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Summary of Benefits and Risks of Roundup Ready Soybeans and Bt Field Corn Now Available

Roundup Ready soybeans and Bt field corn have been rapidly adopted by U.S. farmers, yet their approval for commercialization remains under scrutiny. Much of the criticism seems to be based on poor understanding of the U.S. regulatory process and a lack of knowledge about the environmental and health risk studies that were conducted prior to the commercialization of these products. A new study by the National Center for Food and Agricultural Policy (NCFAP) provides a description of the regulatory process governing agricultural biotechnology and traces the approval of Roundup Ready soybeans and Bt corn through the U.S. regulatory agencies (EPA, USDA, FDA).

Roundup Ready Soybeans and Bt corn are products of genetic engineering. These cultivars were transformed through insertion of genetic material from soil bacteria that confers herbicide tolerance (Roundup Ready soybeans) or kills insects who feed on the plant (Bt corn). Estimates of the impact that the adoption of these crops has had on U.S. agriculture are also provided. Potential risks considered by the regulatory agencies include allergenicity, toxicity, pesticide resistance, out-crossing, non-target impacts and antibiotic resistance. Benefits include increased yields, reduced production costs and reduced pesticide use.

The NCFAP report summarizes information that was submitted to the regulatory agencies, providing an accessible review of mostly unpublished documents and studies conducted on the potential risks associated with commercial introduction of genetically engineered varieties.

The developer of Roundup Ready soybeans, Monsanto, conducted numerous studies comparing the composition of Roundup Ready whole and processed soybeans to that of conventional soybeans. Animal feeding studies were conducted using rats, broiler chickens, dairy cattle, catfish and bobwhite quail to assess the feed characteristics of Roundup Ready soybeans. Potential toxicity was assessed in a mouse study. The safety assessment of altered herbicide use patterns was based on animal studies conducted using dogs, mice, rats, and rabbits. Environmental impacts related to potential increased weediness and outcrossing were considered minimal due to the self-pollinating nature of soybeans, lack of weediness of conventional soybeans and lack of related weed species in the U.S. The results of the studies conducted and submitted by Monsanto to the regulatory agencies was judged to demonstrate the safety of Roundup Ready soybeans.

Bt field corn seed and silage composition was compared to conventional corn in several studies conducted by the developers of two Bt corn lines, Novartis and Monsanto. Potential toxicity and allergenicity were assessed based on a mouse study and digestibility studies. Laboratory and field studies were used in the assessment of environmental fate. Studies of potential impact on several non-target organisms were performed: honey bee, parasitic wasp, green lacewing, lady beetles, bobwhite quail, earthworm, soil organism, catfish and a crustaceous species. Weediness and outcrossing were judged to not be significant risks, as cultivated corn does not exist in uncultivated areas and the Bt trait was not expected to confer any significant advantage to cultivated corn. One related wild species grows on the southern tip of Florida, though no cases of gene flow from corn to this relative have been reported. Insect resistance management plans, developed by the registrants to address concerns about the development of resistance of insect populations to the Bt pesticide, were considered in the approvals of Bt field corn lines.

The review of information submitted to the agencies to address potential environmental and human health risks associated with commercial introduction of Roundup Ready soybeans and Bt corn shows careful consideration of a wide range of potential impacts. Roundup Ready soybeans were granted unconditional approval for commercialization. Bt corn lines were granted conditional registrations pending the submission of additional studies on non-target impacts and further development of insect resistance management programs. These registrations are currently under review by the Environmental Protection Agency.

In addition to providing a summary of the approval of Roundup Ready soybeans and Bt corn, the NCFAP study also includes a description of the regulatory process, its history and current structure. This account of the development of the U.S. regulatory system reveals a system that has evolved over the past 25 years, as the technology allowing for genetic modification of plants developed.

The benefits of the introduction of Roundup Ready soybeans include savings of \$216 million annually in weed control costs and 19 million fewer soybean herbicide applications per year. The primary benefit of the introduction of Bt corn has been increased yields, by 66 million bushels in 1999. Growers have also achieved modest reductions in insecticide use, as only a small proportion of U.S. field corn acreage was sprayed for the target pest prior to the introduction of Bt varieties.

Case Studies in Benefits and Risks of Agricultural Biotechnology: Roundup Ready Soybeans and Bt Field Corn, by Janet E. Carpenter, is available at www.ncfap.org. Preparation of this report was supported by the Rockefeller Foundation.