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GeneWatch

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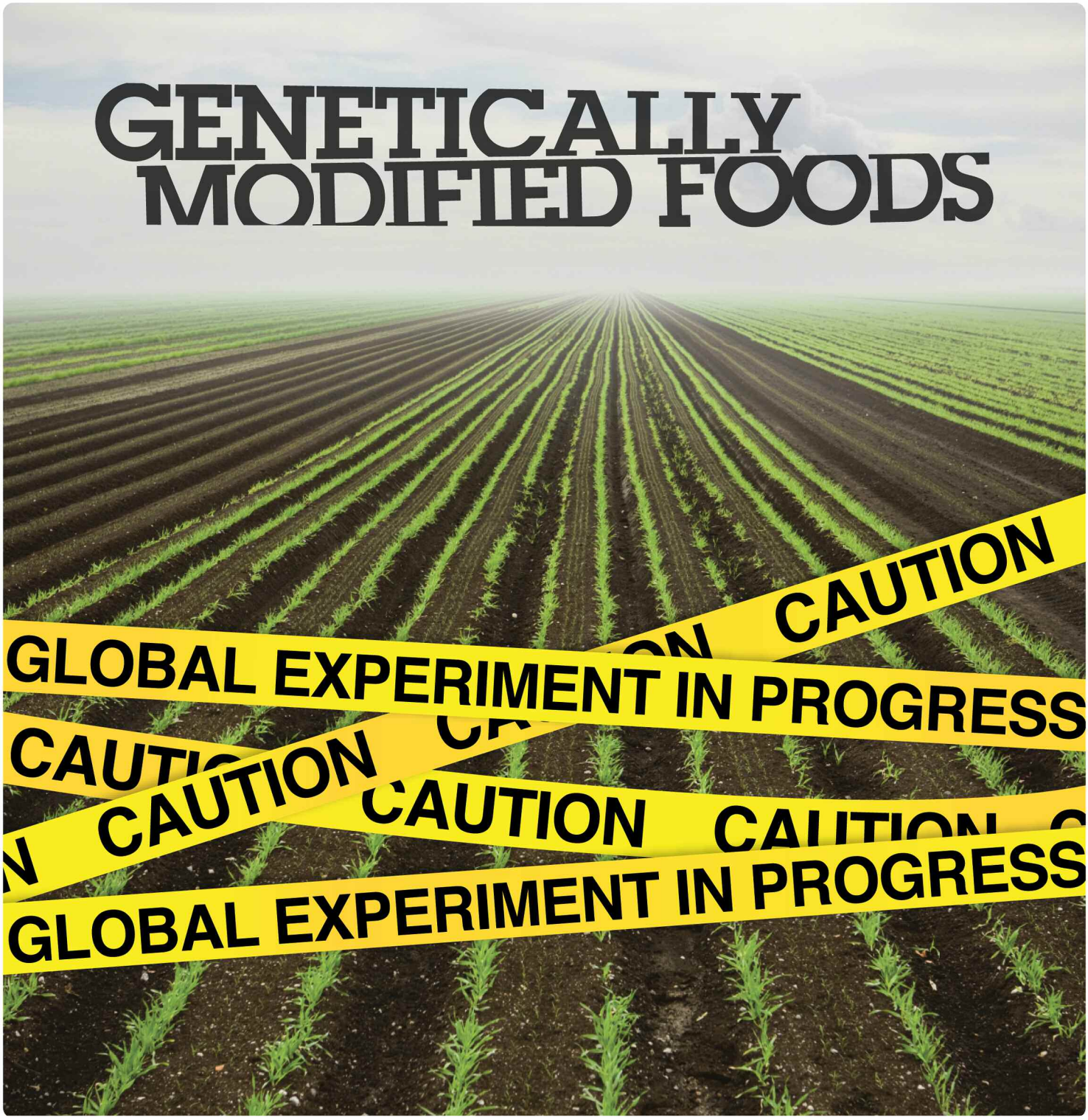

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Not long ago I was watching a telenovela, trying to brush up on my Spanish. The main character of one story was a woman who, based on what I could understand, was told by a doctor that she would die unless she had a certain surgery. She tearfully agreed, only to find out that not only was the surgery an experimental one with (I gathered) a questionable-at-best safety record, but also that she didn't really need it to begin with; furthermore, now that she had signed up for the operation, she was somehow legally barred from changing her mind. The rest played out in typical soap opera fashion, involving a great deal of sobbing and wails of "No quiero morir!"

The unfortunate woman's situation struck me as a sort of critical (albeit melodramatic) retelling of the genetically modified foods saga. We have been told that we need GM crops in order to feed the world, but we have not been told (at least, not by biotechnology companies and pro-GM advocates) of the potential risks involved, or that much of the ostensible promise of biotech crops has no real track record to support it. Speculation is rampant on either end of the debate, though; indeed, some of the most dedicated opponents of GM crops can be heard making dire predictions which seem to be based less on science than on paranoia. The debate sometimes seems to come down to two positions: that GM crops will save the world, or that they will destroy it.

Must we commit to one conviction or the other? Considering how little we know, even now, about where these technologies will take us, how much can we really be certain about? As the contributors to this issue point out, uncertainty pervades almost any assessment of the risks and benefits of genetically modified crops.

Dr. Árpád Pusztai, who was thrust into the GM foods debate in Britain when one of his studies returned unsettling results, stresses in an interview on page 10 that the gamble of GM crops is exemplified by the unpredictability of their impacts and the irreversibility of their adoption. And if we cannot determine their risks, he says, the next question is: "Who is to benefit?"

Herbicide-tolerant cash crops can certainly be called a commercial success in the U.S., and other traits, particularly insect resistance, have also been effectively engineered into several crops. But, Bill Freese asks (page 6), who really benefits from this technology? Biotech companies have claimed that GM crops will be key in solving world hunger, yet those same companies have focused their efforts on, as can only be expected, the traits and crops which will reap the most profits for the company – and drought-resistant cassava hardly figures into that equation.

On the other hand, that might be just as well, considering Monsanto's unscrupulous track record in developing countries. On page 17, Aruna Rodrigues criticizes safety studies conducted by Monsanto and a partner company on genetically modified brinjal (eggplant) which it aims to commercialize in India, and the Indian government's inability or unwillingness to effectively regulate this and other genetically modified crops. Developing countries also have much to lose if the much-hyped new synthetic biofuel technology is adopted, writes Kathy Jo Wetter (page 3). Using biotechnology to produce agrofuels is being touted as an environmentally friendly "no compromise" solution to climate change, but the risks associated with a new "sugar economy" would not be distributed evenly, and would demand more than a little compromise.

Continued on page 5

CRG Chooses New President/Executive Director

After a national search, the Board of the Council for Responsible Genetics has selected Jeremy Gruber as its new President/Executive Director. Mr. Gruber holds a Juris Doctor (J.D.) from St. John's University School of Law and a B.A. in Politics from Brandeis University. Previously he served as the legal director of the National Workrights Institute, a human rights organization dedicated to the rights of American workers. Prior to that he served as the field director for the ACLU's National Taskforce on Civil Liberties in the Workplace. Jeremy has worked for over a decade on genetic non-discrimination legislation at the state and Federal level. He helped author and pass numerous state laws on genetic non-discrimination. Mr. Gruber is a founder and executive committee member of the Coalition for Genetic Fairness, a group of 500 organizations that advocated for genetic non-discrimination legislation on Capitol Hill and played a major role in the recently passed Genetic Information Non-Discrimination Act (GINA) by Congress. Jeremy worked closely with members of Congress and staff on GINA language as well as strategy and support. He is a prolific writer on privacy issues and is often consulted by state legislatures. He is regularly featured in print, radio and television.

Synthetic Biology May Usher in a Post-Petroleum Era, But It Won't Be Green

By Kathy Jo Wetter

New biofuels technology comes at a price

In a classic children's book by Dr. Seuss, wily entrepreneur Sylvester McMonkey McBean persuades the Sneetches, whom he finds playing on the beaches, to pay three dollars each(es) to enter a mysterious-looking machine. McBean promises them they will enter one end of the machine a certain kind of Sneetch and come out the other end a different, better kind of Sneetch. That, in a nutshell, is the sales pitch of biofuel production using synthetic biology. Aristides Patrinos, formerly of the US Department of Energy and now President of Synthetic Genomics, Inc., describes it this way: "The ideal situation would essentially just be one big vat, where in one place you just stick the raw material – it could be switch grass – and out the other end comes fuel."[1] Stephen Chu, Nobel laureate and Barack Obama's pick for U.S. Energy Secretary, is also excited by the prospect of the "biorefinery" approach to fuel production using synthetic biology; he calls them "fourth-generation biofuels." In his Senate confirmation hearing on January 13th, Chu enthused about the brilliant scientists who have been able to produce gasoline-like substitutes – not ethanol – directly from simple plant sugars. Now, he says, they're working to scale-up production.

In Dr. Seuss's story, the Sneetches turn out to have been hoodwinked. As McBean drives away surrounded by piles of cash, leaving the Sneetches behind alone on their beaches, he states the lamentable and obvious truth: "You can't teach a Sneetch." It seems we're having trouble learning, too. Recent experience with industrial agrofuels (critics prefer the more precise "agrofuels" to "biofuels" to describe fuels derived

from agricultural products) offers a modern day parable about the dangers of techno-fixes that are promoted as green and sustainable solutions to peak oil and climate change. It has become increasingly clear that industrial agrofuels are not a socially or ecologically sustainable response to climate

change. Not only are they driving the world's poorest farmers off their land and into deeper poverty, they are competing with food crops and, according to an internal World Bank study, are the single greatest factor contributing to the rise in food prices.[2] Oxfam reported in June 2008 that agrofuels have pushed over 30 million people from subsistence to hunger.[3] Recent scientific papers conclude that today's industrial agrofuel production actually increases greenhouse gas emissions – contributing to climate change rather than arresting it.[4]

Now we're being told that synthetic biology is the game-changing solution we need. Advocates assure us that the "food vs. fuel" conundrum will be irrelevant in the future "sugar economy." They say feedstocks for biorefineries will come from cheap and plentiful cellulosic biomass – plant matter composed of cellulose fibers, including crop residues such as rice straw, corn stalks, wheat straw, wood chips, and dedicated "energy crops" such as switch grass, fast-growing (and, eventually, genetically-engineered) trees, even algae. But there are technical barriers. Switch grass, corn stalks and wood chips aren't efficient agrofuel feedstocks for the same reason they aren't good (human) food sources: they are difficult to break down and turn into energy. Only certain microbial enzymes – some of which exist in the guts of ruminants – can digest and process the cellulose and hemicellulose found within the cells of these plants. Another hurdle is high lignin content. Lignin, present to some degree in almost all plants, is responsible for water transport and plays a major role in a plant's ability to sequester carbon. But it's indigestible to enzymes and can be broken down only by certain bacteria and fungi. Synthetic biologists are developing improved "pretreatments" for biomass, including engineered microbes that can more efficiently separate cellulose from lignin and can break down the cellulosic materials for further processing.

A post-petroleum era driven by plant-derived fuels may sound fresh and green, but there will be a great deal of compromise involved.

But synthetic biologists are focusing most of their attention on the fermentation part of the process, the stage where plant sugars are converted to fuel. Inside a cell, a series of chemical reactions takes place, triggered and regulated by enzymes. The chemical reactions occur sequentially. Imagine a line of dominoes standing on end; knocking down a domino at one end of the line can trigger changes along its entire length. Scientists have figured out how to manipulate a cell's "metabolic pathways" along which chemical reactions take place, in order to alter which chemicals are ultimately produced. By changing the metabolic pathways in microbes such as yeast or E. coli, researchers have been able to "train" them to convert sugar directly into fuels that resemble petrochemicals. The advantage is that fuels produced this way are compatible with existing infrastructure. Theoretically, with enough targeted manipulation, any chemical substance could be produced, not just fuels, but other high-value chemicals, plastics and pharmaceuticals.

Amyris Biotechnologies, a California-based synthetic biology start-up, found the spotlight in 2004 when its high-profile efforts to coax engineered microbes to produce an anti-malarial compound received support from the Bill & Melinda Gates Foundation. Nowadays, the company's primary goal is to modify the metabolic pathways of yeast so that it ferments sugars to produce gasoline, diesel and jet fuel. In 2007, Amyris raised $70 million in venture capital to develop synthetic fuel technology. In April 2008, Amyris announced a joint venture with Brazil's Crystalsev to commercialize "advanced renewable fuels" made from sugarcane.[5] Amyris calls the products of its proprietary technology "No Compromise" and describes them as "low cost renewable fuels and chemicals that are intended to be environmentally friendly, compatible with the existing infrastructure, and have performance attributes comparable to petroleum-based fuels."[6]

No compromise? A post-petroleum era driven by plant-derived fuels may sound fresh and green, but if synthetic biology's fuels are dependent on agricultural biomass, there will be a great deal of compromise involved. What happens when all plant matter becomes a potential feedstock? Who decides what qualifies as agricultural waste or residue? Whose land will grow the feedstocks? Civil society organizations concerned with climate change, agriculture and food policy, human rights and indigenous peoples' rights and biodiversity have vigorously opposed first-generation industrial agrofuels and are voicing concerns over next-generation agrofuels – most recently in an open letter published January 15th, 2009, as a new agrofuel-loving administration comes to power in the U.S. The letter argues that "virtually all of the proposed cellulosic feedstocks...present serious ecological concerns on the scale required to maintain biorefinery operations and significantly contribute to U.S. energy demands."[7]

The earth's plant biomass is rapidly dwindling. Forests and grasslands, in particular, are disappearing at an alarming rate. Researchers estimate that humans already consume almost a quarter of global biomass (24%).[8] Of that amount, more than half (53%) is harvested for food, fuel, heating and lumber, 40% is lost through land use changes, and 7% is burned in human-induced fires.[9] The U.S. currently consumes 190 million dry tons of biomass annually for energy, and the government wants to increase that figure to one billion tons. Researchers conclude that the goal is technically feasible, but only by increasing yields of energy crops by 50% and by removing large quantities (~75%) of agricultural residues from cropland.[10] Impacts of increased residue removal will include impoverished soils (requiring more industrial fertilizers) and dangerous increases in soil erosion. We will see vast increases in pesticide- and herbicide-use. Removal of dead and dying trees from forests will increase biodiversity losses and decrease forest carbon-sequestration capacity. Additionally, many plants identified as good candidates for second-generation agrofuels are harmful to the environment

as invasive species (e.g., miscanthus, switch grass, reed canary grass).[11]

Some synthetic biologists recognize that fermenting plant sugars is not the best way for society to move beyond petroleum. But we may find ourselves equally disturbed by their proposed alternatives. J. Craig Venter, founder of Synthetic Genomics, Inc., has been researching photosynthetic bacteria to see if he can engineer them to produce fuel directly, using water as a feedstock. "It's infinitely scalable," Venter says.[12] Late last year, the World Intellectual Property Organization published a patent application (WO2008143630A2) from the J. Craig Venter Institute for the invention of a "recombinant hydrogen-producing cyanobacterium...useful for generating hydrogen from water." That engineered microbes could wreak havoc if released – intentionally or unintentionally – in the environment is one obvious concern. Venter says he shares the concerns and is working on ways to engineer his microbes so they are not viable in the natural environment. "We should be totally aligned with the environmentalists on this,"[13] says Venter, but experience with agricultural biotechnology has shown that a promise of containment is not enough to control genetically modified organisms once they're in farmers' fields. Synthetic biology's living organisms will be no less difficult to contain and control. ■■■

***Katy Jo Wetter** has worked as a researcher with Action Group on Erosion, Technology and Concentration, or ETC Group, since 2001. She holds a Ph.D. from the University of North Carolina at Chapel Hill.*

Editorial

Continued from page 2

Another GM crop technology that has garnered relatively little press despite big implications is the development of plants engineered to produce pharmaceutical products, known as "pharmacrops." Timo Assmuth and Sheldon Krimsky (page 13) address the risks and lack of regtulations involved with planting open-air pharmacrop test plots – and yes, these tests have already been conducted in the U.S.

According to the Grocery Manufacturers of America, roughly 75% of processed foods sold in the U.S. contain some amount of genetically modified material. With no labeling scheme in place, that figure seems unlikely to decline anytime soon. We may never hear cries of "No quiero morir," but willing or no, we are participants in a broad biological, economic, and sociological experiment, and we would do well to watch it closely.

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Why GM Crops Will Not Feed the World

By Bill Freese

A closer look at who benefits from biotech crops - and who doesn't

Last spring marked a tipping point for rising global food prices. Haiti's prime minister was ousted amid rice riots; Mexican tortillas have quadrupled in price. African countries were hit especially hard.[1] According to the World Bank, global food prices have risen a shocking 83% from 2005 to 2008.[2] And for the world's poor, high prices mean hunger. In fact, the food crisis recently prompted University of Minnesota food experts to double their projection of the number of the world's hungry by the year 2025 - from 625 million to 1.2 billion.[3]

Many in the biotechnology industry seem to believe there's a simple solution to the global food crisis: genetically modified (GM or biotech) crops.[4] Biotech multinationals have been in media blitz mode ever since the food crisis first made headlines, touting miracle crops that will purportedly increase yields, tolerate drought, and cure all manner of ills.

Not everyone is convinced. The UN and World Bank recently completed an unprecedentedly broad scientific assessment of world agriculture, the *International Assessment of Agricultural Knowledge, Science and Technology for Development*, which concluded that biotech crops have very little potential to alleviate poverty and hunger.[5] This four-year effort, which engaged some 400 experts from multiple disciplines, originally included industry representatives. Just three months before the final report was released, however, agrichemical/seed giants Monsanto, Syngenta and BASF pulled out of the process, miffed by the poor marks given their favorite technology. This withdrawal upset even the industry-friendly journal *Nature*, which chided the companies in an editorial entitled "Deserting the Hungry?"[6]

GM crops: the facts on the ground

GM crops are heavily concentrated in a handful of countries with industrialized, export-oriented agricultural sectors. Nearly 90% of the world's biotech acres in 2007 were found in just six countries of North and South America, with the U.S., Argentina and Brazil accounting for 80%.[7] GM soybeans rule in South America, and Argentina and Brazil are known for some of the largest soybean plantations in the world. In most other countries, including India and China, biotech crops (mainly GM cotton) account for 3% or less of total harvested crop area.[8]

GM soybeans, corn, cotton and canola, the same four GM crops that were grown a decade ago, comprise virtually 100% of world biotech crop acreage.[9] Soybeans and corn predominate and are used mainly to feed animals or fuel cars in rich nations. Argentina, Brazil and Paraguay export the great majority of their soybeans as livestock feed, while more than three-fourths of the US corn crop is either fed to animals or used to generate ethanol for automobiles. Expanding GM soybean monocultures in South America are displacing small farmers who grow food crops for local consumption, and thus contribute to food insecurity. In Argentina, production of potatoes, beans, beef, poultry, pork and milk have all fallen with rising GM soybean production, while hunger and poverty have increased.[10] In Paraguay, the poverty rate increased from 33% to 39% of the population from 2000 to 2005, the years in which huge soybean plantations (about 90% of them now GM soybeans) expanded to cover over half of Paraguay's total cropland.[11] The only other commercial GM crops are papaya, squash and beets, all grown on miniscule acreage, and only in the U.S.

Most revealing, however, is what the biotech companies have engineered these crops *for.* Hype notwithstanding, there is not a single GM crop on the market engineered for

increased yield, drought-tolerance, salt-tolerance, enhanced nutrition or other attractive-sounding traits touted by the industry. Disease-resistant GM crops are practically non-existent.

In fact, commercialized GM crops incorporate just two "traits" – herbicide tolerance and/or insect resistance. Insect-resistant or *Bt* cotton and corn produce their own built-in insecticide(s) derived from a soil bacterium, *Bacillus thuringiensis* (*Bt*), to protect against certain insect pests. Herbicide-tolerant crops are engineered to withstand direct application of an herbicide to more conveniently kill nearby weeds. Crops with herbicide tolerance predominate, occupying 82% of global biotech crop acreage in 2007.[12]

Herbicide-tolerant crops (mainly soybeans) are popular with larger growers because they simplify and reduce labor needs for weed control. They have thus facilitated the worldwide trend to concentration of farmland in fewer, ever bigger, farms. Gustavo Grobocopatel, who farms 200,000 acres of soybeans in Argentina (an area the size of New York City), prefers to plant Monsanto's GM herbicide-tolerant variety (Roundup Ready) for the sake of simplified weed control, even though he obtains consistently higher yields with conventional soybeans. According to the Argentine Sub-Secretary of Agriculture, this labor-saving effect means that only one new job is created for every 1235 acres of land converted to GM soybeans. This same amount land, devoted to conventional food crops on moderate-size family farms, supports four to five families and employs at least half-a-dozen.[13] Small wonder that family farmers are disappearing and food security declining. The rapid expansion of "labor-saving" GM soybeans in South America has led to "agricultura sin agricultores" ("farming without farmers").

Increased pesticide use, resistant weeds, lower yields

According to the most authoritative independent study to date, adoption of herbicide-tolerant GM crops in the U.S. increased the overall amount of weed-killers applied by 138 million lbs. in the nine years from 1996 to 2004, while *Bt* corn and cotton reduced insecticide use by just 16 million lbs. Thus, GM crops have increased overall use of pesticides (herbicides + insecticides) in the U.S. by 122 million lbs. in less than a decade.[14]

The vast majority of HT crop acres are planted to Monsanto's "Roundup Ready" varieties, tolerant to the herbicide glyphosate (aka Roundup). The excessive use of glyphosate associated with continuous planting of Roundup Ready crops is responsible for a growing worldwide epidemic of weeds that have evolved resistance to this chemical, alarming the world's agronomists.[15] Millions of acres of cropland have become infested with glyphosate-resistant weeds in the U.S., Argentina and Brazil, precisely those countries that rely most heavily on Roundup Ready crops, leading to a vicious cycle of increasing pesticide use and evolution of still greater levels of weed resistance.[16] Hence a technology often fraudulently promoted as moving agriculture beyond the era of chemicals has in fact increased chemical dependency. And of course, expensive inputs like herbicides (the price of glyphosate has more than doubled over the past two years) are beyond the means of most poor farmers, especially in combination with more expensive GM seeds.

What about yield? The most widely cultivated biotech crop, Roundup Ready soybeans, suffers from a 5-10% "yield drag" versus conventional varieties, due to both adverse effects of glyphosate on plant health as well as unintended effects of the genetic engineering process used to create the plant.[17] Unintended, yield-lowering effects are a serious though little-acknowledged technical obstacle of genetic engineering, and are one of several factors foiling efforts to develop viable GM crops with drought-tolerance.[18] While insect-resistant crops can reduce yield losses under conditions of heavy pest infestation, such conditions are relatively infrequent with corn. And because cotton is afflicted with so many pests not killed by the built-in insecticide, biotech cotton farmers in India, China and elsewhere often apply as much chemical insecticide as growers of conventional cotton. Only because they have paid up to four times as much for the biotech seed, they end up falling into debt. Each year, hundreds of Indian cotton farmers commit suicide from despair over insurmountable debts.[19]

Biotech firms have employed genetic engineering chiefly to exploit 'synergies' between their seed and pesticide divisions.

Biotechnology = patented seeds + chemicals

If biotech crops are not about feeding the world, what *is* the point? The agricultural biotechnology industry represents an historic merger of two distinct sectors – agrichemicals and seeds. In the 1990s, the world's largest pesticide makers – companies like Monsanto, DuPont, Syngenta and Bayer – began buying up the world's seed firms. These four biotech giants now control a substantial 41% of the world's commercial seed supply.[20] The motivations for this buying spree were two-fold: the new technology of genetic engineering, and the issuance of the first patents on seeds in the 1980s. As we have seen, biotech firms employ genetic engineering chiefly to develop herbicide-tolerant crops to exploit "synergies" between their seed and pesticide divisions. Seed patents ensure greater control of and higher profits from seeds, in part by allowing biotech firms to outlaw seed-saving.

While patents on biotech seeds normally apply to inserted genes (or methods for introducing the gene), courts have perversely interpreted these "gene patents" as granting biotech/seed firms comprehensive rights to the seeds that contain them. One consequence is that a farmer can be held liable for patent infringement even if the patented gene/plant appears in his fields through no fault of his own (e.g. cross-pollination or seed dispersal), as happened most famously to Canadian canola farmer Percy Schmeiser. Another consequence is that farmers can be sued for patent infringement if they engage in the millenia-old practice of seed-saving – that is, replanting seeds saved from their harvest.

In the U.S., industry leader Monsanto has pursued thousands of farmers for allegedly saving and replanting its patented Roundup Ready soybean seeds. An analysis by Center for Food Safety has documented court-imposed payments of over $21 million from farmers to Monsanto for alleged patent infringement. However, when one includes the much greater number of pre-trial settlements, the total jumps to over $85 million dollars, collected from several thousand farmers.[21]

Spurred on by the biotech multinationals, the U.S. and European governments are pressuring developing nations to adopt similar gene and seed patenting laws. This is being pursued through the World Trade Organization, which requires member nations to establish intellectual property regimes for plants, as well as through bilateral trade agreements. Since an estimated 80-90% of seeds planted in poorer nations are produced on-farm (i.e. saved seed), the revenue to be gained from elimination of seed-saving is considerable – conservatively estimated at $7 billion dollars.[22] If biotech/seed firms have their way, the "seed servitude" of US farmers could soon become a global reality.

Biotech firms also have Terminator technology waiting in the wings. Terminator is a genetic manipulation that renders harvested seed sterile, and represents a biological means to achieve the same end as patents: elimination of seed-saving. While international protests have thus far blocked deployment of Terminator, Monsanto recently purchased the seed company (Delta and Pine Land) that holds several major patents on the technology (together with USDA). And while Monsanto has "pledged" not to deploy Terminator, the company has clearly stated that this "pledge" is revocable at any time.

GM Crops: Private Profit Replaces Public Interest

The rise of GM crops has been accompanied by a massive shift in plant breeding from the public to the private sector. Breeders at universities and non-profit agricultural research institutes once played a major role in delivering useful new crop varieties, guided at least in part by the interests of farmers. Today, public sector breeding is fast dying, the victim of dramatic cutbacks in funding from rich nations and the World Bank. Organizations like the International Rice Research Institute and Center for Improvement of Maize and Wheat lack funds to even distribute useful new crop varieties they have already developed to farmers who need them – including conventionally-bred wheat and rice with high yield, disease- and/or insect-resistance. In contrast, GM crop development is overwhelmingly dominated by profit-seeking biotech firms. In the U.S., 96% of approved GM crop varieties were developed by private firms, 88% by the "big five" biotech companies.[23] Monsanto alone is responsible for the traits in at least 87% of GM crops worldwide.[24] Public relations aside, biotech firms continue to devote the bulk of their research efforts to develop new herbicide-tolerant crops for use with their proprietary chemicals, labor-saving crops best-suited to larger farmers.[25]

Fewer seed choices, higher seed prices

To make matters worse, high-quality conventional seeds are rapidly disappearing, thanks to the biotech multinationals' tightening stranglehold on the world's seed supply. Biotech seeds presently cost two to over four times as much as conventional varieties. The price ratchets up with each new "trait" that is introduced. Seeds with one trait were once the norm, but are rapidly being replaced with two- and three-trait versions. As Monsanto put it in a presentation to investors, its overriding goals are "acceleration of biotech trait penetration" and "to invest in "penetration of higher-[profit-]margin traits..."[26] Monsanto and Dow recently announced plans to introduce GM corn with 8 different traits (6 insecticides and tolerance to 2 different herbicides). Farmers who want more affordable conventional seed, or even biotech seed with just one or two traits, may soon be out of luck. As University of Kentucky agronomist Chad Lee put it: "The cost of corn seed keeps getting higher and there doesn't appear to be a stopping point in sight." The biotech industry's growing control of the world's seed supply ensures that farmers in developing countries that accept GM crops will face dramatically rising seed prices from "trait penetration."

True solutions

The authors of the UN-World Bank-sponsored IAASTD report mentioned above recommend agroecological farming techniques as the most promising path forward for the world's small farmers. Ever since the Green Revolution, the agricultural development establishment has focused primarily on crop breeding and expensive inputs (e.g. fertilizers, pesticides and "improved seeds"), not least because input-centered schemes offer potential market opportunities to multinational agribusinesses. In contrast, agroecology minimizes inputs, and relies instead on innovative cultivation and pest control practices to increase food production. A 2001 review of 200 developing country agricultural projects involving a switch to agroecological techniques conducted by University of Essex researchers found an average yield gain of 93%.[27]

One strikingly successful example is the push-pull system, practiced by 10,000 farmers in East Africa. Push-pull involves intercropping maize with plants that naturally exude chemicals to control insect and weed pests, which increases yields while also enhancing soil fertility and providing a new source of fodder for livestock.[28] A new dryland rice farming technique called the System of Rice Intensification substantially increases yield, and is spreading rapidly in rice-growing nations despite dismissal by the agricultural development establishment. Small farmers like agroecological techniques because they foster independence and reduce expenditures on inputs.

Conclusion

The tremendous hype surrounding biotechnology has obscured some basic facts. Most GM crops feed animals or fuel cars in rich nations, are engineered for use with expensive weed killers to save labor, often have reduced yields, and are grown by larger farmers in industrial monocultures for export. The technology is dominated by multinational firms

intent on controlling the world's seed supply, raising seed prices, and eliminating farmer seed-saving.

Real solutions will require radical changes. Rich nations must stop dumping their agricultural surpluses in the global South, respect the right of developing countries to support their farmers, and fund agroecological techniques to enhance small farmers' ability to feed their families and their nations' citizens. ■■■

***Bill Freese** is science policy analyst at the Center for Food Safety, a nonprofit group that supports sustainable agriculture. For more on GM crops in developing countries, see: "Who Benefits from GM Crops," Friends of the Earth International and Center for Food Safety, 2008, at: http://www.centerforfoodsafety.org/WhoBenefitsPR2_13_08.cfm.*

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A Conversation with Dr. Árpád Pusztai

By Sam Anderson

Dr. Árpád Pusztai became the center of a political firestorm in Britain in the late 1990s when, on a television program, he expressed his concern with the results of a study he and a colleague had conducted on genetically modified potatoes. In the study, rats were fed either a) potatoes that had been genetically engineered (by a biotech company now called Axis Genetics) to express a protein called snowdrop lectin, b) conventional potatoes, or c) conventional potatoes mixed with snowdrop lectin. To Dr. Pusztai's surprise, the group of rats that had been fed GM potatoes showed damage to their intestines and immune systems, while the other groups did not.

With the permission of his employer, the Rowett Institute in Aberdeen, Scotland, Dr. Pusztai raised his concerns in a TV interview. The day after the program aired, the Rowett Institute suspended him and dismantled his research team, and he was ordered by the government not to speak on his research. According to one Rowett Institute colleague, the Institute had received phone calls from the British government, and the line of communication could be traced to Monsanto via the U.S. government. The incident, referred to in the press as "the Pusztai affair," sparked fierce debate in the scientific community, with many criticizing the study even though it had not yet been published. Many people credit (or blame) Dr. Pusztai for tipping public opinion in Britain against GM foods.

Today Dr. Pusztai continues to work and remains one of the world's foremost experts on lectins. He spoke with GeneWatch by phone from Hungary, where he teaches.

Dr. Árpád Pusztai: So you're interested in whether there have been any attempts to repeat our experiment?

GeneWatch: Yes, you said that nobody has had the courage to do it.

AP: I don't think that there has been any attempt. It would need a very ... how shall I put it ... a very brave person. I don't think that anybody will have the, I can say, the audacity to try to repeat our experiments – because they know perfectly well that they will get something very similar, if not identical results.

GW: You said that the methodologies you've established are not necessarily specific to GM materials – so what did you find was different in those studies, if anything?

AP: Any new source of protein has to be tested. And you can just regard GM material as a new source of protein. And most of the time, what you do is you try to assess the nutritional value of this new protein source. There are quite a number of protocols for this, and the essence of all of them is the comparison. So for that reason, you can only compare things that are what you think is, protein-wise, nitrogen-wise, energy-wise, identical or very similar in these various tests. ... But the first essential part of any evaluation is to feed the animals with that diet *in comparison* with the appropriate non-GM material.

And then you do all sorts of more sophisticated tests – you do immunity studies, you do allergenicity studies, you see how much of that nitrogen you're putting in is retained ... see what is happening metabolically. If you are, for example, exposing animals early on to chemical carcinogens, then you can compare the effect of the GM diet versus non-GM diet, how long it takes for the tumors to develop. These are all using models that are already accepted and are already being used for this testing.

Now, with the GM, it's very seldom done.

GW: Why is that?

AP: Because there is a problem of finances. Most of these studies are either financed by the biotechnology companies, or at least you need their agreement to carry out such studies. And not just the agreement, but to get the material from them, bona fide GM material - and very importantly, the appropriate parent line for the comparison. You are at the mercy of these companies, there is no other way to describe it. If they don't give you that material, you are going to have real difficulties. And that was the reason why we did use GM potatoes, because they were developed by a Cambridge team together with our friend in Durham to transfer the transgene into potatoes to make them resistant to aphid attacks. Because we *could* get this material and the parent-line potatoes in sufficient quantities – they were grown side-by-side in the UK under controlled conditions – so we had the material to carry out these studies.

Most of the people who incidentally tried to get to the bottom of this, whether they think the GM is as good as the non-GM, or what are the advantages or disadvantages - they are at the mercy of the biotech companies, such as, for example, Monsanto. Monsanto would never give you any material to do independent studies – or if they agreed to it, you have to sign a contract with them to say that all the results belong to them. Not just that they belong to them, but you would not be

allowed to publish it without their consent. This is something that you have to always take into account when they are talking about safety studies and all that. The companies' interpretation of GM safety is not necessarily the last word in this matter.

GW: In other words, you can't just go and actually buy the product from, say, Monsanto, if you're going to conduct studies on it?

AP: You go and try to do it! Particularly if – the seed, it has to be a direct comparison, so you need the isogenic line. You may be able to buy the GM material somewhere, by hook or crook, but you will never get the isogenic line. And I speak from experience. This is the reason we used the GM potatoes.

GW: So potatoes weren't your ideal crop –

AP: I knew perfectly well that potatoes, on their own, are not one of the best materials, because they contain little protein, less than ten percent. Most of the animals that you are testing for nutritional value of the crops you feed them on require at least ten percent protein input. So with the potatoes, alone as the protein source in a full balanced diet, we had some difficulties. Nevertheless, that was the thing that was available.

So I was told by the Ministry that it was 1.6 million pounds, 3 million dollars – you have to use potatoes. And that's it. You never say no to such a proposition.

GW: So your funding depended on using the potatoes?

AP: Yes. I mean, it had an economic importance for Britain, particularly for Scotland, so it was in their interest that we do the study on potatoes. Remember, I said it many times, I really did believe that the idea [of GM crops] was great, and it was only during the testing process that we found too many snags and started to think about what could be the reason for the snags. So I'm a late convert to skepticism.

Because when we started, I thought that it was great, a great idea. I was still at the university when that guy got a Nobel Prize for the genetic determinism, that you take one gene and that gene is expressing a particular phenotype and whatever. It sounded all right to me, it's just that as we were going ahead with our studies, we started to get results that did not fit into this pattern. And now I know – and anybody in the business, whether they are admitting it or not – they know perfectly well that you cannot splice a gene construct into another crop without making major changes in the genome of the crop that you spliced into.

So now we know what would explain our results. The genome of the potato is in any case quite an unstable genome. I remind you that every bit of the potato plant is poisonous except the tuber, and even the tuber can become poisonous under some conditions. So what we did is by splicing in a gene from the snowdrop plant, we disturbed the potato genome, and it became just as poisonous as any other part of the potato plant. When you look at the stupid idea of "substantially equivalent" ... you can't say that it is substantially equivalent because you change it. This is published in a respectable American journal, the *Journal of Agricultural and Food Chemistry*[1] – you splice the bean alpha-amylase gene in peas, and as a result of it you change all the genome and you are producing something that is chemically, immunogenically, allergenically different from what you intended.

What we found in 1998 is, in my opinion, commonplace. It's just been explained by what we now call insertional mutagenesis.

GW: So you think you might find the same results among commercialized GM crops?

AP: Well, yes – I mean, Monsanto 810 [a type of Bt corn] is commercialized, accepted even in Europe. Admittedly, the Hungarians, the Austrians, the Greeks, and some other parts of Europe have a moratorium on the growing of the stuff. But, I mean, this is now the accepted wisdom. You will never hear this from a biotechnology company, but why should they say it? They have invested a lot of money into this, so they are obviously going to defend their position and deny the existence of these things.

"I'm not saying that there is going to be a cataclysmic consequence of this. What I'm saying is that the cataclysmic thing about it is that we don't know what is going to happen."

GW: Why do you suppose, considering that so many people know this but a lot of people will just never tell you - what do you suppose is keeping these ideas out of consumer consciousness? Maybe not in Europe, but certainly in the U.S.

AP: Because U.S. consumers don't know what they eat! It's not just with GM. For a very long time now, the American production system tried to put a huge gap between production and consumption, so that you would not be able to get this farm-to-fork idea. You would nicely package something – I used to live in the States, so I know it exactly – beautiful packaging, but what's actually in the package is not very well known. And there's no great interest in it either.

GW: So what's the difference in Europe?

AP: In Europe, there are some traditional values that don't seem to agree with this uncertainty. We don't know – I mean, many times people ask me, 'What do you think is the main danger of GM?' And the main danger is that we do not know what the main danger is. We need reasonable hypotheses that could be tested by experiments.

GW: And sometimes the argument you might hear in favor of accepting GM foods is the opposite – that you can't prove anything is *wrong* with those foods.

AP: I think one of your great thinkers said, 'this is an irreversible technology.' Therefore, when you are approaching it, either conceptually or in practice, you have to take into account that this is in essence irreversible – and unpredictable. You don't know what the consequences will be. If you

put a plant into the ground, that plant is a living thing. Through the roots, you are communicating with the soil; through the leaves you are communicating with the air, with other organisms. You cannot look at it in isolation. This is a living thing, and that living thing is going to produce new DNA which gets into the ground, gets into the gut of animals and everything.

So it's something that you can't predict. You can't even predict how to test for it! It's common knowledge – probably a conservative estimate – that we don't know 98% of the living organisms in the soil. So how can you do an experiment? I mean, you can pick out some organisms, but what about all the others? So I think this is an extremely dangerous experiment - with our globe, with our Gaia, with our people - and if you ask me what are the likely consequences, I can only say that I haven't the faintest idea.

Once you've got this out, you can't turn around and say, 'oh, I've made a mistake.' This is an abrupt change. We have had no time for the system to adapt to the changes.

GW: Have we already passed the point of trying to warn people that it's irreversible, now that GM crops are so widely commercialized?

AP: Well, it depends on the country. In your country, in the U.S.A., a very large portion of the lands have been converted to it – but when you look all over the world, it's still only about two to three percent of the soil that has been exposed to it. So I don't know – I don't know much about population genetics – the only thing I know is that this is an experiment that has unpredictable, unmeasurable consequences, and I don't know what will happen. I am 78, so it shouldn't really concern me, but I am concerned because we are leaving something to our descendants to deal with, and they will be put in a situation where they have no choice, they just have to deal with it. And I suspect even then they may not know much about it. We know now that DNA constructs can survive for thousands of years in the ground.

I'm not saying that there is going to be a cataclysmic consequence of this. What I'm saying is that the cataclysmic thing about it is that we don't know what is going to happen.

GW: It seems so difficult for anyone to even obtain these materials for independent studies – is there any way for government to step in and make sure these studies happen. Do you have any sense of whether this has happened?

AP: You're quite right – the trouble is that the U.S. government is not doing it. Most of the stuff comes from the U.S., so it's very, very unlikely. Even your president-elect Obama has people on his advisory team who are coming from Monsanto. So what can you expect?

Humanity is mostly stupid. They only take something seriously once a disaster occurs.

GW: So they have to see the results?

AP: This is history. We'll have to just wait for some sort of disaster to happen.

GW: Or even if it's not a disaster, it seems people need to just be able to see the problems with their own eyes.

AP: We have to consider this, if it gives any advantage to the consumer. The consumers are carrying all of the risks but they aren't getting any of the benefits. That's one of the reasons why the biotech companies are now touting this idea, "the world is short of food, we're going to provide it."

GW: One of the contributors to this issue, Bill Freese, writes about those promises, and about how in reality the crops actually being commercialized carry traits that are not beneficial for consumers ... it seems that those promises really rest on technologies which haven't even been developed yet.

AP: We always say that everything is in the future. Promises, promises. You cannot exclude the possibility that they are right, but you have to take in the present situation. I can only say something about what is available, what has been looked at. When it comes, we'll have a look at it, but at the moment, there are no crops that can tolerate abiotic stress. That is a fact. Now Monsanto says that they will have this in twenty years' time. We'll have a look at it when it comes.

The future is, maybe, very rosy. You know, I am a Hungarian refugee who lived in Britain for 52 years. I remember back before I took refuge in Britain in 1956. Our 'great leader,' our communist leader here in Hungary, used to say, "We must not eat the chicken or the hen that's going to produce the golden egg of the future." We've been waiting for this golden egg for hundreds of years, and I believe that GM is not going to be that golden egg.

Scientifically, these are the key words: *insertional mutagenesis.* When you are inserting the transgene construct, you are changing the whole genome. Anything can happen. It could be that the disaster is just around the corner.

GW: You talked about being concerned about people who are overly certain about these technologies. These people may mostly be those in favor of the genetically modified foods, those who are overly certain of the benefits and the risks – but do you think there is also a problem with those who oppose the technologies, but not based on science?

AP: I know that in 1998 Monsanto spent over one million pounds advertising GM crops, and they were always saying that people weren't accepting it because they don't know anything about it, and it was their job to illuminate the subject.

But the fact is that at the end of the million pounds spent, there were more people disbelieving Monsanto's story.

Now everyone agrees – even the biotech companies agree – that they were shooting themselves in the foot. If they had gone about it quietly, they might have been fine, but instead they made a big deal about it. And people are not stupid. The issue is made out of all this, and people began to ask the question: what is Monsanto getting out of this?

GW: So in advertising they just drew attention to themselves.

AP: Yes. And I have great respect for the British general public. They can ask these very uncomfortable questions of the biotech industry: who is going to benefit from it? They know perfectly well that *I* didn't benefit from it! But they made a huge hullaballoo about this, and the companies know now that the right way for them would have been to put a lid on it, to keep quiet about it. But the public knows that something is happening, no matter how much they try to explain it. I know that people may not be nutrition-wise or science-wise very clever, but they have a common sense. They do understand that ... look, we are doing something that is fundamentally different from what we've done before. Therefore, just like the FDA's scientists whose sentiment was that we are doing something different, therefore the risks will be different – it is our responsibility to determine what these risks are. And if we can't come up with an acceptable answer, the next question is "who is to benefit?"

So here we are. Most importantly, what distinguishes the skeptics from the GM partisan? The skeptics try to speak to the facts. And it is therefore extremely important that the facts ought to be really facts, so that there are no mistakes. If I can help in any sense with this, then I shall do my best. ■■■

Dr. Árpád Pusztai has published nearly 300 papers and several books on plant lectins. Since the "Pusztai affair," he has given nearly 200 lectures around the world and received the Federation of German Scientists' whistleblower award. He was commissioned by the German government in 2004 to evaluate safety studies of Monsanto's Mon 863 corn.

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Antibiotics in Your Corn

By Timo Assmuth and Sheldon Krimsky

The risky business of pharmacrops

Biotechnology, including technologies based on genetic engineering or genetic modification, is becoming increasingly important in the global economy, ecology and politics. Agricultural biotechnology for food production has been the subject of much interest and debate in international politics, but in terms of market value, health care represents the largest sector of biotechnology, with pharmaceutical substances playing the major role. Most biotechnological pharmaceuticals are produced in microbes, but the use of genetically modified plants (often called "pharmacrops") to this end has gained increasing attention.[1] The first field trial permit for GM plants based on an application using the term "pharmaceutical" was issued in January 1991 in the U.S. By the year 2006 there had been 237 applications for field trials in the US alone; however, no commercial products have resulted to date.[2] Among the drugs being produced in plants are vaccines, antibodies, antigens, hormones, growth factors and structural proteins.

The possible advantages of plants over other systems in producing drugs include the production of larger volumes of drugs, more flexibility and cost-effectiveness in manufacture, better suitability of plant cells for production, and the potential of using plants and seeds for drug storage and delivery.[3] Plants have also some safety advantages over other pharmaceutical production systems, such as safety from contamination with human pathogens, endotoxins and tumorigenic DNA sequences.[4]

On the other hand, pharmacrops present important new risks and safety issues. By definition, they are used to produce substances that have potent biological effects on humans and

other higher animals. Pharmacrops contain higher concentrations of active substances than these animals are ordinarily exposed to in GM plants. Several genetic modifications are often carried out simultaneously, increasing risks.[5] Risks arise not only from biological but also socio-economic factors.

Pharmacrops consequently introduce special challenges to regulation. This is inherent in their position between agricultural, medical and general industrial biotechnology, and the special ecological-physical and socio-technological characteristics of these technologies. Some of these regulatory challenges include:

- The extension of new-generation GM crops to novel processes wherein the plants are not intended to be utilized as food crops but rather as plant-based 'drug factories.'
- Emergence of new forms of biopollution in possible gene transfers of GM pharmacrops to conventional crops.
- New methods required to evaluate drugs derived from plants that are grown in open fields.
- The need to align environmental, food and agricultural, as well as pharmaceutical and medicinal policies and regulatory procedures.
- The subsequent introduction of new actors, new interests and new contested issues regarding the development and application of the technology.

Risk issues are particularly urgent when pharmaceuticals are produced in plants that are potential food crops.[6] The need to control these risks has been stressed, by both consumers and food processors.[7] Currently pharmacrop risks are still addressed mainly within the conceptual frameworks of other GM food plants, and it is unclear how to accomplish the protection and management of food supplies as the distinction between food and pharmaceuticals becomes blurred.

The main direct risks associated with pharmacrops can be categorized in terms of causative agents (for instance, the drug being produced); dispersal processes (especially gene flow) and environmental fate of the produce; exposed organisms or systems (such as animals which feed on pharmacrops in field trials); and biological (toxic, allergenic, ecological), agricultural and social effects. All of these need to be accounted for in the life-cycle of the technology (see **Figure 1**).

Indirect risks arise in complex socio-ecological processes, also from attempts to control risks which inadvertently create new risks, for instance when using unproven 'terminator' technology to render GM plants sterile, combating vandalism by non-disclosure of information on field trial sites, or causing losses of relative benefits from pharmacrops as compared with conventional drug manufacture.[8] Some risks may be irreversible, especially in regard to gene flow into the environment. Accidental outbreaks from field trials and associated food chain contamination scandals indicate that the transgenes cannot be totally contained.[9] The crucial questions become how the different kinds of risks are judged and weighed against each other, what risks are deemed acceptable and on whose criteria, and what are feasible and justified risk abatement or prevention options.

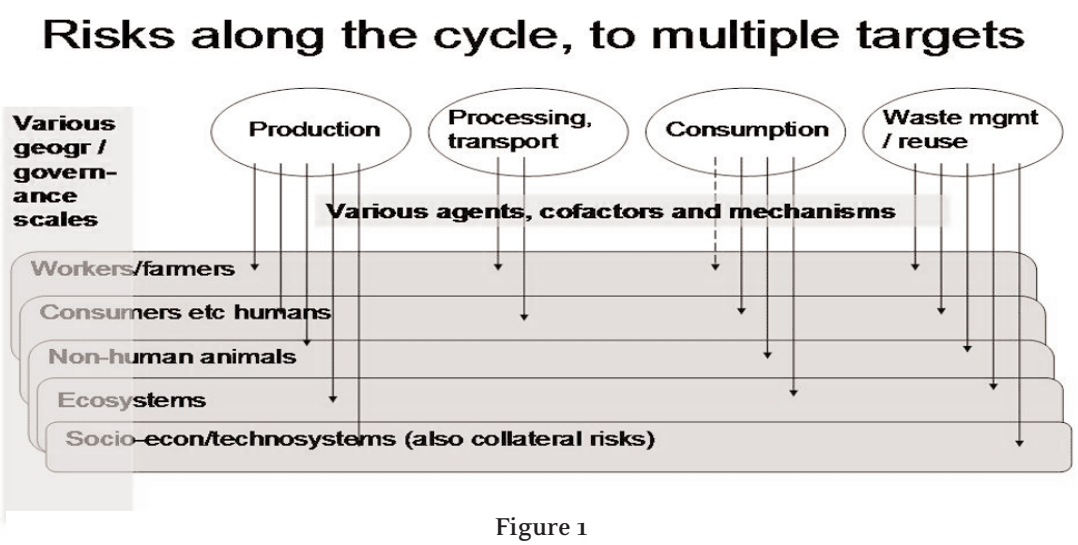

Figure 1

The risks of pharmacrops are unevenly distributed geographically. The map of field trials in the United States (**Figure 2**) shows that transgenic corn with pharmaceutical proteins has been tested mainly in the Corn Bbelt. Threats to food production systems, biodiversity, worker safety and rural development also vary according to location. If a pharmacrop is grown near fields of the same species, the risk of transferring the "drug gene" to a conventional crop is increased. The benefits are unevenly distributed as well; those who stand to directly benefit from a field test (such as a pharmaceutical companies or landowners paid to allow test plots on their land) do not necessarily share the risks, and thus the presence of potential risks does not necessarily inform decisions such as location of field plots (for a discussion of some of the political issues herein see Freese, 2002). For example, Iowa and Nebraska – two of the top corn producing states in the United States – have some of the highest numbers of corn pharmacrop test plots, despite the heightened risk of contamination or cross-pollination.

Castle (2008) singled out informed consent, risks to agricultural policy and intellectual property rights as the key global challenges for ethical production of vaccines in plants. The awareness, willingness (political) and capacity to respond to these issues varies between and within societies, and as a result there can be a mismatch between risks and responses. The geographical heterogeneity of risks and regulation increases from small nations to the US, the EU and the global systems.[10]

In the US, the policy toward pharmacrops has been relatively lax, but the regulatory procedures for assessing and

managing their risks have been upgraded in response to contamination accidents. In the EU, even after passage of a moratorium on GM plants, a more precautionary stance contributes to the lag of pharmacrop applications. The specific regulatory risk management options for pharmacrops are focused on technical measures at production sites, particularly containment, while options in other stages of the product life-cycle and risks of other dimensions have been given less attention (**Table 1**).[11] Additionally, critics point out that the seemingly self-evident options of restricting pharmacrops to closed systems and to inherently safer self-pollinating or non-food species have been a secondary consideration.[12]

In Europe, pharmacrop field trials have been carried out since 1995, but the number of trials declined after 1996; the cultivation acreage was nearly zero in 2002-2004. The onset of a more cautious approach to GM plants in general influenced these fluctuations. The regulatory approach in EU countries was pro-GM until 1990's, only later to be replaced by a *de facto* moratorium on commercial cultivation of GM crops for human consumption, due largely to growing concerns among consumers and Member States.[13]

However, even if the European stance toward GMOs has been precautionary overall for over a decade, pharmacrop risks have not been officially singled out. Increased R&D activities suggest that the EU may seek to switch back to a more pro-pharmacrop policy despite official caution, due in part to reasons of global trade policy and competition. Biopollution and other risk issues have been debated in connection with the proximity of GM crops to organic or conventional farms and with the buffer distance required to ensure safe coexistence of GM and non-GM plants.[14] These issues are potentially even more pronounced with pharmacrops, because crops can be contaminated with the pollen and residues of pharmacrops and because pharmacologically modified plants (PMPs) carry particular potency; yet such distances have not been specified in the EU for pharmacrops (**Table 1**).

The politics and practices of pharmacrop development and application involve the interplay and also tensions and clashes between different concepts of and approaches to risks, technology and regulation, and between interests and actors in various sectors and geographical regimes. Some of the polarization and conflicts in GMO politics influences pharmacrop policies, even if differently and as yet more subtly, due in part to the promises of producing wonder cures. Framing and evaluations of the risks from new-generation pharmacrops and other GMO 'industrials' are only emerging, and the confidence in their safety very greatly between and even within regulatory cultures.[15] Because of the complexity of the processes and influential factors, the trajectories of the technology and of regulation remain uncertain.

Although pharmacrops have been pursued actively, especially in the United States, some caution seems to hold commercialization back. It remains to be seen whether a fertile hybrid of pharmaceutical, agricultural and industrial technology will arise, and how the particular risks of pharmacrops will be dealt with. The development is likely to be uneven and turbulent. It will introduce the need to integrate activities on pharmacrops in partly new forms of communication, cooperation, negotiation and conflict resolution. These take time and effort to develop, due to differing concepts and traditions among actors and different views of the value-laden issues. Whatever action is taken needs to allow the legitimate involvement of a broader range of stakeholders. Even so, regulatory practices are as yet poorly equipped to deal with pharmacrops and their multi-dimensional largely unknown risks on a commercial scale. Meanwhile, certain concrete steps – such as restricting pharmacrops to closed systems and self-pollinating or non-food species – could provide a more immediate buffer against the risks, but even such solutions require the active engagement and interaction of concerned citizens including scientists and experts as well as regulators, consumer representatives and others. ■■■

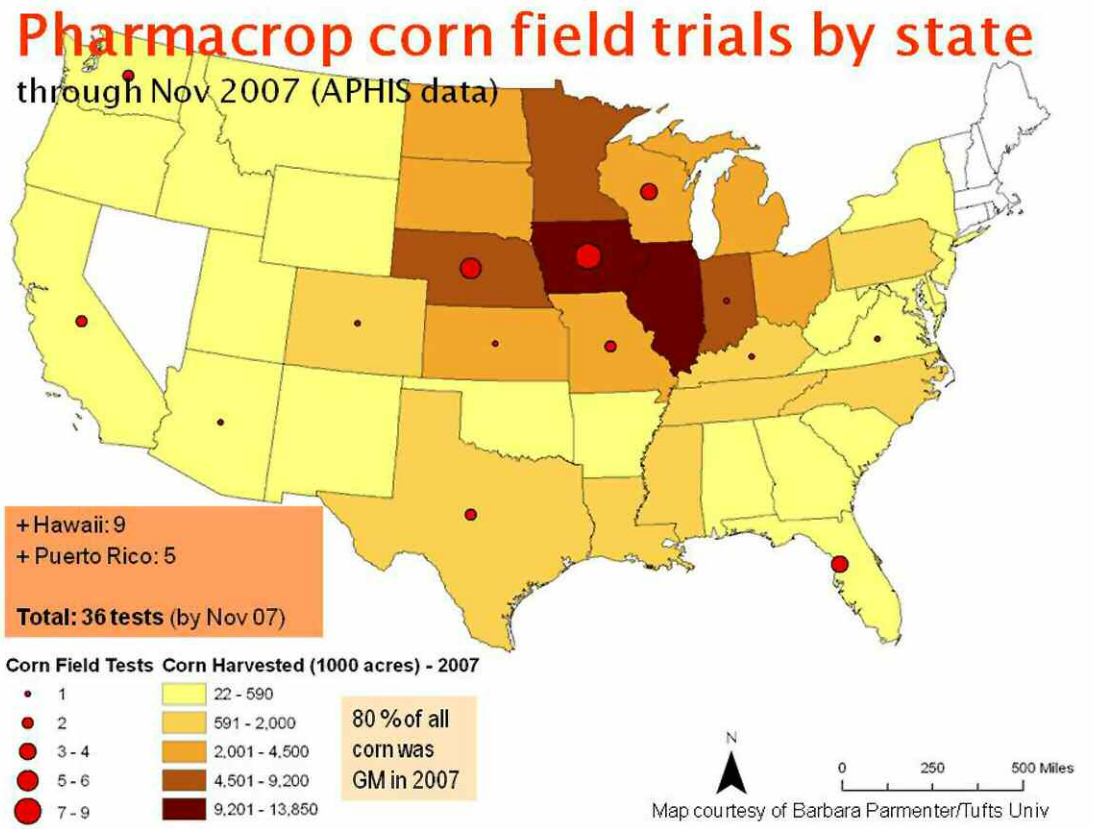

Figure 2

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Type of measure	*Inclusion in US procedures*	*Inclusion in EU procedures*
Selection of plant species	Low (little requirements for inherently safer species)	Moderate (high dispersal potential species not favored)
Selection of GM type	Low (many types of GM)	Low-moderate
Preparation of cultivation material, incl. sterilization and non-dispersing constructs	Moderate (developing, inherently risky)	Moderate
Selection of place of application (coexistence rules)	Low (non-GM crops often nearby)	Moderate (greenhouse not required)
Selection of timing and duration (coexistence)	Low (up to 1 year fallow period)	Low
Containment or buffer zones	Low to moderate	Emerging/unspecified for PMPs
Eradication of offspring	Moderate	As above
Prevention of seed transport	Moderate (failures occurred)	As above
Protection and control of wildlife	Low-moderate (few provisions)	As above
Cleaning of agricultural/processing machines	Moderate (failures occurred)	As above
Purification of products	Moderate (private interest)	As above
Testing of cultivar and product safety	Low-moderate?	As above
Occupational safety measures	Low-moderate?	Moderate (high overall)
Liability, insurance etc risk management provisions	Low-moderate (improved post-2002)	Emerging/unspecified for PMPs
Monitoring and oversight	Low-moderate; self-monitoring allowed	As above
Confidentiality of information	Moderate; low transparency	Moderate
Transparency and public availability of information	Low-moderate (improved post-2002)	Moderate (still cryptic for PMPs)
Inherently contained culture (greenhouse)	Low (not a focus)	Low (not a focus)
Labeling / consumer information	Low (resisted)	Moderate (partial)

Table 1. Inclusion of specific risk management measures in regulatory planning and implementation processes for pharma-crop applications mainly in field trials (based on U.S. and Canadian regulations and proposals).[16]

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Bt Brinjal in India: Why It Must Not Be Released

By Aruna Rodrigues

India is the world's second leading producer of brinjal (eggplant), a species which originated there. In 2008, the Indian government approved the production of brinjal genetically modified to internally produce bacillus thuringiensis, or Bt, which kills insects. Bt cotton has already been widely commercialized in India, but this would be country's first commercialized GM food crop. The applicants, Monsanto and Indian biotech company Mahyco, conducted safety studies on the Bt brinjal, and while the regulating agencies accepted the results of those studies, independent scientists and activists have sharply criticized them as severely deficient. This article's author and others have petitioned India's Supreme Court to halt the release of Bt brinjal.

The pressing need for an overhaul of GM foods regulation in India was made clear when India's governmental regulators accepted the conclusions of Mahyco-Monsanto's safety studies of its own Bt brinjal without subjecting the studies to independent scrutiny or oversight or separate tests not funded and carried out by the product's own producers.

It has taken two years for these safety studies to be put in the public domain. The regulator is complicit in having supported the biotech industry, and Monsanto in particular, in their attempts to keep the studies secret by claiming them as "confidential business information," until forced to change their stance by a court order.

Much more serious than Mahyco's 'misdemeanours' is the role of the Regulators, the Genetic Engineering Approval Committee (GEAC) and Review Committee on Genetic Modification, who appear to be incapable of conducting a proper safety assessment of Bt brinjal, and therefore possibly of any GM crop.

Independent scientists have examined the studies, and their appraisals provide evidence of badly designed studies; fuzzy data masked by too many controls; no 'p' values, a most serious omission; paucity of raw data; no peer review; and sam-

ple sizes which make sheer mockery of good biosafety testing, among other things. The Mahyco-Monsanto studies are a Gold Standard for how bio-safety testing ought not to be conducted.

In short, the studies are a smokescreen. The study defects are long and would fill a dossier on their own demerits. It is difficult to avoid the serious conclusion of intent to mislead, even cover-up and fraud.

There is no scientific basis for the industry claim that Bt crops are safe to eat. Furthermore, to base such a claim on apparent evidence of the success of Bt cotton misses the point - particularly, that cotton is not a food crop, and that Bt cotton as an animal feed has never been tested for human safety and is seriously implicated in animal toxicity, infertility and deaths.

In nature, bacillus thuringiensis (Bt) kills insects. Bt or the Cry class of proteins are toxic, are not eaten by human beings (or other mammals) and are not declared safe for human consumption. When the Bt protein is engineered into a plant, that plant produces the toxin internally in grain and other plant tissue. Bt plants are shown to have 1000 times more of the Cry protein expressed in kernels than would ever result from use of topical Bt toxin as a pesticide. Now, study after study by independent scientists, especially in the last two years, is producing evidence of the toxicity of the Bt transgene and the transgenic Bt plants.

Bt Brinjal protests in India.
Photo credit: Dr. G. V. Ramanjaneyulu, Centre for Sustainable Agriculture (available at http://picasaweb.google.com/gvramanjaneyulu/DelhiGMProtest)

Two eminently qualified independent scientists, Judy Carman and Gilles-Eric Seralini are two eminently qualified independent scientists, who have critiqued the feeding studies of the Mahyco biosafety dossier of Bt brinjal. Their appraisals represent the first independent scientific scrutiny of any crop developer's safety dossier in India and the first of its kind for a 'near commercialised food crop'. They have stated that Bt brinjal has not been properly and adequately tested by Mahyco, is unsafe and must not be released.

In reply, Mahyco says that "all its studies followed norms prescribed by GEAC [India's apex GM regulator]. We are at advanced stages of field trial for GM brinjal and our results are extremely promising."

Mahyco is quite right in saying that they have followed norms prescribed by the GEAC. This is exactly the point of the public interest Writ Petition in the Supreme Court of India: that there are no proper bio-safety regulations for the environmental release of transgenic crops in India, with the apex regulator, the GEAC, essentially adopting U.S.-style lack of regulation for GMOs.

It gets worse. The regulators have seriously misled successive Indian Prime Ministers about the truth of GM crops and in particular the inadvisability of introducing these crops in a center of megadiversity like India. Thus, having received got the political mandate they need, they now function under this mandate openly to promote GMOs without safety testing.

The lack of safety testing is very clear from 4 years of evidence submitted to the court on a whole range of issues including information under the RTI (Right to Information). The Mahyco Bt brinjal dossier of safety studies along with the critical issue of contamination of rice fields as a result of criminally negligent field trials of Bt rice in Jharkhand in July 2008 (in the corridor of the center of origin for rice), are the litmus test of the culpability of the Indian Regulator, who which is now being asked to stand down.

India is one of the world's most biodiverse countries and a 'center of origin' of many plants, the wild species of which have important traits for drought or insect resistance etc., (the same plant traits that biotechnology companies must rely on to produce their GMOs). India is also a center of domestication for many of these plants, and existing domesticated varieties that have been bred over hundreds or thousands of years are, properly, a part of farmers' capital. Transgenic crops, due to the inevitable threat of contamination, threaten biodiversity of both wild and domesticated varieties. Extreme caution should be required before India is exposed to GM crops - and especially a food crop like brinjal, for which India is a centerre of origin and diversity, and for rice, for which India is *the* center of origin.

No GM crop has been commercialized anywhere in the world in a country that is the center of origin for that crop. That the GEAC, That India's premier rRegulator, the GEAC, sees fit to pay scant attention to such a critical issue defines its their approach and itstheir culpability. I shall return to this point.

On the other hand, Mahyco-Monsanto has done exactly what was expected of them: to put their Bt brinjal in the best possible light by any available means. They have managed this thanks largely to the lack of obstacles in their way - particularly full, stringent and scientifically rigorous regulation.

Given the track record of Monsanto's performance in various countries, it can hardly be expected that the bio-safety dossier of Bt brinjal would include an admission of the inadequate design of Mahyco's safety studies.

The flaws and gaps in safety testing are significant and serious in the Bt brinjal dossier. With regard to environmental studies, the woefully inadequate gene flow studies and the lack of testing for non-target organisms, soil toxicity and other routes to contamination is a disgrace. Furthermore, Mahyco should have been required by the rRegulators to undertake long-term, multi-generational feeding studies on a large number of animals (e.g. at least 50 rats per group), using species that are proper proxies for humans and to measure outcomes that are relevant to human health (such as full haematology and blood biochemistry and histology on all rats). Such studies should also be designed well enough to stand a chance of determining whether GM brinjal causes any adverse effects on the animals.

Mahyco should also have been required to fully analyze the data and to properly report the findings of the study according to internationally accepted scientific standards (e.g. to at least report the full nature of each statistical test undertaken and the p-values resulting from the tests). It is of considerable concern that they did not do so. These studies were not subjected to any kind of independent scrutiny and oversight, nor did they have the benefit of public-funded safety-testing institutions that are internationally accredited – because we have none.

The inescapable conclusion of these feeding studies is that they have been 'engineered' or designed to throw up 'no significant differences'. It is also clear that the Indian regulator either (i) did not understand that the information it was given by Mahyco was woefully inadequate, which suggests serious incompetence on the regulator's part, or (ii) did understand that the information was inadequate but still passed it as adequate, which invites a charge of criminal negligence.

The GEAC is on record as wanting to "trust" the crop's developers because it would be wrong not to do so without reason – despite Monsanto's history of corporate criminality, including court indictments for some shocking violations. This history includes the production of Agent Orange, dioxin, and PCBs - all of which they declared as safe.

Other examples of Monsanto's business ethics hardly paint the corporations as trustworthy. According to the U.S. Securities & Exchange Commission, Monsanto bribed at least 140 Indonesian officials or their families. Dr. Margaret Haydon told the Canadian Senate Committee of Monsanto's 'offer' of a bribe of between $1-2 million to the scientists from Health Canada and how notes and files critical of scientific data provided by Monsanto were stolen from a locked filing cabinet in her office. Monsanto devotes more than $10 million per year to harassing, intimidating, suing, and in some cases bankrupting American farmers over alleged improper use of its patented seeds.

The urgent question is this: Is India as a nation prepared to risk our entire future for all time, in terms of contamination of our biodiversity, health, farmers & farming environment, and food security, because of an inappropriate investment of "trust" by our Government and its Regulator, in Mahyco-Monsanto and other GM crop developers?

Thus, India is at great threat from its own Regulators. The result is that field trials in India have been conducted on every conceivable food crop – based mainly on the Bt gene, which is undeniably toxic – over a period of about a decade without proper biosafety tests being done.

The Bt brinjal dossier clearly shows what things have come to. Bt brinjal has not been properly and adequately tested, and is now declared to be un-safe by experts, yet it is on the verge of commercialization and would have been commercialized by now except for the courageous opposition to it by farmers and civil society groups plus legal opposition.

Dr. Pushpa Bhargava (the Supreme Court's nominee to the GEAC to provide some balance to this committee) has advocated a core list of tests that must be done before any GMO is approved for release. This list has the unqualified agreement of leading international scientists who state that they conform to world class scientific standards for safety assessment. These experts have supported the stand that Dr. Bhargava has taken in the GEAC despite facing severe opposition from the Regulator that is both unscientific and unprofessional.

In the ultimate analyses, the Bt brinjal tests quite astoundingly amount to this: In the best of the tests, one study of 10 rats, which have been caged for 90 days, has been conducted. It has been subjected to independent scientific analyses by Seralini and Carman, and even with its severe deficiencies, it shows worrying results both clinically and statistically on various parameters which Mahyco dismiss as not being significant.

Both scientists say the release of Bt brinjal must be forbidden until full and proper safety assessments are done to a proper standard, preferably by researchers who are independent of vested interests, and the results are published in a peer-reviewed scientific journal for other scientists to read and comment upon.

On the best construction of 'intent' of the GEAC, on the basis of their 'trust' in Mahyco-Monsanto, our government and its apex regulator are prepared to take a risk on the health of one billion Indians – and in perpetuity, because once introduced into the environment, GMOs can never truly be recalled and thus can have irreversible impacts.

As Dr. Carman has pointed out, if only 1 in 1,000 of exposed people later gets ill, or has an underlying illness made worse, over one million Indians would require treatment. This would result in a huge cost to the Indian government and community.

This risks a social cost and a health scam of almost unimaginable magnitude that will make 'chicken-feed' of every other scam in the country. Clearly, the Government of India must be made to see reason in its policy on GM crops. We must announce a moratorium of at least 5 years, while we get GM regulation on track in the manner required.

Aruna Rodrigues *is spearheading a legal battle in India seeking a moratorium on release of genetically modified crops, a ban on imports of genetically modified products, and setting up an independent testing facility which meets international standards.*

(This analysis is based on evidence provided to the Supreme Court of India. The official GEAC Bt brinjal biosafety dossier is available at http://www.envfor.nic.in/divisions/csurv/geac/information_brinjal.htm.)

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