European Parliament Talk – April 2007

Regulation:

* In late 1980s and early 1990s, Reagan and Bush senior administrations insisted that GM crops be regulated under existing statutes designed for invasive plants, chemical pesticides and food additives

* No new statute passed to regulate this radical new technology

* Biotech industry, especially Monsanto, exerted enormous influence on the resulting regulatory system:

> "In this area, the US government agencies have done exactly what big agribusiness has asked them to do and told them to do" (Henry Miller, in charge of biotechnology at the FDA from 1979-1994: as quoted in New York Times, 2001).
>
> "Even longtime Washington hands said that the control this nascent industry exerted over its own regulatory destiny through the Environmental Protection Agency, the Agriculture Department and ultimately the Food and Drug Administration was astonishing." (NYT 2001)
>
> "What Monsanto wished for from Washington, Monsanto and, by extension, the biotechnology industry got. If the company's strategy demanded regulations, rules favored by the industry were adopted. And when the company abruptly decided that it needed to throw off the regulations and speed its foods to market, the White House quickly ushered through an unusually generous policy of self-policing." (NYT 2001)

* Regulation of genetically engineered foods is divided among three federal agencies.

1) The *US Department of Agriculture* oversees GM crop field trials and is responsible for deregulating (i.e. permitting the unregulated cultivation and sale of) GM crops (more below).

2) The *Environmental Protection Agency:*
   a) Regulates pesticides in GM pesticide-producing crops (i.e. Bt crops);
   b) Increases the amount of weedkiller residues that are permitted on some herbicide-tolerant GM crops
   c) Does not require animal feeding trials with GM pesticide-producing crops
   d) Accepts biotech company's assertions about safety of these crops
   e) Does require "refuges" to slow development of insect resistance to Bt pesticides

3) The *Food and Drug Administration* conducts voluntary consultations on other aspects of GM foods with those companies that choose to consult with it.
   a) FDA receives "summary data" from biotech company
   b) Companies sometimes refuse to provide additional data requested by FDA
   c) FDA does not require animal feeding studies for GM crops
   d) FDA does not approve GM foods as safe
   e) FDA merely repeats biotech company's assertion that GM crop is no different than conventional crop

* European GM crop regulation somewhat better than in U.S., but not much, as EU regulators increasingly adopt U.S. government's sloppy practices

Risks

1) Extensive mutations in GM crops can create novel toxins, increase amounts of natural low-level toxins in plants, and decrease nutritional content. Evidence that Roundup Ready soybeans have lower levels of beneficial phytoestrogens

2) Novel insecticides introduced into GM Bt crops could cause food allergies – as with StarLink corn and other Bt crops

3) Other harms: EU recently approved a Monsanto Bt corn (MON 863) despite a peer-reviewed study showing signs of liver and kidney damage in rats fed the corn for just 90 days. U.S. government doesn't even require 90-day feeding trials.

Current Status of GM crops:

1) Four GM crops – soybeans, corn, cotton and canola – comprise virtually 100% of global acreage planted to GM crops. The few commercialized GE crops other than these four are planted to a miniscule percentage (<< 0.1%) of global GE crop acreage.

2) These four GM crops have been engineered for one or both of two traits – herbicide-tolerance and insect-resistance (internal production of the Bt insecticide).

   a) **GM crops with herbicide-tolerance (HT) make up 81% of global GM crop acreage** (68% are HT alone; 13% are HT and IR)
   b) GM crops with other traits, such as virus resistance and sterile pollen, are planted to a miniscule percentage (<< 0.1%) of global GE crop acreage.

3) There are NO commercialized GM crops with enhanced nutrition, increased yield, drought-resistance, salt-tolerance or other widely publicized traits, which at best are at the early experimental stage.

4) Biotech company research for future GM crops still focused on HT crops

GM Herbicide-Tolerant Crops

1) GM HT crops are almost all (roughly 99%) Roundup Ready soybeans, corn, cotton and canola; Bayer's LibertyLink corn, cotton and canola make up the rest

2) Impacts of Roundup Ready crops include massive increase in use of glyphosate (i.e. Roundup); generation of glyphosate-resistant superweeds; harm to soil life critical to crop health and productivity; and possible harm to frogs and other amphibians.

Roundup Ready Crop Acreage and Glyphosate Use:

a) According to Monsanto's figures, Roundup Ready (RR) soybeans, corn, cotton and canola were grown on 117 million acres in the U.S. in 2006, up 13% from 103 million acres in 2005.

b) Glyphosate use in U.S. agriculture increased six-fold from 1992 to 2002, mirroring the rapid rise in Roundup Ready cotton and soybean acreage

c) Glyphosate use on corn has increased more than seven-fold in just the four years from 2002-2005, reflecting rapid adoption of RR corn

Glyphosate-resistant weeds:

a) Monsanto introduced Roundup in the U.S. in 1976

b) Glyphosate-resistant weeds were almost unknown until the introduction of Roundup Ready crops in the mid 1990s

c) Glyphosate-resistant weeds now infest at least two million acres of American cropland in the South, with superweeds spreading rapidly to the Midwest and West

d) North Carolina State University weed scientist Alan York stated that glyphosate-resistant weeds pose a threat to the cotton industry comparable to the infamous boll weevil

e) Farmers in Arkansas and other states are spending millions of dollars more to fight glyphosate-resistant weeds

f) Glyphosate-resistant weeds are leading to increased use of even more toxic weedkillers such as 2,4-D, a component of the infamous Agent Orange

g) Farmers in Tennessee and other states are abandoning soil-saving "no-till" cultivation to kill glyphosate-resistant weeds, leading to increased soil erosion

Soil Life, Crop Health and Productivity

a) Growing body of research shows that glyphosate applied to RR crops enters plant tissues and moves to roots, where it leaks into the surrounding soil

b) Glyphosate in plant itself blocks uptake of important mineral nutrients

c) Glyphosate that leaks into soil kills beneficial soil life that help the crop to absorb mineral nutrients like iron and manganese, causing mineral deficiencies and weakening plant

d) Roundup in soil promotes disease-causing fungi such as Fusarium, increasing susceptibility of crop to disease

Roundup and Frogs:

Recent research shows that supposedly inert ingredients in Roundup brand herbicide are toxic to tadpoles and young frogs, much more so than glyphosate alone.

Illegal Actions by USDA

1) USDA has lost three federal court cases in just the past year for violating federal law by failing to regulate GM crops

Hawaii biopharm case – decision August 31, 2006

2) USDA illegally approved field trials of drug-producing, GM crops (including corn and sugarcane) throughout Hawaii without considering the effects to endangered species and without conducting any environmental review

"APHIS's utter disregard for this simple investigation requirement [under the ESA], especially given the extraordinary number of endangered species and threatened plants and animals in Hawaii, constitutes an unequivocal violation of a clear congressional mandate." – *Judge Seabright*

3) Pharmaceutical crops, genetically modified to produce pharmaceutical compounds such as hormones, vaccines, and cancer fighting agents, pose unique human health and environmental risks, such as:
   a) threats to endangered species that feed on such crops;
   b) releasing unwanted chemicals into the air, water, and soil;
   c) contamination of non-GE crops with the genes to produce these compounds; and
   d) threats to the economic livelihood of organic and conventional farmers that could lose their markets if contamination occurred

4) USDA poised to approve planting of up to 3200 acres of pharmaceutical rice in Kansas

Creeping bentgrass case – decision Feb. 5, 2007

1) USDA illegally approved open-air field trials of GM "Round Up Ready" Creeping Bentgrass and Kentucky Bluegrass by claiming that these tests were "categorically excluded" from needing any environmental risk assessment.

2) Creeping Bentgrass and Kentucky Bluegrass are two robust, weedy perennial grasses that pose significant environmental risks to the environment when genetically engineered for resistance to Roundup:

   a) Biological contamination of naturally occurring grass species through pollen transfer or seed disperal;
   b) Enhanced weediness makes contaminated grasses more difficult to remove from naturally protected areas; and
   c) Increased use of Roundup and more toxic pesticides as Roundup resistance develops.

3) Judge Kennedy of the Federal District Court of the District of Columbia ordered that USDA must halt approval of all new field trials across the country until more rigorous environmental reviews are conducted for each GM crop field trial.

"The record contains substantial evidence that the field tests may have had the potential to affect significantly the quality of the human environment, and that the tests may have involved, at the least, novel modifications (if not "new organisms") that raised new environmental issues. APHIS failed, however, to consider any of these possibilities. … [D]efendants are permanently ENJOINED from processing any acknowledgment or permit … without [complying with NEPA and this opinion]." – Judge Kennedy

4) USDA has approved over a thousand field trials for new GE crops each year without doing any environmental assessment under the "categorical exclusion" loophole. This court decision forces USDA to significantly slow down its dangerous, fast-tracked approval of experimental GE crop field trials, and to comply with environmental protection laws by adequately assessing the significant environmental consequences of such field trials before they are allowed to occur.

Roundup Ready alfalfa – decision Feb. 14, 2007

1) Two cases above involved USDA's illegal approval of field trials of GM crops

2) In this case, the court ruled that USDA illegally approved GM Roundup Ready alfalfa for commercial cultivation by failing to conduct a serious review of environmental impacts

3) Risks include:
   a) Unintentional biological contamination of conventional and organic alfalfa with GM alfalfa genes;
   b) Increased use of the toxic herbicide Roundup, endangering protected species and biodiversity;
   c) Creation of Roundup resistant "superweeds" resulting from increased Roundup use; and
   d) Threats to the economic livelihood of organic and conventional alfalfa growers.

4) Alfalfa is the fourth largest crop grown in the U.S. and would be the first perennial crop approved for GE commercialization.

5) For the first time, a Federal court held that USDA failed to abide by environmental protection laws when it approved a genetically engineered crop for commercialization without conducting a full Environment Impact Statement (EIS).

> "For those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop." … "A federal action that eliminates a farmer's choice to grow non-genetically engineered crops, or a consumers' choice to eat non-genetically engineered food, is an undesirable consequence." – Judge Breyer

> "The Court notes, however, that it is unclear from the record whether any federal agency is considering the cumulative impact of the introduction of so many glyphosate resistant crops; **one would expect that some federal agency is considering whether there is some risk to engineering all of America's crops to include the gene that confers resistance to glyphosate"**

6) Roundup Ready alfalfa seed cannot be sold until USDA conducts a full environmental impact statement that addresses the risks noted above

USDA Inspector General's Report – December 2005

In 2005, the USDA's Inspector General conducted an audit covering GM crop field trials conducted in 2002 and 2003, finding numerous basic deficiencies in APHIS oversight. A few of the more flagrant deficiencies include:

1) USDA often doesn't know where or even if many GM crop field tests have been planted. In 85% of the pharmaceutical crop field trials and 100% of other GM crop field trials that the IG reviewed, only the company's business address, or the state and county of the field trial, was listed as the planting location.

2) USDA does not require submission of written protocols, and thus cannot review them, prior to issuing most permits for GM crop field trials.

3) APHIS failed to conduct scheduled inspections of numerous field trials of pharmaceutical-producing crops. Only 1 of 12 sites inspected by the IG in 2003 had all 5 required inspections; only 18 of the 55 required inspections were performed for the other 11 sites.

4) In two cases, the IG discovered that 2 tons of harvested pharma crops had been stored onsite for over 1 year, without USDA's knowledge or consent, and thus without USDA inspection of the storage facility.

5) The IG made 28 recommendations to USDA to remedy these egregious deficiencies and lapses in its regulatory performance. USDA rejected 7 of these recommendations, and agreed to only partially comply with two others. Some of the measures USDA refused to implement include:

    a) Development of policies to restrict public access to edible GM pharmaceutical crops
    b) Require companies to submit and USDA to review written protocols, including "gene containment" measures, prior to approving field trials of non-pharma GM crops
    c) Distribute these written protocols to inspection personnel
    d) Impose sanctions for missing or late progress reports from the field trial operators
    e) Require applicants to report planned date of disposal of harvests of GE crops producing pharmaceuticals or industrial proteins.

f) Develop and implement written policies and procedures for selecting specific field tests sites for inspection based on risk.
g) Require submission of planting notices, 4-week reports, and harvest/termination reports.

USDA Fails to Regulate Pharmaceutical Rice in 2005

1) USDA says it has improved its performance since the Inspector General's audit, but the facts show otherwise

2) In 2005, several hundred acres of pharmaceutical rice was planted under USDA permit in North Carolina less than one mile from a government rice-breeding station. Hurricane Ophelia passed over the planting site while the pharma rice was in the ground.

3) USDA documents obtained by Union of Concerned Scientists show that:

   a) No record that USDA or the company (Ventria) inspected the planting site to see if Hurricane Ophelia had spread the pharma rice. Hurricane force winds and the associated flooding quite likely spread Ventria's pharma rice into the environment, and perhaps to a government rice breeding station located just 0.6 miles from Ventria's field test sites;
   b) USDA completed only 3 of 5 "required" inspections of each of three field test plots
   c) USDA collected only one of nine "required" reports from Ventria on the pharma crice planting

4) USDA is poised to approve cultivation of up to 3,200 acres of pharmaceutical rice in Kansas

Real-World Consequences of USDA's Neglect

1) In 2006 and 2007, two unapproved genetically engineered rice varieties developed by Bayer CropScience (LL601, LL604) grown under permits issued by USDA massively contaminated conventional rice, and found their way into rice imported by European countries, and even rice products on supermarket shelves.

2) LL601 was found in 33 of 162 rice samples tested by the EU

3) LL601-contaminated rice or rice products found in nine European countries, including the UK, France, Germany, Greece, Norway, Ireland, Austria, Slovenia and Italy.

Supermarket products contaminated with LL601 have been withdrawn in the UK, Germany, France, Switzerland, Norway, and perhaps other countries.

4) The UK Rice Industry Association reportedly stopped importing any U.S. long-grain rice. The world's largest rice processor, Ebro Puleva, stopped importing U.S. rice in August 2006.

5) The economic fallout from LL601 is huge. Prices on the rice futures market dropped dramatically in the weeks after contamination was first announced. Some in the rice industry predict losses of $150 million.

6) On March 5, 2007, USDA announced a second contamination episode in which a another experimental GM rice (LL604) unapproved for commercial cultivation massively contaminated a popular conventional line of rice, CL 131. As a direct result, both this line of rice and the one contaminated with LL601 (Cheniere) are unavailable for planting by Southern rice growers this spring, occasioning a severe shortage in the rice seed supply for rice farmers, imposing a great hardship on U.S. rice farmers.