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/THE FIRST WORD**Waiter, There's a Protein in My Soup**

Public concern about the safety of biotechnology products percolates around fears that the companies making them will ignore public safety in favor of quarterly profits and that products now touted as safe will turn out to be not-so-safe-after-all 10 years down the road. Biotech food products already face a good deal of opposition, and they haven't even gone to market. Although I would venture that the vegetables consumed in soup alone have been bombarded with more DNA-unraveling substances from the moment they pop up out of the ground to the moment they hit the plate than one would ever care to imagine, and although an average human being, of necessity, eats hundreds of thousands of proteins safely on a daily basis, the possible dangers of biotech food products have captured the public's uneasy imagination.

Are they safe? In the case of genetically modified plants containing neomycin phosphotransferase II (NPTII) protein, all signs, and a good deal of evidence, point to an enthusiastic yes.

This issue of *Bio/Technology* contains two impressive studies (beginning on p. 1537) by Roy Fuchs and his colleagues in the Agricultural Group at Monsanto (Chesterfield, MO) of NPTII, a selectable gene marker protein product. The gene encoding NPTII has been used regularly to produce many kinds of genetically engineered plants, some of which, like Calgene's (Davis, CA) Flavr Savr tomato, may be among the next biotech products to clear the regulatory rapids.

The new studies are continuations of already extensive work indicating that neither the gene nor its product pose any discernible risk to food, feed, or the environment. In them, the authors wanted to determine whether the NPTII protein posed any direct threat to mammals. But first they had to come up with a method to produce a large enough quantity to study, as the amount available from NPTII-containing plants is negligible—according to their research, it would take about 70,000 genetically modified potatoes to produce a mere 10 grams of NPTII. So the authors took the same coding sequence that was used to genetically transform potatoes, tomatoes, and cotton seed, put it into *Escherichia coli*, fermented a bit, and ended up with 30 grams of purified NPTII. Characterizing the microbially derived protein and examining the chemical and biological equivalences between it and the NPTII produced in genetically engineered plants confirmed that the protein produced in both was indistinguishable.

With a ready source of NPTII at hand, they took up the question of whether NPTII was safe for mammal (and therefore, human) consumption. First, they looked at the metabolic fate of NPTII after it was exposed to simulated mammalian gastric and intestinal digestive juices. The digestion model was one that has already been used to test protein quality and digestibility, food additives, pharmaceutical tablet dissolution rates, and the controlled release rates of pharmaceuticals. Fate was not kind to NPTII—the protein degraded very rapidly, succumbing much like other edible proteins. This rapid degradation also indicated that NPTII was not likely to be an allergen, as one characteristic of food allergens is that they do not break down in the digestive tract.

In a second experiment, mice were given excessively large doses of NPTII by stomach tube, which had no observable ill effects on the animals. In a final test, rats were fed NPTII-containing tomatoes or potatoes at levels equivalent to a human eating 40 raw potatoes or 100 tomatoes a day for 28 days, again with no adverse effects, further confirming the safety of the protein produced in the plants.

As with the data on bovine somatotropin, another Monsanto-championed product that finally won long-overdue approval from the Food and Drug Administration (Bethesda, MD) in early November, the data on NPTII and its potential toxicity, allergenicity, and environmental side effects have been in for some time now, and they all look good. The Monsanto researchers are to be commended for their careful work. That NPTII-containing fruits and vegetables are safe seems clear. Whether the consumers who will be offered these products will be willing to separate food biotech safety issues from those of politics and economics remains to be seen.

—S U S A N H A S S L E R