## WHAT ARE THE 'GMO' ISSUES?

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"All crops are GMOs. But some GMOs are more GM than others." Paraphrasing George Orwell.

**Overview of Controversies.** The range of criticism of biotechnology can be described broadly in five words: perversion, poison, promiscuity, profit and power.

**Perversion.** The transfer of genes from one species to another is viewed by some as a perversion against nature or God. With some new technologies, from blood transfusions to organ transfer to test-tube babies, what was considered a sacrilege by one generation becomes a sacrament to the next. Genomics will also be underscoring the idea the relatedness of all living things, and the idea that transfer of genes across what humans call 'the species barrier' occurs in nature and is natural.

**Poison.** Moving a gene from one organism to another may result in the production of a new toxin or allergen, or a decrease in nutrients in a food organism. This is true, and it is true for all types of genetic modification. This point is an opportunity to distinguish between the risk associated with the gene transferred, and the risk associated with the technique of gene transfer.

**Promiscuity** describes the idea that genes can flow by pollination from wild relatives to crops, and from crops to wild relatives and to weedy relatives. The risk is that genes from crops can move into populations of weeds and result in "superweeds". If cultivated crops are grown in the same location as wild relatives or local varieties of the crop called landraces, then genes may flow from the commercial variety into the population of wild relatives or landraces. ". These risks hold for genes of any source, conventional or transgenes, but the criticism is aimed usually at transgenes. Although the concern expressed is higher, it is not clear that the risks are higher.

**Profit.** Biotechnology is being commercialized primarily by biotechnology companies, which are often former chemical companies. They are motivated by profit. They seek patents and other protections of intellectual property. They often sell not just seed but a license to use seed with a provision of the license that farmers agree not to save seed from year to year, or sell seed to other farmers. The companies try to beat their competition or buy them out. The seed business in North America and in Europe has concentrated in the past five years. For some critiques, the fact that companies are motivated by profit suffices.

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**Power.** Companies holding patents have the power to refuse to let others use the patented technology. Companies may choose not to use their technology on staple crops because they see no economic return in the money and time that would have to be invested. The influence of biotechnology and of biotechnology companies may change the distribution of wealth, land and decision-making power. Some critics contend that biotechnology gets too big a slice of the public research budget at the expense of other technologies such as organic agriculture or agroecology. Biotechnology issues have created tension in international trade and in international agreements on biodiversity.

## The Biological Basics

Nearly all our food comes from living things: plants, animals, microbes. Humans select or develop crops, livestock and microbial cultures based on those traits favorable to humans. Those favorable traits include taste, color, ease of preparing, yield, vigor, storability.

Biologists hold that the traits, or the phenotype, of living things result from the interaction of genotype and the environment.

To generate better varieties of crops, livestock and microbes, humans can manipulate the genotype and can modify the environment.

To generate new varieties through breeding, a breeder requires a source of genetic variation.

Genetic variation is expressed in the term "gene pool": all the genes available to a breeder useful in improving a breed through generating combinations of genes that result in superior traits.

The plant breeder's bread and butter are 1) the gene pool and 2) the methods for selecting and manipulating individuals or populations to get new varieties with more desirable traits.

In nature, genes mutate and genes flow and recombine from generation to generation within a species. Genes flow among unrelated species through transformation, transduction, conjugation, cell fusion, and viral infection. (Since a gene is a concept and DNA is the physical stuff that carries genetic information, it is more accurate to say DNA mutates and flows and recombines)

In science, the evolving understanding of humans about how genes change and flow affects how humans apply this knowledge.

Until 1973, the gene pool for a corn breeder was limited to corn and its close relatives that could cross-pollinate with it.

Plant breeders genetically modified plants using selection, breeding, grafting, hybridization, mutagenesis, tissue culture, somaclonal variation, embryogenesis, cell fusion, transposons, and viral infection.

But with the invention of cut-and-splice recombinant DNA technology by Cohen and Boyer in 1973, the gene pool became a gene ocean. Because all known life on Earth uses DNA-based information systems, genes from one species can be understood in other species, provided there is a way to transfer the gene-carrying DNA molecule from one to the other.

Recombinant DNA has been around since before humans. Recombinant DNA technology is nearly 30 years old. It is one of the most powerful tools ever invented. The gene-splicing tools used to copy and move gene-carrying pieces of DNA from one species to a completely unrelated, or perhaps it is more accurate to say a distantly related organism.

## **Risk Analysis**

The changing and moving of DNA, that is, the changing and moving of genes, by nature alone or by the hands of humans, present risks of changing the traits of crops for ill as well as for good.

At the time of its invention recombinant DNA technology gave even leading scientists pause—and cause to ask a series of questions: Is it safe? Is it safe enough? How safe or risky is it compared to other methods of genetic modification?

To explore these questions, scientists in mid-1974 declared and observed a moratorium on gene-splicing technology and Paul Berg and others organized the Asilomar Conference in 1975. In 1976 committees of scientists in many countries established guidelines for using recombinant DNA technology. By the end of the 1980's, the general consensus among scientific organizations was that recombinant DNA technology per se poses no known risks beyond those posed by other methods of genetic manipulation (Milller, 1999).

Mark Cantley of the European Commission calls this "a now classic example of applying the 'precautionary principle'—start tough, and adapt as you learn." (Cantley, 1999).

The debate over the risk and safety of recombinant DNA technology compared to other methods of genetic modifications continues and is being revisited, in the US notably by the sponsorship of the US Department of Agriculture and the National Academy of Sciences.

Assessing risk is one thing, and it is a thing for which science is elegantly useful.

But drawing the line of acceptable risk is another thing, and that is a political decision that may be informed by science but not formed solely by it.

The daunting question that combines politics and science becomes "how safe is safe enough?" (Butler and Reichhardt, 1999).

One option is to state that the new recDNA technology, even if it poses no new risks that we know of yet, may pose unknown risks and therefore we must be prudent and precautionary until we are sure.

Another option is to state that all methods of genetic manipulation may pose unknown risks, and that even though a technique is old and familiar, it may still be posing risks that have gone undetected be cause we have not yet looked for them or because we have assigned the risks to other causes.

There remains then at least two options for setting the bar of acceptable risk. The first is to choose an expectation for recombinant DNA technology applied to crops, for example, that it be at least as safe as other methods of plant breeding. The second is to choose an expectation that is greater than that for other methods of genetic manipulation. The second may reassure or assuage the perception of risk but it is not clear at all that it reduces overall risk.

Greater scrutiny and higher expectations of safety may be applied to a new technology. This may happen even in the absence of evidence that the new technology is riskier than an older technology, and in the face of evidence that the technology is in some ways less risky than an older technology. But in such cases, it is imperative to avoid delusion. Such higher standards of scrutiny and safety are not based on risk; a risk-based analysis would apply comparable scrutiny for comparable risk. Such reassurance regulations also come with opportunity costs from opportunities lost.

Caution, even precaution, can be a prudent policy, especially for societies with a problem of overproduction of food rather than a problem of hunger and malnutrition. But when precaution slips into an expectation of omniscience, when the mere statement that "questions remain" suffices to block government review, then precaution becomes paralysis. Science is not omniscience; questions will always remain.

Great expectations may be useful, even necessary, to gain public acceptance for commerce, if not to protect the common weal. But in such cases, it is necessary to distinguish risk-based regulations designed to protect the public from biotechnology, and reassurance-driven regulations designed to protect biotechnology from the public. (Cantley, 1999)

## Labeling, Fungibility and Identity Preservation

Many foods are labeled. Labels can inform, and labels can incite.

Societies that label food face a basic question: on what principles will food labels be compulsory, permitted or prohibited?

Compulsory means that such information must be provided.

Permitted means that certain information can be given or omitted at the choice of the labeler or of the consumer.

Prohibited means that some information or claims cannot be made by the labeler.

Different cultures may choose different principles and processes for judging what shall be compulsory, permitted and prohibited.

In the United States, labels are required to be both truthful and not misleading. This holds for statements made on labels put on the food package, and for information provided at the store or point of purchase.

This two-tiered standard shows that governments and consumers recognize that even statements that are formally true may be misleading. A true statement can be misleading, and so the standard takes into consideration not just what the label writer states, but also how a label reader might interpret the label.

In the United States, the issue of composition is fundamental. Food is judged in terms of composition and adulteration. Is the food what the label says it is? Does it contain anything that would adulterate it? Labeling of unwholesome or adulterated food is not much of an issue because it is illegal to market it or sell it.

In the United States, it is compulsory to tell on the label the composition and ingredients, in order of concentration, of a processed food, and to give a standard set of nutritional information.

Information on the methods used to process a food is sometimes required (eg, pasteurized, frozen, cooked, irradiated.)

Information on the methods used to produce a food, including the breeding of a crop, is not compulsory. Plant breeders can use any of a dozen methods of genetically altering crops, from selection and breeding to random mutagenesis to recombinant DNA technology, and the key principle is the resulting product, not the process used. For example, after developing a new variety of tomato, the question is this: is the new variety of tomato still a tomato? Or is it something significantly different in composition from other tomatoes?

Since tomatoes come in a wide range of sizes, colors, shapes, and flavors, the question implies an understanding of the essence of being a tomato. Biologists can have such an understanding or convention as to the essence of tomato. Lawyers do, too. The legal term is the "standard of identity." A new variety of tomato can be labeled simply as a tomato provided the composition of the new tomato is not significantly different from all the other varieties of tomatoes. The composition can be changed—in fact, it is expected

that most new varieties would differ in some ways in composition or else they wouldn't be a different variety from the types they were bred from. The question is whether the new variety still falls within the "standard of identity" for tomato.

Not all governments will choose to hold to the principle that standards of identity are determined by composition. Some will hold that it is the not presence of a new gene or a new protein that is important, but how that gene got there. This is the "product versus process" debate. It is a debate involving whether regulations will be made on the basis of risk or of risk perception. It is a debate over how to deal with unknown risks. It is a debate on whether familiar unknown risks are safer than unfamiliar unknown risks.

To understand the choices and decisions to be made regarding the labeling of food from gene-spliced organisms, it is essential to understand the principles and precedents used in assessing and labeling food from organisms that are genetically modified by other techniques, such as plant cross-breeding.

Legislators, regulators and consumers face a decision.

Will we have a system based on a standard of risk, or on a standard of perceived risk?

If the system of labeling is based on a standard of perceived risk, then an assessment of risk is not vital.

If the system of labeling is based on risk, then a fair comparison of risks is vital to having a consistently meaningful system of informing consumers.

There is one line of argument that states that since many consumers are not convinced of the safety of gene-spliced food, therefore such food should be labeled so consumers can choose to avoid them. Likewise, there is an argument that says since we do not know all the long-term risks for gene-spliced food, such foods should be labeled to help in any possible future studies that could help trace a problem back to gene-spliced food.

These arguments imply that the food is not safe enough, and that labeling is a way to allow food on the market while allowing concerned consumers to avoid it since it is dangerous. However, labels are not a substitute route of access to market for substandard or unsafe food. Food that is marketed is required to be wholesome and unadulterated. No label warning can make unwholesome food or adulterated food legal to market.

Second, all food is risky. But there is a difference between food that doesn't meet the safety standards established by the authorized governmental agencies, and food that meets those standards of the government but does meet the higher standards of some consumers.

Consumers are entitled to have expectations higher than the governmental standards. Consumers have the right to have profound concerns, even concerns unfounded by the scientific data. Consumers have a right to find any food loathsome for any reason. But being loathsome is different from wholesome.

A wholesome food—as measured by scientific experiment, or as determined by governmental standards—may be considered a loathsome food, as determined by tradition, habit, taste, preference or religion.

To accommodate consumers who wish to know if food on the market is not loathsome, governments permit food processors to make label claims such as "organic" or "kosher" or "hallal".

Consumers have a right to know such information, even though food producers are not compelled by law to provide such information. For a consumer whose right to information is not fulfilled, the legal remedy is to refuse to choose food that does not provide all the information the consumer desires. These desires do not have to be reasonable or rational. Any consumer can decide on any basis what they have a right to know.

Who should pay for additional labeling information beyond the information on composition and nutrition and safety required of all foods?

One approach is the Consumer Sovereignty argument. Consumers have a sovereign right to know whatever they want to know about what they eat. Furthermore, given a sufficiently influential appeal, governments may enact special rules that compel information and segregation based on political considerations, even in the face of evidence of absence of special risks. It is democratic but not necessarily just. By its nature it is a double standard based on political sensibility more than scientific sense.

Another approach to distributing or assigning the costs of labeling is the Economic Justice argument. Here special label information, beyond the standard information on composition, safety and nutrition required equally of all foods, should be considered an economic service or good. As with all economic services or goods, the concept of consumer freedom to choose or to decline should operate. If special label information is a consumer good or service, then those consumers who value the information (service or good) should pay for it, and those who do not value the information should not have to pay for (Robin Douthitt, personal communication).

This approach accommodates consumer concerns or preferences, without shifting the burden of costs for wholesome food to consumers who do not share the tastes or standards of loathsome.

A weakness of the economic justice argument is that some people cannot easily pay for the extra cost of the information. On the other hand, a weakness of the capricious caseby-case approach is that some people who do not share the standards of loathsomeness of the majority will have to pay more for food because of the labeling, certification and segregation required. Butler, Declan and Tony Reichhardt. Long-term effect of GM crops serves up food for thought. Nature 398:651-656. 22 April 1999.

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