

# AMBERWAVES

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ALEX JACK, PRESIDENT

EDWARD ESKO, VICE PRESIDENT

July 24, 2002

Food and Drug Administration  
Dockets Management Branch  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: Genetically Engineered Rice, Wheat, and Other Essential Foods

Amberwaves is a network of individuals, families, farms, businesses, schools, and other organizations concerned with keeping America beautiful by preserving natural quality crops, foods, and products. Our name comes from the opening lines of the national hymn *America the Beautiful*: "O beautiful, for spacious skies, for amber waves of grain . . ." Amberwaves is a project of Planetary Health, Inc., a nonprofit educational organization with headquarters in Massachusetts and supporters "from sea to shining sea."

The board of directors is made up of educators, chefs, and health care practitioners, including Wendy Esko, natural foods cooking teacher and author of the *Complete Whole Grain Cookbook*; Michael Potter, founder and president of Eden Foods and organic adviser to the Michigan Department of Agriculture; and Judge Karen Fort Hood, chief presiding criminal judge in Detroit and a leader of the African-American community. Key advisers and supporters include Christina Pirello, Emmy award winning host of *Christina Cooks!* on PBS-TV; Dr. T. Colin Campbell, director of the China Health Study and professor of nutrition at Cornell University; Congressman Dennis J. Kucinich, sponsor of the GE Right to Know Bill in Congress; Dr. Jane Teas, a cancer researcher at the University of South Carolina and expert in the relationship of diet and breast cancer; and Roxane Koteles, a Ritz-Carlton chef who is currently based in Charleston, South Carolina.

Amberwaves sponsors community dinners, musical celebrations, and lectures and workshops. Over the last year, approximately 10,000 people have signed our petition to

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preserve natural wheat, rice, and other essential foods from the potential hazards of genetic engineering. This spring we are formally presenting the petition to the U.S. Congress, the EPA, the FDA, trade associations, and other organizations devoted to food safety, health, and the environment.

Also enclosed is an independent analysis of LibertyLink Rice that Amberwaves commissioned by Dr. Joe Cummins, an internationally noted geneticist. He concludes that glufosinate ammonium, the herbicide used in conjunction with this crop, is potentially hazardous to human health and the environment and should not be released. Several years ago the government of Brazil banned LibertyLink rice used with glufosinate for health and environmental reasons.

We are also deeply concerned about a field of experimental GM rice in California that contains human proteins for pharmaceutical use. Since federal and state agencies require only a 20-foot barrier between open GM test fields and neighboring farms, genetic material could be carried by pollen, birds, insects, bacteria, or viruses to the surrounding area, where 80% of the organic rice in the United States is grown.

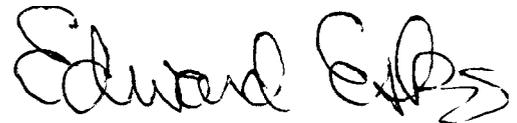
Moreover, over 200 species of birds, mammals, insects, amphibians, and reptiles live in the rice fields of California, including 30 species that are already endangered or threatened. Twenty percent of all the migrating waterfowl in North America pass through the rice fields in the winter. Duck, geese, swans, teal, hawks, grosbeaks, orioles, kingbirds, and dozens of others are at risk from this horrifying, potentially catastrophic experiment.

We respectfully ask that the FDA deny approval of LibertyLink Rice for use in the United States, immediately end the production of pharmaceutical rice in California, and implement a moratorium on all genetically engineered crops pending comprehensive long-term studies of their effects on human health and the environment.

Sincerely,



Alex Jack  
President



Edward Esko  
Vice President

**PLANETARY HEALTH, INC.****AMBERWAVES NETWORK****305 BROOKER HILL ROAD****BECKET, MA 01223****TEL. (413) 623-0012 • FAX (413) 623-6042****ALEX JACK, PRESIDENT**

August 19, 2002

Food and Drug Administration  
Dockets Management Branch  
Room 1061, 5630 Fishers Lane  
Rockville, MD 20852  
Fax 301-827-6870

On behalf of approximately 10,000 people who have signed the Planetary Health/Amberwaves' petition, we request that the Commissioner of Food and Drugs 1) deny approval of genetically engineered LibertyLink Rice for use in the United States and 2) end the production of genetically engineered pharmaceutical rice in California and other states, pending comprehensive long-term studies of their effects on human health and the environment.

The factual and legal grounds for the petition were submitted to the FDA in person on July 24, 2002, including an independent scientific analysis and environmental impact statement of LibertyLink Rice that Planetary Health/Amberwaves commissioned by Dr. Joe Cummins, an internationally noted geneticist. He concludes that glufosinate ammonium, the herbicide used in conjunction with this crop, is potentially hazardous to human health and the environment and should not be released. Several years ago the government of Brazil banned LibertyLink rice used with glufosinate for health and environmental reasons. We have also submitted a book that we published, *Saving Organic Rice*, with essays by prominent scientists, environmentalists, and health specialists opposing the introduction of genetically engineered rice.

To the best of our knowledge, the petition includes all information relevant to the petition, favorable or not.

Sincerely,



Alex Jack  
President

**PLANETARY HEALTH, INC.**

**AMBERWAVES NETWORK**

**305 BROOKER HILL ROAD**

**BECKET, MA 01223**

**TEL. (413) 623-0012 • FAX (413) 623-6042**

**ALEX JACK, PRESIDENT**

August 19, 2002

Jenny Butler  
Food and Drug Administration  
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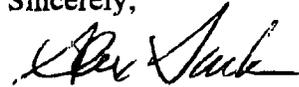
Dear Ms. Butler:

Enclosed is the revised letter that you suggested we submit with the Planetary Health/Amberwaves petition that we dropped off last month. I believe we dropped off a copy of Dr. Cummins' scientific report, but am not sure if we included the book, *Saving Organic Rice*. If not, please let me know and I will mail a copy since it has much supporting data.

Finally, as you noted, it might be time-consuming to scan and publish all the signatures, so it is fine with us if you publish just the text of the petition and my signature and address on behalf of the organization, as it is noted in the accompanying letter that approximately 10,000 persons have signed.

If there are any further corrections or materials needed, please contact me. I very much appreciate your help in this matter.

Sincerely,



Alex Jack  
President

## ***Amberwaves Special Report:***

# **The First Independent Study of Genetically Engineered LibertyLink Rice**

**By Dr. Joe Cummins**

*LibertyLink Rice, the first GE rice in America, was introduced this year in Texas by Aventis, a large biotech company. However, because of the controversy surrounding StarLink Corn and its contamination of conventional and organic crops, the company decided to destroy all 5 million pounds. Since LibertyLink Rice may be released in the future, Amberwaves, a grassroots organization devoted to preserving natural and organic rice, wheat, and other essential foods, asked Professor Joe Cummins, a Canadian geneticist, to prepare a scientific report on LibertyLink Rice and its possible effects on human health and the environment.*

LibertyLink Rice is rice resistant to the herbicide glufosinate (Liberty or Basta); it was produced by the AgrEvo company (which consolidated and is currently Aventis). The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) approved the AgrEvo petition (98-329-01p 26 Jan 2001 found online at ([http://www.aphis.usda.gov/biotech/dec\\_docs/9832901p\\_det\\_ea.HTM](http://www.aphis.usda.gov/biotech/dec_docs/9832901p_det_ea.HTM)) to determine non regulated status for the glufosinate tolerant rice. The APHIS review included a cursory environment assessment concluding that the rice will not harm the environment. The plants will have no plant pathogenic properties, are not likely to become weeds, will not increase weediness of cultivated or weedy species with which they interbreed, will not harm beneficial organisms nor will they damage agricultural commodities. The genetically modified (GM) rice were obtained by transforming rice varieties M202 and Bengal, respectively, with the bar gene derived from the soil-borne bacterium *Streptomyces hygrosopicus*. The bar gene encodes phosphinothricin-N-acetyltransferase (PAT), an enzyme which inactivates the herbicide glufosinate ammonium. The bar gene was introduced via a well characterized method that introduces DNA directly without the use of vector agents according to the APHIS report. It is presumed that the cryptic comment means that the rice was transformed using the biolistic (gene gun) method, and APHIS seemed unaware of the viral promoter (CaMV promoter is usually employed), antibiotic resistance gene, and residual bacterial genes from the plasmid used in propagating the genes used in the engineering of the rice. The 18-page APHIS report seemed to have been generated using the bureaucratic rubber stamp. For example, there is clear agreement that the glufosinate tolerance gene will be spread to the weed red rice, but APHIS agrees with AgrEvo that the resistant red rice does not pose a threat because it can be controlled by other herbicides!

Rice is an allotetraploid whose cultivated varieties are relatively current in evolutionary terms (Ge et al 1999). Allotetraploids are made up of two or more diploid chromosome sets combined from grass species to make hybrids. Rice is the world's most important food crop. GM rice is effected by somaclonal variation—a form of gene and chromosome instability that results from the tissue culture embryos used to propagate GM crops (Labra et al 2001). Somaclonal variation occurs in tissue culture embryos from both normal and GM crops, but the effect is greatest in

GM crops. Somaclonal variation is caused by replication of genetic elements called retrotransposons that replicate in the plant cell nucleus and are inserted into structural genes to cause mutation and chromosome rearrangement (Agrawal et al 2001). The genetic changes activated in producing GM crops may be numerous and subtle and may produce gradual loss in productivity of GM varieties or unexpected toxic plant products. Governmental regulators seem to have been blissfully unaware of such complications. For example, glyphosate resistant soybean cultivars had significantly lower yield than did sister lines which were not genetically modified (Elmorer et al 2001). Regulators should require full and truthful analysis of GM crops.

In conclusion, government regulators appear to be closely allied to the chemical industry giants. USDA engages in commercial enterprises on a grand scale in joining commercial interests to patent numerous genetic engineering techniques including the terminator procedure which benefits only commercial interests and works against farmers who traditionally save seed. USDA and the food and drug administration (FDA) are too closely associated with commercial interests, and such association seems to blind the government agencies to legitimate concerns and clear dangers. Truly independent regulators that are fully protected from industrial and political influences are needed at this time.

### **Notes on the Teratogenicity of Glufosinate**

Glufosinate is a herbicide that kills almost everything green; it is used extensively with genetically engineered crops including corn, canola, and soybeans. The herbicide resistant crops were approved by the Canadian and United States governments, even though there was clear evidence that the herbicide caused birth defects in experimental animals. The chemical acts by causing premature cell death in the immature brain by a process called apoptosis. It also prevents development of glutamate channels in the brain, thus disrupting cellular communication. The birth defects observed in animals included brain defects leading to behavioral changes. Cleft lip and skeletal defects or kidney and urethra injury were observed in treated newborn. The herbicide also caused miscarriage and reduced conception in treated mothers. Exposure of male farm workers caused birth defects in their children.

Glufosinate use may be increased greatly by introduction of liberty link crops such as corn, canola, and soybeans along with commercial rice. The herbicide may also be used as a desiccant prior to grain harvest on crops that are not resistant to glufosinate (such applications are used to mature grains threatened by frost damage). Such applications are undesirable because the microbial activity is reduced at low temperature and more teratogen will enter the surface and groundwater.

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*Professor Joe Cummins, professor emeritus of genetics at the University of Western Ontario, is one of the foremost scientists active in the campaign to protect the safety of crops, foods, human health, and the environment. Prior to joining Western in 1972, he taught genetics at Rutgers University and the University of Washington (Seattle) and since 1968 has been involved in a range of environmental issues related to mercury, asbestos, PCBs, pesticides, toxic waste, and genetic engineering. Prof. Cummins is the author of more than 200 scientific and popular articles and has published recently in Nature Biotechnology, The Ecologist, and Biotechnology and Development Review. He lives in London, Ontario, Canada. His e-mail: [jcummins@uwo.ca](mailto:jcummins@uwo.ca)*

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