foods. GAO-02-566 Washington DC. (http://www.gao.gov/new.items/d02566.pdf)

functioning of FDA with respect to GE foods. The report concluded:

> Biotechnology experts believe that the current regimen of tests has been adequate for ensuring that GE foods marketed to consumers are as safe as conventional foods. However, some of these experts also believe that the agency's evaluation process could be enhanced. Specifically, FDA could verify companies' summary test data on GE foods, thus further ensuring the accuracy and completeness of this data. In addition, the agency could more clearly explain to the public the scientific rationale for its evaluation of these foods' safety, thereby increasing the transparency of, and public confidence in, FDA's evaluation process. By addressing these issues, FDA's assurance to consumers that GE foods are safe could be strengthened.

A survey showed that the public trust in FDA has declined significantly since 2001[40]. Enhancing the safety without putting too much burden on the industry will strengthen the trust in regulatory agencies, which in turn would promote the popularity of GE foods. The Pew Initiative study indeed has suggested that a continued use of biotechnology products without any safety issues increased their safety perception about these foods.

VII. Conclusion

The genetic engineering has a tremendous potential to create a diverse range of GE foods. Whereas these foods promise to deliver huge benefits, they raise certain concerns on their use and development. The public perception on these concerns is greatly influenced by the developers, merchants, regulatory

[40] Pew Initiatives on Food and Biotechnology – Public Sentiment About Genetically Modified Food. Dec. 01, 2006. (www.pewtrusts.org/our_work_detail.aspx?id=442).

agencies and the media. Public awareness and its participation in the development of certain GE foods with contentious issues can boost the confidence in these foods. Although GE foods can have certain associated risks but when appropriately addressed these should be deemed as safe as non-GE foods. To harvest the rewards of gene technology in its benign form, it is critical that the regulatory framework is robust and effective. To keep the trust and positive perception, however, no Chernobyl of biotechnology should happen.