

From Rice to Mice

by Tania Rojas

Facing the legal woes of genetically modified organisms

It's a sad day for Ventria Bioscience, a biotechnology company based in Sacramento, California. After a tough battle, the California Department of Food and Agriculture stopped the company's plan to plant genetically modified rice expressing two human proteins. The department stated that Ventria must acquire federal approvals and permits before the planting could proceed. Ventria had hoped to utilize these proteins as treatments for malnourished children and patients suffering from diarrhea and iron deficiency.

Ventria's legal battle demonstrates a recurring problem in U.S. policy: the absence of national standards for genetically modified organisms (GMOs). This has proven to be one of the most controversial tasks for policymakers. Balancing ethical concerns, consumer values and economic reality is a tough job, but one that becomes increasingly pressing as global markets become increasingly exposed to GMO products. According to the U.S. Department of Energy Office of Science, in the year 2000 alone, countries that grew 99% of the global transgenic crops were the United States (68%), Argentina (23%), Canada (7%), and China (1%). That same year, around 109.2 million acres were used to plant transgenic crops including herbicide- and pesticide-resistant soybeans, corn, cotton, and canola.

GMOs are also remarkably valuable for scientific research. Dr. William B. Hurlbut, Stanford Professor of Human Biology and a member of the President's Council on Bioethics, states, "I am in favor of the progress of science, especially if it relates to serious purposes, such as the advancement of understanding, disease treatments, and urgent issue of human dignity related to proper nutrition in the developing world."

As the 21st century witnesses the entry of GMO products into mainstream consumer markets and

health care research, national standards will prove crucial in balancing ethical considerations and practical applications.

U.S. Policy Now: Much Ado about Nothing

In the United States today, there is no governing body presiding over the regulation of genetically modified organisms. The approval of GMO developments is done on a case by case basis. The standard piece of legislation used is the 1986 Coordinated Framework for Regulation of Biotechnology issued by the Office of Science and Technology Policy. Under the policy, because "there are no statutory provisions or regulations that address biotechnology specifically, the laws and regulations under which the agency approves products place the burden of proof of safety as well as effectiveness of products on the manufacturer." In addition, the Federal Food and Drug Administration provides no new procedures or requirements for regulated industry or individuals; different agencies from multiple government sectors are called to regulate new



Courtesy of Karl Stolleis/Houston Chronicle/AP
This truck dumps 50,000 pounds of genetically modified rice at an Alvin, Texas, landfill — a routine act after such crops are tested.

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biotechnology products and their intended uses.

The legal muddle blurs further. The Animal Welfare Act, which outlines the legal standards of welfare for all animals, is somewhat obscure and outdated with regards to transgenic developments. Signed in 1966, the Act is the minimum acceptable standard to which all other laws concerning animal welfare refers. However, the law is evasive in outlining criteria for GMO production. Even



the official Animal Welfare Information Center acknowledges that to the student, journalist or researcher, dissecting the law to find out how biomedical research is carried out can be a “daunting task.”

There is literally no direct reference to regulate the incoming biotech revolution. Several sections of the Animal Welfare Act decree that “no animal will be used in more than one major operative procedure...unless it is justified for scientific reasons by the principal investigator, in writing.” A major operative procedure, as defined by section 1.1. of the Act, is one that includes “any procedure which produces permanent impairment of physical or physiological functions.” Thus, scientists attempting to develop GMOs must abide by an ambiguous and unaccommodating definition of what animal research should be allowed.

A blow to those who believe in increased GMO regulation occurred last May 2002 when President Bush signed the Farm Bill into action. The bill,

expanded the list of animals excluded from the Animal Welfare act to include: (1) birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, and (2) horses not used for research purposes.

Finding the Right Path

It can be argued that unlike the US, the United Kingdom has developed ways to effectively legislate the genetic modification of organisms. Under the Animal Scientific Procedure Act of 1986, scientists in the UK are required to license their work with animals. This involves “any experiment or other scientific procedure carried out on living, protected animals which may cause them pain, suffering, distress or lasting harm.” The act protects all vertebrate species (except for man) and one invertebrate species, the octopus *Octopus vulgaris*.

As part of the licensing process, UK laboratories must register under the Genetically Modified



Purdue Ag Communications Photo by Tom Campbell

Purdue animal scientist Bill Muir and colleagues hope to extend their research on bioengineered fish to species that may be used in fish farming, such as this tilapia.

Organisms Regulations 2000. The registration involves submitting a notification to the Health and Safety Executive describing the research. This notification is then reviewed by the Genetic Modification Safety Committees established under the Regulations 2000. The notifications are also examined by several government departments (including the Department of the Environment, Transport and the Regions, the Ministry of Agriculture, Fisheries and Food, the Department of Health, the Scottish Executive, and the National Assembly for Wales, if applicable) and an independent advisory committee, the Advisory Committee on Genetic Modification, may also be consulted.

While the U.K. has already set GMO standards, the U.S. has just finished implementing a national advisory body. In November 2001, President Bush signed into order the President's Council on Bioethics to advise him about the bioethical issues at stake with future advances in



Genetic engineering technology allows scientists to transfer genes of interest into agricultural crops.

biomedical science and technology. The Council has made commendable progress in evaluating bioethical issues from human cloning to biological enhancements. Dr. Hurlbut, a member of this council, commented regarding GMO developments that “I don't feel the same weight of concern about

genetically modified organisms as with those moral issues dealing with interventions in human life. I don't see the genetic modification of crops so much as a moral concern but a prudential concern. The legitimate modification of plants and animals has already provided wonderful new tools for scientific research, models for the study of specific diseases and sources of pharmaceuticals.”

The new tools Hurlbut mentions have provided many beneficial applications across the industry. Despite the legal ambiguities, the

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agriculture and livestock industries are undergoing a biotechnology boom. The most promising applications include methods to increase soil nutrient levels with genetically modified (GM) bacteria, develop novel oils from GM oilseed, cultivate firmer tomatoes with better flavor, and use GM insect viruses as pesticides. To “boldly grow where no crop has grown before,” as biologist Michael Wilson put it, cytogeneticists (scientists working at the level of plant chromosomes) have been developing GM plants to survive extremely acidic, salty, freezing, or dry environments. One scientist has even outlined a procedure to boost bovine milk yields with hormones produced by transgenic bacteria.

Besides reaping millions of dollars worth of cash crops, thwarting food shortfalls, and developing organisms for practical industrial purposes, genetic modifications promise to serve at the forefront of the understanding of human disease. GMO has provided a source of viable alternatives to treat many previously untreatable medical conditions, particularly through the production of transgenic mice as “models” for human diseases. The research has yielded numerous biological discoveries, from understanding cancerous tumor initiation and growth to identifying genetic obesity factors, developing methods to fight the herpes B virus or finding approaches to halt narcolepsy symptoms.

Even though developments in the science of GMOs holds great potential, Hurlbut pinpoints the need for ethical considerations to be taken into account because there is “a whole layer concerning

the genetic modification of animals that would be morally questionable where you cause suffering and the degradation of stable life forms.” After the recent creation of featherless chickens by Israeli scientists he believes there was a feeling that something more than efficient food production was relevant. Issues of bioethics, he observed, revolved around the idea of species integrity, where nature was not just seen as a resource to be used instrumentally for projects of the human will.

In a similar vein, opponents of GMO research argue that it is intrinsically wrong for humans to play the hand of God. Each organism, they contend, is bestowed with the right to live in its unaltered, natural form.

Others argue that there are unknown hazards that are likely to emerge with increased use of GMOs. The National Academy of Science announced in a report issued two years ago that genetically modified animals may pose environmental risks. Citing the work on a transgenic fast-growing salmon, the report voiced concern over the salmon escaping into the wild and breeding, “polluting” wild populations with their transgenes. The Committee on Defining Science-Based Concerns associated with the Products of Animal Biotechnology is wary of GMOs entering the food chain because of the possibility of human exposure to harmful transgenes. “We need to be sensitive and use our modifications for serious, not frivolous, purposes,” Hurlbut remarked. “We



According to the U.S. Department of Energy Office of Science, the U.S. grew 68% of the global transgenic crops in the year 2000.

should think carefully of the moral issues involved and prevent the creation of these organisms for mere amusement or just for the shock value of novelty.”

There are several ways a balance can be achieved between the practical applications and ethical considerations of GMOs. One solution could be the mutual cooperation between the public sector, scientists, research institutions and government bodies. By establishing a single organization or committee to direct the incoming onslaught of GM research, the bureaucratic game of tag can be halted. Furthermore, a community rapport should be established between scientists and people, so that the nation is well informed about current and prospective transgenic research. Public hearings to assuage mistaken public presumptions and media tall tales would facilitate the tackling of an ethical dilemma posed by GMOs.

As for now, Ventria will have to wait until next year’s growing season to have its rice crop evaluated by department officials again. With time ticking away as millions of people face nutritional deprivation, the company’s promising GMO applications are windswept by the U.S.’s legal cyclones. Despite the obstacles, our best strategy is to set a precedent for informed public choices the next time another decision has to be made. As Hurlbut said regarding the future course of genetic modification regulations, “the answers will come from a combination of good science, humility, and forethought.” **S**



A genetically modified rice crop.