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GENETICALLY MODIFIED FOODS AND ORGANISMS: WHAT IN THE WORLD...?

A Comparative Analysis of the Environmental, Economic and Social Issues Surrounding GMOs and the Current Regulatory Response in the United States, European Union and United Kingdom[a]

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ABSTRACT

This paper examines the current controversy over genetically modified organisms and foods and compares the regulatory response in the United States, European Union and United Kingdom. The paper begins with a discussion of the issues central to the debate on genetically modified foods and organisms: the safety of GM food products, potential environmental risks from GMOs, potential benefits of GMOs and resulting products, economic and trade issues, availability of consumer information, and social/ethical issues. The authors argue first, that there is an environmental, social, and economic basis for regulation. Second, while the reaction of regulators in the European Union and the United Kingdom has been to apply the "precautionary principle", reflecting the public's intense distrust of any type of genetic engineering, the current regulatory response in the United States may not adequately protect against potential environmental and health risks, nor does it provide sufficient information to potential consumers of GM foods.

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1. INTRODUCTION

On January 29, 2000 in Montreal, delegates from more than 130 nations adopted a treaty regulating trade in genetically modified products. The treaty, called the Cartagena Protocol on Biosafety, allows countries to bar imports of genetically altered seeds, microbes, animals and crops that are deemed a threat to the environment. This followed a year in which controversy over genetically modified (GM) foods soared; major food companies including Frito-Lay, Gerber, McCain Foods and McDonald's vowed not to buy the crops from genetically modified plants, shareholder resolutions related to genetically modified foods appeared on proxy statements of companies including Kellog and Philip Morris, and farmers from the United States reported for the first time since the introduction of genetically modified seeds that they intended to plant fewer acres of GM seed in the future. Yet despite the overwhelming attention GM food and genetically modified organisms (GMOs) have received recently, reliable information on the safety of the technology for human health or potential environmental impacts is scarce. Further, in the United States, it is difficult to even determine whether, and which, regulatory agencies are monitoring and assessing the health and environmental risks posed by this emerging technology.

2. ISSUES CENTRAL TO THE DEBATE OF GENETICALLY MODIFIED FOODS AND ORGANSIMS

Every organism is made up of cells which contain within the nucleus a substance known as deoxyribonucleic acid, or DNA. DNA is often referred to as the "blueprint" for the cell, in that it directs the functions and structure of all the cells of the organism. Genes are sequences of DNA which code for a specific characteristic or trait. Each organism contains hundreds of thousands of genes, each with a specific purpose.

The ability to manipulate the genetic structure of a living organism is the key to designing an organism with certain desired traits. In traditional agricultural breeding, this ability is limited to those traits which are available within the gene pool of a given species. Thus, for example, a specific hybrid of wheat can be obtained by crossing two types of wheat with varying characteristics, eventually giving rise to a crop with what might be considered "superior" traits. However, this type of breeding cannot bend the rules of nature in that it may not borrow characteristics from another species. Only those traits which occur naturally in some variety of wheat can be bred into a new wheat hybrid.

A genetically modified organism, or GMO, is one in which those limits have been breached. A gene from one species can now be spliced and inserted into a totally unrelated species, conferring a new and unusual characteristic in the host species. While some interspecies breeding has been accomplished (i.e. a tangelo is a cross between a grapefruit and a tangerine and a mule is a cross

between a horse and a donkey), these are *related* species, or species in the same genus. These cross bred results are almost always infertile. When we consider genetically engineered lifeforms, we are discussing end-products which contain genetic material from two unrelated species, sometimes from different kingdoms entirely. (For example: the SuperSavr tomato which has genetic material from a flounder). While theoretically possible for quite some time, the practical matter of inserting the gene was a major obstacle until the last 15 years or so. Now genetic material can be taken from flounder, for example, and inserted into tomatoes, or from bacteria and inserted into potatoes.[i] It is a difficult and expensive technology, to be sure, and the success rate in the lab is usually low, but the potential economic rewards are extremely high.

The lucrative possibilities have motivated a number of firms, including Monsanto, Novartis and DuPont to focus on this emerging technology. Currently there are a number of products sold commercially which are the result of genetic modifications including: potatoes and corn with "in-plant" insect protection, and soybean which is impervious to herbicide. In the United States in 1998, 33% of the US corn crop, 42% of the cotton crop and 35% of the soybean crop were GM varieties (Kluger 1999).

2.1 ISSUES CENTRAL TO THE DEBATE

The public reaction to GMOs has varied from public protest and outcry in the European Union upon the introduction of GMOs and GM food products to almost no reaction until quite recently in the United States. The issues central to the debate include: the safety of GM food products, potential environmental risks from GMOs, potential benefits of GMOs and resulting products, economic and trade issues, availability of consumer information, and social/ethical issues. Each issue is explored below.

2.2 THE SAFETY OF GM FOOD PRODUCTS

Unlike the European Union, the U.K. and other nations, the U.S. attitude toward GMOs and the biotech food industry seems to be "innocent until proven guilty". While no serious health-related problems seem to have surfaced thus far, consumer and industry critics alike voice concerns about undetected allergens in the new products. For example, in 1996 Pioneer Hi-Bred researchers developed a genetically engineered soybean containing a Brazil nut protein with the goal of creating a more nutritional product. Concerned with the known allergic reactions to Brazil nuts experienced by some individuals, scientists tested the soybean for human response. Some reactions did occur, were reported in *The New England Journal of Medicine*, and consumers were put on alert to that which might have had lethal consequences (GEF 35). This is especially troublesome to those who believe that these products may contain substances which would constitute "new allergens" and would therefore not be noticed in traditional tests of allergenicity. Bt (bacillus thuriniensis), for example, is considered safe in so far as it is used as a spray for pesticide

purposes. It quickly degrades, and is non-toxic to humans. However, no study has been done to determine what effects, if any, might occur when massive amounts of Bt are ingested through GM food products which contain Bt in every cell of that product (or of a key ingredient in the product). General toxicity might be a problem. However, allergenicity has not been considered.

This, added to the oftime "hidden" nature of modifications fuels the rising rate of consumer suspicion. Food-related biotech companies claim that agriculture has, at its core, modification, but critics counter that industry's manipulations are far different and more troublesome than farmers' and nature's selection processes. While there is no evidence which suggests that GM food products are toxic or will promote disease, there is of course no proof that the products are safe. Thus, in many minds the "big unknown", the potential for human risk is impossible to accurately assess at this point. For this reason, no new GM crops or food products have been approved in the E.U. since early 1998.

The National Academy of Sciences, in the U.S., released a report in April on its yearlong study of GM crops, and concluded that there is no evidence that GM foods are unsafe to eat. However it recommended that scientists develop better methods of identifying potential allergens and focus on new tests relevant to the human immune system.

2.3 POTENTIAL ENVIRONMENTAL RISKS FROM GMOs

Environmentalists have been concerned for a long time about the increased dependence upon monocultures to feed an ever growing world population. These crops pose two major problems for future food production. The first concern is the vulnerability of a monocrop to disease and pests. Large tracts of land given over to one crop alone provides an opportunity for disaster. Perhaps the most dramatic example is the Irish Potato Famine of the mid 19th century. Although there are thousand s of varieties of potatoes grown in Central and South America (where potatoes originated), the Irish crops were genetically limited and therefore extremely vulnerable to a disease known as *Phytophtora infestans,* or potato blight. In a matter of only a few years, this lack of resistance led to the ravaging of crops in Ireland.[ii]

The second concern is the loss of biodiversity and the growing extinction of many native species and landraces[iii]. As we lose these varieties of plant species, we lose the valuable genetic material we might need to save major food crops in the event of the aforementioned disasters.

Genetic engineering increases the risk quotient in several ways. It promotes rather than discourages the monoculture mentality. Industry offers a way to "fix" an industry-caused problem without solving the larger issue. Nature has always adapted to an ever-changing environment, and there is no reason to believe that genetically manipulated plants and animals are in any way immune to the effects of such adaptations. The very pests and diseases these genetically engineered plants were designed to withstand will, in fact, mutate and develop resistance to the engineered changes, starting a cycle of increased

dependence on further manipulation in the genetic makeup of the plant. These mutated agents, by definition, will have developed resistance and will therefore pose an even greater threat. Some organic farmers are concerned because Bt (Bacillus thuringiensis) bacterium, a natural pesticide which has been sprayed on crops for years, has been genetically engineered into potatoes, corn, soybean and other crops. They fear that this natural pesticide will become ineffective as bugs develop resistance. Further, as the "killer" bees, which were the result of African bees breeding with domestic bees, arrive in California, some wonder if "killer" weeds or other life-forms will result from GMOs. It is impossible to assess the risk of "genetic pollution" as genetically engineered animals and crops "accidentally" cross-breed with wild species, creating novel life forms in an unsuspecting environment. However, in May 1999, a research team from Cornell University published the results of a study in the journal, *Nature,* showing that pollen from Bt engineered corn was lethal to Monarch butterflies. What made this study particularly noteworthy was that the Corn Belt is the breeding range for these butterflies. While this research was conducted in a lab, and no studies have conclusively shown that there is a significant threat in actual fields, the results are troubling since they highlight how little is known about unanticipated and long-term implications of genetic engineering.

In its April report on GM crops, the National Academy of Sciences noted that the decision by the EPA to treat many GM crops as inherently safe is unwarranted since too little is known about crop biotechnology. Currently GM crops which are the result of genes transplanted from a closely related plant and crops which include a gene from a virus aimed at immunization against disease are viewed by the EPA as safe.

2.4 POTENTIAL BENEFITS OF GMOs AND RESULTING PRODUCTS

Despite the valid fears raised by critics, GMOs do offer significant benefits and potential benefits in a number of areas. Proponents argue that genetic modification will lead to a second "green revolution" in agriculture. Indeed the USDA claims that increased yields from genetically engineered crops and seeds altered to withstand harsh conditions will play a pivotal role in feeding the growing world population. The two most important bioengineered traits to date have been herbicide tolerance and insect resistance. Herbicide tolerance allows plants to withstand the use of selected pesticides, enabling farmers to easily apply these chemicals without fear of crop destruction. Seeds which have been engineered to provide "in-plant" insect protection reduce the need for pesticides and the need for the fuel used to produce, distribute and apply the pesticides. Growing world populations may also benefit from crops recently engineered to provide viral , fungal and drought resistance. Since those living in the developing world spend a large portion of their income on food, improvements in yield and reductions in crop prices would have a significant positive impact on the standard of living in these regions. While the focus has been on produce, Aqua Bounty Farms has developed a GM salmon which matures in half the time of a natural salmon and goats, sheep and pigs

have been genetically modified to produce human proteins for pharmaceutical purposes, providng a cheaper means of obtaining these substances (Boyens 152).

According to US Department of Agriculture records, over 4500 genetically altered plant varieties have been tested in the US and over 50 have been approved for unlimited release (Mann 1999). These include more crops with "in-plant" insect protection and seeds with an extended shelf-life. And under development are lower cholesterol foods like leaner pigs, golden rice which contains vitamin A and would benefit those poor suffering from vitamin A deficiency, bananas which protect against hepatitis and vegetables designed to fight cancer.

2.5 ECONOMIC AND TRADE ISSUES

The GMO debate has at its core two economic issues: first, the extent of the "rights" of corporations to pursue promising and potentially very lucrative new developments in biotechnology; and second, the role of the impact of rapid population growth in the developing world. As mentioned above, an important benefit of GM crops and seeds is that genetic modifications may lead to improved yields which may very well be necessary to feed the growing world population. Some argue that critics of biotechnology live in more developed nations and face no threat of starvation. Firms engaged in biotechnology argue that developments will enhance the standard of living in the developing world, as well as the rest of the world, and that all products and processes are carefully tested and entail no significant health or environmental risk.

The GMO debate has trade implications as well. The Cartagena Protocol on Biosafety, signed by 130 nations on January 29 of this year in Montreal, regulates trade in GM products. The treaty allows countries to bar imports of genetically altered seeds, microbes, animals and crops that are deemed a threat to the environment. Many aspects of the treaty were fought bitterly by the U.S., especially during the earlier negotiations in Cartagena. Since the U.S. never ratified the Convention of Biodiversity in Rio de Janeiro in 1992, it cannot become a party to the Biosafety Protocol. However, American firms exporting to countries which are parties to the Protocol, will have to comply. The Protocol is based on the "precautionary principle", that is, it permits a country to take action to protect itself even in the absence of scientific evidence of danger. The U.S. claims it fears European nations will use this principle to exclude some American imports. To protect against such a situation, the Protocol does not relieve nations from World Trade Organization obligations implying that bans could be subject to challenge under WTO trade rules.

The trade debate rages on and raises interesting questions including: Should the U.S. force its views on what constitutes a "threat" to the environment? What if there is an incident of environmental damage? Should the pressing needs of the developing world for greater yields and crops which can resist fungus, drought, pests and viruses imply that some risk of environmental damage is tolerable?

2.6 AVAILABILITY OF CONSUMER INFORMATION

While Europeans are generally aware of the presence of GM foods, most Americans do not realize what GM food is or whether they have eaten it. A 1999 *Consumer Report* test found genetically engineered ingredients "in everything from infant formula to corn-muffin mix to McDonald's *McVeggie Burgers.*"(September 1999).

While many groups involved in the GM debate claim to be protecting the public interest, membership seems skewed toward corporations active in the industry. Even on the Codex Alimetarius Commission, an international agency of the U.N.'s World Health Organization charged with setting labeling standards, the majority of non-governmental members represent large corporations and industry groups. Many of these industry giants cite "fear of consumer hysteria" as the reason for their reluctance to label GM foods and seeds. Unwilling to wait for Codex to issue international standards, many countries (i.e. Britain through its British Medical Association -BMA) have begun a move to protect their citizens by calling for caution, demanding labeling, and urging a halt to the planting of GM crops until there is a consensus regarding the allergenicity and long-term affects of these products.

In the U.S., however, White House officials continue to defend the current course of voluntary labeling *unless* the nature of the food has been altered or that potential allergens have been introduced. Environmental and consumer groups, however, are demanding that the FDA follow the lead of the European Union and Japan by requiring GM labeling. So the debate rages on with one camp calling for universal labeling to enlighten the consumer, and the other claiming that such labeling would confuse, rather than inform, because of the variety of genetic modifications applied to these organisms.

2.7 SOCIAL AND ETHICAL ISSUES

From its beginning, world-wide agriculture has been based on a system of slavery and serfdom (GEF 90). Traditionally, farmers have become more independent as they struggled for autonomy over their land and livelihood. Enter...the biotech agricultural revolution. Once more the specter of serfdom has arisen because farmers may no longer plant the seeds saved from the previous harvest or buy a sack of seeds from the local feed store. In effect, farmers no longer own the seeds they plant and crops they bring to market, but rather raise, harvest and sell "the corporation's product". Then, the farmers must return annually not only for the seed, but also for the latest rules regarding what must be done with, to, and on their land. Thus, they have become "bioserfs" (GEF 99). All this without the assurance of long and short-term safety of the "products".

Furthermore, this Brave New World of agriculture introduces the concept of "ethically sensitive genes". This term refers to the ethical implications of transferring genes between humans and animals. This transfer may be forbidden by certain religions and undesirable to other groups, for

example vegetarians. While the U.S. has yet to come to grips with this issue, Britain's *Committee on the Ethics of Gene Modification and Food Use* was recently created to identify any "moral taint" associated with GM food.

The recent history of the public debate concerning GM foods in the UK demonstrates that ethical issues relating to GM foods relate to four main areas: the special nature of the risks; the distribution of potential hazards and potential benefits; consumer choice: and trust in scientific and government authority.

Aspects of the risks surrounding GM food make them particularly sensitive. Health risks related to food are notoriously emotive, scoring highly in terms of perceived 'dread' factors, and raising issues of voluntary versus involuntary imposition of risks (Starr, 1969) and control over what we eat (Lang,1998). In addition, technologies which can be seen as interfering with the building blocks of life, implying that scientists are 'playing God', also provoke great unease (Kasperson & Kasperson, 1991, Burke,1998), illustrated by the concerns raised by HRH the Prince of Wales in a public lecture given on May 17th 2000, in which he argued that our ideas of stewardship for the Earth had become "smothered by impenetrable layers of scientific rationalism" and that we need to rediscover "a sense of the sacred" in our dealings with the natural world and each other (The Times, 18/5/00) .

The potential environmental risks of the deliberate or accidental release of GM organisms, meanwhile, are perceived as potentially irreversible, raising concerns about putting the gene genie back into the bottle (Mannion,1992). The impossibility of "controlled containment" of GM organisms was demonstrated the day after Prince Charles' lecture by the revelation that the government had been informed on April 17th by Advanta Seeds UK, that some of its supplies of conventional rapeseed, imported from Canada and sold and sown in 1999 and 2000, contained a small proportion--about 1 per cent.--of genetically modified rapeseed, with the result that an estimated 9000 hectares had been unwittingly planted in the UK in 1999, and 4,700 hectares in spring 2000 (Hansard, 18/5/00). The modification in question had been cleared by ACRE (the Advisory Committee on Releases to the Environment) and ACNFP (the Advisory Committee on Novel Foods and Processes) for use in controlled field trials, but not for commercial planting until the results of these trials are known, in 2002.

The acceptability of GM foods depends heavily on perceptions of choice, control, and the distribution of benefits and risks. The first GM product to be released for sale in the UK was a tomato paste, approved by ACRE in 1994, and sold by two supermarket chains, Safeway and Sainsburys. Jars of paste made from GM ingredients, clearly labelled, were sold side by side on the shelves with the conventional product, offering consumers a clear choice (Burke,1998). ACRE also approved for sale products made from Monsanto's "Roundup-ready" soya, genetically modified to resist the herbicide glyphosate, and widely grown in the US and Canada. However, in the case of these products, it was not possible to provide labelling and hence consumer choice, because of the difficulty of separating GM from non-GM soya. At that time, labelling of GM products was not a legal requirement, and Monsanto argued that

it was unnecessary as the products were "substantially equivalent". However, this lack of choice aroused concern among consumer groups in the UK, and led to a rising tide of disquiet during the late 1990s. While the potential hazards of GM are seen to be distributed universally, in the case of environmental risks, and to all who may unwittingly eat the products which contain them (in the absence of adequate labeling and identification procedures), the benefits are seen to accrue only to those multinational companies, such as Monsanto, with an interest in marketing these products.

These worries were met with a barrage of assurances of the "safety" of GM products. However, the complexity and high degree of uncertainty mean that the plausibility of such reassurances is dependent on a high degree of trust in scientific authority and government on the part of consumers. The issue of consumer confidence was brought to a head in August 1998, when a World in Action TV program included an interview with a scientist, Dr Arpad Pusztai, describing his work at the Rowett Research Institute, in which rats fed with genetically modified potatoes appeared to exhibit symptoms of poor growth and reduced immune function. Dr Pusztai's employers immediately suspended him and banned him from speaking to the media, leading to allegations of "cover-up", and intense debate over the validity of the results and their relevance to the wider debate over GM foods. The experimental results and methods have since been investigated and criticized by bodies such as the Royal Society, the government's Committee on Toxicology and the ACNFP. While Dr Pusztai has also been supported by other groups of scientists, the major contribution of this incident has been to bring the issue of GM crops to the attention of a public already suspicious of the assurances of government appointed scientists through a number of crises such as the BSE scandal of the early 1990s (see Hadfield, forthcoming).

The impact of this controversy has led to a wave of consumer resistance to GM, which has affected sales of even the previously acceptable GM tomato paste. In response to consumers voting with their wallets, several retail chains, for example Iceland, Sainsbury's and Tesco, have backed off from the sale of GM products, and now stress their "GM-free" credentials .

Critics, while acknowledging the benefits to be reaped from biotech agricultural science, are troubled by remaining questions. If testing is done primarily at the corporate level and if the results of these tests are posted...though only on the internet, how do we know what lurks in the rice we harvest, the fish we catch, and the tomatoes we eat? Who will enlighten us about and protect us from so-called "Frankenfoods"? Do corporations have the "right" to proceed with this technology when there is a chance that there will be environmental damage which may be irreparable? Who gets to decide? Who will be responsible for any environmental damage which results?

3 THE ROLE OF THE GOVERNMENT IN OVERSIGHT AND REGULATION

The issues outlined above illustrate that there is a compelling environmental, social and economic basis for regulation. Government oversight and regulation is necessary to ensure that independent testing and monitoring occurs. Until it can be established that GMOs and resulting food products cause absolutely no environmental and/or health problems, the introduction of these products should proceed cautiously and with strong and independent supervision and testing. While severely damaging health threats appear less likely than environmental threats, we cannot be certain there are no health risks without independent testing and monitoring *over time*. Further, the risk of environmental problems is not insignificant and could be very difficult to predict and perhaps impossible to correct. Finally, ethically consumers have the "right to know". While the agriscience industry may prefer self-regulation, government oversight and regulation provide the best solution to the potential health and environmental risks and the demand for public information. Indeed, it has been well established in economics that regulation can improve the social outcome in situations where there are environmental or public health costs resulting from the production process which accrue to third parties (Lyons et al 1999).

3.1 A COMPARISON OT THE REGULATORY RESPONSE IN THE UNITED STATES, EUROPEAN UNION AND UNITED KINGDOM

Yet the reaction by regulatory agencies around the world has varied dramatically. A comparison of the processes in the U.S. and E.U. illustrate the two ends of the spectrum of current regulatory treatment.

Legislation in the E.U. and U.K.

EU and UK regulations regarding GMO are three-fold:

- Controlled use of GMOs (eg in laboratories) is regulated under Directive 90/219/EEC, through the Health and Safety Executive (HSE) advised by the Advisory Committee on Genetic Modification.
- Releases to the environment, for example in field trials and cultivation, are controlled by the Department of the Environment, Transport and the Regions (DETR), advised by the Advisory Committee on Releases to the Environment (ACRE) under 90/220/EEC.
- Applications for the introduction of GM and other novel foods to the market were initially regulated by the Ministry of Agriculture, Fisheries and Food (MAFF), replaced on April 1st 2000 by the new Food Standards Agency, advised by the Advisory Committee on Novel Foods and Processes (ACNFP) under EU Council Regulation 1139/98.

Releases to the environment

The introduction of new genetically modified organisms into the environment (i.e. any use which is not strictly not contained within laboratories) is governed by the European Union Directive 90/220/EEC, which represents "the minimal consensus of the member states that the introduction of genetically modified organisms should be regulated" (von Schomberg, 1998). The Directive adopts a precautionary approach, stating that "Member states may undertake all appropriate measures `to avoid adverse effects on human health and the environment' from GMO releases" (EU Directive 90/220/EEC, 1990, Article 4). Each member state is required to appoint a statutory body to oversee and approve applications for the release of GMOs. Before a GMO may be released, the applicant must submit an environmental risk assessment to the appropriate statutory body for review and approval.

In the UK, this function is performed by the Advisory Committee on Releases to the Environment (ACRE). ACRE was originally established as an advisory body by the Secretary of State for the Environment under the Environmental Protection Act 1990. It is a committee of independent experts, including scientists and representatives of industry and environmental groups, which gives advice to the Secretary of State for the Environment on all aspects relating to human health and safety and environmental safety with respect to the release and marketing of novel organisms. (SCST). Since February 1993, under the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (which implements Directive 90/220/EEC and was amended in 1995 and 1997), ACRE provides advice to the Secretary of State on whether or not consent should be granted for particular applications, and what if any conditions should be imposed.

Between 1/2/1993 to 31/5/1996, ACRE issued 103 Consents for the release of GMOs, of which the largest group (35) were concerned with herbicide resistance (Amijee, 1996). However, the limits of this "rigorous" regulatory system were revealed on May 18 2000, when Mr Nick Brown, The Minister of Agriculture, Fisheries and Food, made a statement to the House of Commons announcing the accidental planting of an estimated 13,700 hectares in the UK with rapeseed contaminated with genetically modified rapeseed (Hansard, 18/5/00). On May 27th, MAFF issued an announcement recommending that farmers who suspected their crops of being contaminated, should destroy them, as they would face prosecution if they attempt to sell on the crops within the EU. However, the Government has no powers to enforce these recommendations, or to trace those farmers who have planted contaminated seed, leading to a situation where farmers have little incentive to comply. Given the already precarious state of the British agricultural industry, and the severe financial disadvantages to farmers of destroying these crops, it is more than likely that at least some GM rapeseed will be sold for processing (The Sunday Times, 28/5/00). Thus, as with the case of BSE, the authorities are powerless to prevent the introduction into the food chain and environment of agricultural products of unknown potential impacts.

GMOs in Food

The commercial exploitation of new types of food product and process, including those based on GMOs, is regulated by MAFF under the advice of the Advisory Committee on Novel Foods and Processes (ACNFP). ACNFP was established in 1988 as a government appointed group of independent technical experts, with secretariat from MAFF and the Department of Health, and including a consumer representative and an ethicist (SCST). Initially, the safety assessment scheme operated on a voluntary basis, with manufacturers requesting approval to market novel foods from the ACNFP. However, in 1997 this scheme was placed on a statutory footing, in response to the (EU) Novel Foods and Novel Food Ingredients Regulation 258/97. This requires a mandatory pre-market approval process "for all food and food ingredients without a history of significant consumption in the EU" (IFSFT). By October 1999, 35 applications to market GMOs under Directive 90/220/EEC had been considered by the member states, of which 15 were agreed and 17 were pending. Again, the main purpose of the modifications was herbicide resistance, with 8 of the agreed applications and 12 of the pending applications relating to this.

Implementation of EU Regulations

Although the regulations established through the implementation of Directive 90/220/EEC have replaced a voluntary system of approvals with a mandatory one, they have been severely criticised. The difficulty arises because approval of a GM product in one Member State automatically permits the release or sale of the product throughout the EU. With regard to releases to the environment, it has been argued that this ignores the substantial differences in habitat and species, and hence potential impacts on biodiversity, between different geographical areas of the EU (SCST):

"The directive means in practice that the Biotech industry will rapidly find out what country has the most favourable position versus GMO release and have their products released there first. As it is left open to the member states to interpret what is a hazard, this leaves the field open to considerable arbitrariness." (PSRAST).

The regulations have also been criticised for lack of clarity over the scope of risk assessments required before acceptance (SCST), and over its definitions of the concepts "evidence for safety", "environmental harm", and "adverse effects on human health and environment", which are left open for interpretation by the member states (PSRAST). The Royal Commission on Environmental Pollution has criticised the case-by-case nature of the approach, which does not allow for the possibility of cumulative and long-term effects of multiple releases of organisms, and has argued for the need for greater involvement of public and consumer groups, in view of the widespread concern about GM among the public (RCEP). Amendments to Directive 90/220/EEC are currently under consideration by the European Parliament and council of Ministers, and agreement on an amended Directive is expected in 2001 (ACRE,1999).

Labelling

Prior to 1997, although labeling of food containing GM ingredients was not mandatory, some manufactures and retailers provided labels indicating that products contained GM ingredients on a voluntary basis. Mandatory labeling of GM foods or foods obtained from GMOs was introduced in 1997 as part of the EU Novel Foods Regulation (Council Regulation 258/97). The original regulations applied to "Key nutrients and toxicants" in foods which were new to the EU and not "substantially equivalent" to an existing food. This approach was extended in September 1998 by Council Regulation 1139/98 to cover soya and maize products containing DNA or protein resulting from GM, detectable above a threshold which was not specified at that time, but in October 1999 was set at 1% (IFST)..

One problem in labeling concerns the difficulty of accurate detection of GM ingredients, although technologies and techniques for this detection are being developed (IFST). It has also been suggested that they may cause more confusion than they convey information (Schmitt). Nevertheless, the UK government has expressed the view that: "the Government is determined to ensure that foods containing GM materials are clearly labeled so that consumers can make informed choices." (DETR).

Legislation in the U.S.

The current structure of the regulatory system in the U.S. pre-dates the arrival of genetically modified organisms in our agricultural processes and food supplies. There are three federal agencies involved in determining the safety of GMOs: the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA). Each agency has a different approach to the issue of regulation of GMOs and resulting food products. The FDA is specifically concerned with food safety and drugs used for both humans and animals. The FDA website states: "Under FDA policy, developers of bioengineered foods are expected to consult with the agency before marketing, to ensure that all safety and regulatory questions have been fully addressed." The EPA monitors pesticide use, and is involved only if the GMO has been genetically altered to produce some form of pesticide (for example Bt Potatoes). The relative safety level of that pesticide must be determined along with the level of environmental risk. The USDA deals with any GMO-related agricultural matters, both in plants and livestock. The USDA Anima and Plant Health Inspections Service (APHIS) is required to "make sure of the safety of genetically engineered plants and other products of biotechnology."

Proponents of this three-pronged system say that this approach allows scrutiny from different angles, thus ensuring a more thorough overview of each GMO. Critics argue that there is little cohesiveness, and that there are too many areas where government oversight provides gaps for potential problems to slip through. Further, no one agency has the final authority to

independently consider *all* aspects and effects of the product. Also, none of the agencies currently requires independent testing to verify corporate claims of safety and effectiveness. Finally, there is the issue of "substantial equivalence", which simply states that when there is no apparent difference in the end product between a GMO and its naturally occurring counterpart, little if any safety testing is required. Critics have pointed out that the concept of "substantial equivalence" has never been properly defined, and it has been described as "a pseudo-scientific concept because it is a commercial and political judgement masquerading as if it were scientific" (Millstone et al, 1999).

Labeling of GMOs in the U.S. is still a voluntary matter, with the industry staunchly opposed and critics fighting for a better informed consumer. The FDA has responded recently with "plans to draft labeling guidance to assist manufacturers who wish to voluntarily label their foods being made with or without the use of bioengineered ingredients. The guidelines will help ensure that labeling is truthful and informative. To receive maximum consumer input, the FDA will develop the guidelines with the use of focus groups and will seek public comment on the draft guidance."

4 CONCLUSIONS AND RECOMMENDATIONS

The recent debate on GMOs and GM food products encompasses environmental, health, economic, trade, social, ethical, political and even religious issues. Thus, it should not be surprising that the approach to regulation has varied across nations. Some nations, like those in the European Union , have applied the precautionary principle (or at least paid it lip-service) while others, notably the United States, have proceeded with far fewer regulatory or consumer information requirements. These views reflect each nation's assessment of the importance of the potential benefits and the perceived risks of GMOs and GM foods. Proponents, like the United States and to a lesser extent Canada, represent nations where industry is active in genetic engineering and at the same time, consumers inherently trust government regulators. Other proponents represent nations in the developing world where the threat of growing populations implies increased numbers of people facing future starvation. In such areas, the potential benefits may overwhelm any possible risks. The tradeoff between potential costs and benefits is viewed very differently in the European Union where potential benefits seem low since there is no real threat of starvation and no GM products are currently available which offer significant and otherwise unavailable benefits. Risks, however, are perceived to be very high in the E.U. in the aftermath of mad cow disease and scandals such as salmonella in eggs (U.K.) and contaminated blood products (France). Further, there is far less trust in the ability of the government to protect consumers through regulation.

There is no simple mechanism for resolving these issues. The global debate should continue with the understanding that nations will, and should, differ in assessments of the extent and significance of potential costs and benefits of

GMOs and GM foods. This uneasy understanding is reflected in the provision of the Cartagena Protocol on Biosafety which permits countries to bar imports of genetically altered seeds, microbes, animals and crops that are deemed a threat to the environment while obliging nations to operate Wold Trade Organization rules. How and whether these dual provisions can be realized remains a vexing question.

Nevertheless, some general recommendations apply to all nations involved. First, the uncertainty regarding potential environmental and health risks provide a compelling basis for governmental regulation of GMOs and GM food products.

Second, the consumer should have the right to participate in the decision on whether or not to consume GM foods. In order for consumers to exercise this right meaningfully, clear and informative labeling is required. Presently, this is difficult because it is not always possible to detect the presence of GM ingredients and, some GM food products, like soybean, are used in small levels in huge numbers of products. Even in the European Union, where very real attempts at informative labeling have occurred, it is unclear whether information or confusion has been conveyed to consumers. Thus, efforts at informative labeling should continue until a meaningful standard can be developed. In the meantime providing some information, even if confusing and incomplete, better serves the consumer than no information.

Third, independent testing of GM foods for long term health effects and allergic reactions should be required. Fourth, independent monitoring of the environmental impact of GMOs should also be required. Results from both types of tests should be publicly available and readily accessible to consumers.

Finally, because the technology encompasses both human health and environmental impacts, regulation, independent testing and monitoring, and consumer labeling and information standards should be coordinated. The European Union appears to have begun this integrative process more successfully than the United States.

In the early days of coal mining, one miner, carrying a canary, entered the shaft ahead of his fellow workers. The bird, whose system was sensitive to harmful gases, alerted the miner to the unknown danger of his workplace. Currently in the United States, we have no one to carry the canary and we've already dismissed as trivial, the harbinger Monarch butterfly. Who then will inform us? We do have a right to know.

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[i] Genetic material from flounder has been inserted into tomatoes to enhance resistance to frost while potatoes have been developed which include a bacteria to provide "in-plant" insect protection.

[ii] In their book Shattering: Food, Politics, and the Loss of Genetic Diversity, Cary Fowler and Pat Mooney argue that there have been numerous other cases of crop failures due primarily to a lack of resistance brought on by a

monoculture. They cite as examples the devastation of the coffee crops in Asia and Africa in the 1870's, the cotton epidemic in the 1890's, wheat epidemics in the United States in 1905 and again in 1917, destruction of the rice crop in India in 1943, major losses in oat crops in the United States in the 1940's and later in the 1950's, the corn blight in the U.S. in the 1970's, and also wheat failures in the Soviet Union in the same decade. They note, "Each time resistance was needed. And each time it was found in the centers of diversity, in landraces that had somehow escaped homogenization, or in those crops' wild relatives. As use of the pure line and hybrid varieties increased, so did pest and disease problems. The greater pest and disease problems grew, the more farmers turned to chemicals to solve them." (Fowler and Mooney, 47).

[iii] A landrace is the most primitive variety or source of a species.