

Rachel's Environment & Health News

#549 - Genetic Engineering Error

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According to the St. Louis POST-DISPATCH, Monsanto, the St. Louis chemical and biotechnology giant, last month announced it had recalled "small quantities" of a genetically engineered canola seed containing an unapproved gene that had gotten into the product by mistake. Canola is a crop grown for livestock feed, and for oil consumed by humans. The canola-recall story, only 84 words long, was buried in the POST-DISPATCH April 18, under a confusing headline, deep in a news-wrapup column on the business page.[1]

Putting the wrong gene into a commercial product by mistake is precisely the kind of error that opponents of genetic engineering have been predicting for a decade. Proponents of genetic engineering have said it could never happen because of rigorous quality-assurance by the industry itself and tight regulation by governments.

The recall was reportedly initiated by Monsanto Canada Ltd., and by Limagrain Canada Seeds, Inc., of Saskatoon, Saskatchewan, which was selling the seed under license from Monsanto. The recalled canola seed was "Roundup ready" --meaning it had been genetically engineered to withstand dousing with Monsanto's herbicide, glyphosate, which is marketed under the trade name Roundup. Since February, 1996, Monsanto has been marketing various genetically-engineered crops that are "Roundup-ready" in an effort to boost sales of Roundup, the herbicide responsible for a large proportion of Monsanto's annual profits.[2] (See REHW #521.) The idea is to douse Roundup-ready crops with Roundup to kill weeds, leaving the genetically-engineered crop intact. According to the Associated Press, Monsanto refused to disclose how much genetically misengineered canola seed is being recalled, but said the amount was "small." [1]

Canadian government officials say the quantity being recalled is not small. Brewster and Cathleen Kneen, publishers of the RAM'S HORN, a Canadian newsletter devoted to analysis of the food system, said that, in mid-April, Monsanto reported to the Evaluation Branch of the Biotechnology Strategies and Coordination Office of the Canadian government that it was recalling 60,000 bag units of two types of canola seeds (types LG3315 and LG3295) because one or both types contained the wrong gene.[3] Thus the amount recalled is sufficient to seed 600,000 to 750,000 acres of land. According to RAM'S HORN, some of the seed had already been planted when Monsanto discovered the mistake.

The MANITOBA CO-OPERATOR, a Canadian agricultural newspaper, quoted Ray Mowling, a Monsanto spokesperson, saying, "In some recent quality assurance testing by us, we've identified that there's a possible variety contamination." [4] Brewster Kneen of RAM'S HORN points out that it takes a long time to produce enough Roundup Ready seed for 600,000 acres, so this error went undetected for a substantial period.

Under Canadian law, there are three levels of approval for genetically engineered crops: environmental (meaning the crop can be planted), livestock (the resulting crop can be fed to livestock), and human (the resulting crop can be fed to humans). Two Roundup-resistant canola genes, RT-73 and RT-200, had been approved for planting, but only RT-73 was approved for livestock and humans. It was the unapproved RT-200 that somehow ended up in the seed that had to be recalled. "The preliminary testing showed it to be the wrong configuration, as opposed to the one approved," Monsanto's Mowling said.

Canola oil is used in low-fat foods, pharmaceuticals, nutritional supplements, confectionery products, margarine and shortening, personal care products, lubricants, soaps, and detergents.

The presence of the unapproved canola gene in a commercial product reveals, at a minimum, that Monsanto's quality-assurance programs failed in this instance, and that the biotechnology regulatory system in Canada is ineffective. The regulatory system in the U.S. is more lax than Canada's.

Limagrain's Gary Bauman said his company will try to discover how the mistake occurred. However, he said it will be difficult to trace exactly where in the process it happened because the seeds available for testing now are progeny (offspring) of the original seeds. "We may never know how it happened," he said.

Bauman later seemed to lay the blame squarely on Monsanto. He said only Monsanto has the expertise to detect genetic differences between seeds. "The apparent contamination, discovered by Monsanto, is something only they are able to detect. We are not even allowed to try to investigate how to look at and discover this gene within our own varieties," Bauman said.[5]

Recent history reveals that serious problems may occur when a genetically engineered product appears on the market without adequate testing. In 1989, a Japanese firm marketed an amino acid, L-tryptophan, which was produced from a genetically-engineered bacteria.[6,7,8] Unexpected trace contaminants --not all of which were ever identified chemically --appeared in the final product and an estimated 5 to 10 thousand people[9] in the U.S. fell ill with a new and exceedingly painful disease called eosinophilia-myalgia syndrome (EMS). At least 37 people died and thousands more were disabled. Something in the biotech-produced L-Tryptophan attacked people's immune systems. Their joints and muscles ached excruciatingly. Their limbs swelled. In many respects, their disease resembled scleroderma.

Studies of the new EMS disease revealed that people with the disease most likely got it from L-tryptophan produced by the fifth genetically-engineered version of a bacteria (called BACILLUS AMYLOLIQUEFACIENS V). [10,11] Unfortunately, the company producing the L-tryptophan made other changes in its production process when it introduced the new bacteria, so researchers have never been able to discern whether the disease was caused by the changes in production methods or by the genetically-altered bacteria (or both).

In any case, it is crystal clear that genetically-engineered products need extensive testing before their effects can be understood. The simple view, that genes control only one characteristic of a bacterium, plant or animal has been shown to be false. Genes contain a potential that can be expressed in various ways, depending upon the environment in which the gene grows. Thus a gene may develop in one way in one environment and another way in another environment. Testing in one environment may not reveal what the gene will do when it finds itself in another environment. This has been demonstrated elegantly by Craig Holdrege in his book, GENETICS AND THE MANIPULATION OF LIFE: THE FORGOTTEN FACTOR OF CONTEXT.[12]

Furthermore, Danish researchers have shown that genetically-manipulated genes (transgenes, they are called) in crops can make their way into nearby weeds under field conditions.[13] Thus genetic errors, of the kind made in Monsanto's canola seeds, may propagate into the environment and permanently alter the natural world in ways that no one is prepared to understand.

Still, Monsanto management has bet the company on biotech and has announced plans to press ahead aggressively. Roundup is Monsanto's best-selling and most profitable product, bringing Monsanto about \$1.5 billion per year. "Roundup is the engine that's driving Monsanto," said Paul Raman, a chemical industry analyst for the investment banking firm S.G. Warburg & Co.[2]

"In five to 10 years Roundup could be a \$4 billion product," Raman said. That extra money would come chiefly from expanding sales of crops that are genetically engineered to resist the weed killer.[2]

Monsanto announced eight months ago that it is selling off its chemical divisions in order to focus its business entirely on biotechnology-related products.[14]

"What you are seeing is the beginning of the agri-industrial complex," Sano Shimoda, president of BioScience Security, Inc., an investment banking company focusing on the biosciences, told BIOTECHNOLOGY NEWSWATCH, an industry newsletter.

"From the big picture standpoint Monsanto has the ability to be the dominant biotech-based ag-food company in the world," Shimoda said.

To get a stream of genetically-engineered products to market, Monsanto will need to convince the U.S. Food and Drug Administration (FDA) that these products are safe for human consumption. In the past, Monsanto has been able to do this partly because former Monsanto officials have become FDA officials, who have then been assigned to approve Monsanto products--in some cases, the products they worked on while at Monsanto. [15]

There can be no doubt that a high-level revolving door exists between Monsanto and the administration in Washington. The WASHINGTON POST reported April 21, 1997, that Marcia Hale, President Clinton's assistant for intergovernmental relations, would be taking a "sweet" job with Monsanto. She will coordinate public affairs and corporate strategy in the United Kingdom and Ireland for about six months. She will then come back to work out of Monsanto's Washington office to handle international and "other matters." [16]

The St. Louis POST-DISPATCH reported May 17, 1997, that Monsanto's vice-president, Virginia Weldon, is a "top candidate" for the job of chief of the U.S. Food and Drug Administration (FDA). [17]

--Peter Montague (National Writers Union, UAW Local 1981/AFL-CIO)

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[1] "Argosy Names Perry New Chief Executive," ST. LOUIS POST-DISPATCH April 18, 1997, pg. C1.

[2] Robert Steyer, "Monsanto Makes a Bestseller Better," ST. LOUIS POST-DISPATCH January 21, 1996, pg. D1.

[3] Brewster Kneen, "Monsanto's Claims Overturned," RAM'S HORN No. 147 (April 1997), pg. 1. RAM'S HORN is available each month (11 months each year) for \$20 per year from: Box 3028, Mission, B.C. V2V 4J3 Canada. Checks should be made out to THE RAM'S HORN. [This is one of the most interesting newsletters I have seen in a long time.--P.M.] Mr. Kneen also quoted Sheri Haas with the Evaluation Branch of the Biotechnology Strategies and Coordination Office of Agriculture Canada, a federal agency: Room 3369, 59 Camelot Drive, Nepean, Ontario K1A 0Y9; telephone (613) 225-2342 ext. 4175; internet: shaas@em.agr.ca.

[4] Laura Rance, "Registration Suspended; Genetic mixup prompts recall of Roundup Ready canola," MANITOBA CO-OPERATOR April 24, 1997. The MANITOBA CO-OPERATOR is published weekly by Manitoba Pool Elevators, 220 Portage Avenue, P.O. Box 9800, Sta. Main, Winnipeg, Manitoba R3C 3K7, Canada. Telephone: (204) 934-0401. Our thanks to Cathleen Kneen of RAM'S HORN for a copy of Laura Rance's story.

[5] Brewster Kneen, "Misguided Canola--Update," RAM'S HORN No. 148 (May 1997) quoting Mary MacArthur, a reporter for the WESTERN PRODUCER, which is published weekly by Western Producer Publications, P.O. Box 2500, Saskatoon, Saskatchewan S7K 2C4, Canada. Telephone: (306) 665-3500.

[6] P.F. D'Arcy and others, "L-tryptophan: eosinophilia-myalgia syndrome," ADVERSE DRUG REACTIONS TOXICOLOGY

REVIEW Vol. 14, no. 1 (1995), pgs. 37-43.

[7] Robert H. Hill, Jr., and others, "Contaminants in L-Tryptophan Associated With Eosinophilia Myalgia Syndrome," ARCHIVES OF ENVIRONMENTAL CONTAMINATION AND TOXICOLOGY Vol. 25 (1993), pgs. 134-142.

[8] Larry Thompson, "Treating L-Tryptophan Patients; Side Effects of the Over-the-Counter Drug, Now Banned, Are Long Lasting," THE WASHINGTON POST, August 7, 1990, p. Z7 in the health section.

[9] S.R. Ahmad and D. Clauw, "USA: EMS and L-tryptophan," LANCET Vol. 338 (December 14, 1991), pg. 1512.

[10] E.A. Belongia and others, "An investigation of the cause of the eosinophilia-myalgia syndrome associated with tryptophan use," NEW ENGLAND JOURNAL OF MEDICINE Vol. 323 (1990), pgs. 357-365.

[11] Arthur N. Mayeno and Gerald J. Gleich, "Eosinophilia-myalgia syndrome and tryptophan production: a cautionary tale," TRENDS IN BIOTECHNOLOGY Vol. 12 (September, 1994), pgs. 346-352.

[12] Craig Holdrege, GENETICS AND THE MANIPULATION OF LIFE: THE FORGOTTEN FACTOR OF CONTEXT (Hudson, N.Y.: Lindisfarne Press [RR4, Box 94 A-1, Hudson, NY 12534], 1996).

[13] Thomas R. Mikkelsen and others, "The risk of crop transgene spread," NATURE Vol. 380 (March 7, 1996), pg. 31.

[14] Mike Pezzella, "Monsanto to sell chem biz in bid to dominate ag bio," BIOTECHNOLOGY NEWSWATCH October 21, 1996, pg. 1.

[15] Bill Lambrecht, "House Members Urge BST Inquiry; Conflict Alleged in Three FDA Officials' Past Work for Monsanto," St. Louis POST DISPATCH April 19, 1994, pg. 2A. And see: "3 FDA Staffers Cleared in Milk Drug Probe," St. Louis POST DISPATCH October 29, 1994, pg. 9A.

[16] Al Kamen, "THE FEDERAL PAGE--IN THE LOOP --Clinton Assistant Going Private," THE WASHINGTON POST, April 21, 1997, pg. A15.

[17] Jerry Berger, "Dr. Weldon is Reported Top Pick to Head FDA," St. Louis POST DISPATCH May 20, 1997, pg. D1.

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