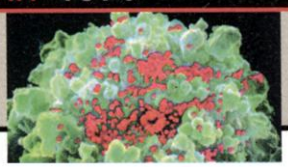

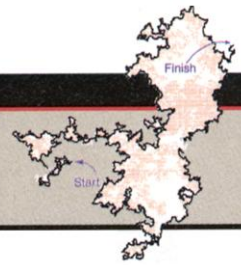

TOXICOLOGY

Panel Urges Further Study of Biotech Corn

This fall, when genetically modified corn that had not been approved for human consumption was found in taco shells in the United States, all hell broke loose. The corn, produced by Aventis CropScience for animal feed, was soon found in a range of foods, prompting product and grain recalls countrywide. Last week, the U.S. Environmental Protection Agency (EPA) convened a scientific panel to review evidence on whether this StarLink corn could harm sensitive people by causing allergic reactions. The panel found that the overall probability is "low," but the EPA appears intent on investigating further before allowing the corn in foods, as Aventis has requested.

At the center of the controversy is a bacterial protein known as Cry9C, the gene for which was added to StarLink corn to make it resistant to insects. Cry9C is one of several so-called Bt proteins, but it is more heat stable and harder for humans to digest than its kin—qualities that are typical of such allergens as peanuts. Although comparisons of Cry9c's structure with known food allergens turned up no signs of allergenicity, EPA's scientific advisers don't consider those tests conclusive. In 1998, when Aventis asked EPA to approve StarLink for human consumption, the agency limited its sale to animal feed and industrial uses.

Then came the September scare when a coalition of activist groups detected the DNA coding for Cry9C in taco shells. Aventis soon pulled its seeds off the market. But facing the multimillion-dollar costs of tracking StarLink corn already in grain elevators and silos, the company asked EPA to allow it in food for the 4 years it will likely remain in the food supply.

To bolster its case, Aventis gave EPA new studies showing that the blood of people with food allergies doesn't cross-react with Cry9C. They also presented evidence that the amounts of the protein showing up in contaminated food would be perhaps 1/100 the level needed to sensitize people to allergens such as peanuts. But the review panel didn't find these arguments persuasive. It's unknown exactly what makes a protein trigger allergic reactions, they argued, and allergists don't know whether there is a safe level for the protein. "Unfortunately, there are no valid animal models that will tell you that something's an allergen" in people, says Hugh Sampson, a New York University allergist on the panel.

Evidence on Cry9C's allergenicity may be coming soon, however. Following the flurry of press reports over StarLink, at least 34 people reported to the U.S. Food and Drug Administration (FDA) that they had allergic reactions after eating corn products. The panel concluded that up to 14 of these 34 reports merit further investigation. The cases "have not been corroborated medically or scientifically," notes allergist and panel member Marc Rothenberg of the University of Cincinnati. To begin to do that, FDA and the U.S. Centers for Disease Control and Prevention hope to test the blood of these 14 or so people for the presence of antibodies to Cry9C. "If even two have them, then that sort of gives you the answer" that Cry9C has the potential to cause allergies, says Sampson. But developing the protocol and test could take several months, says Karl Klontz of FDA.

GMO sleuth. Larry Bohlen of Friends of the Earth discovered biotech corn approved only for animals in taco shells.

CREDIT: LINDA SPILLERS/AP

Whether EPA will grant Aventis the 4-year exemption is anyone's guess, but some observers don't expect a quick decision. Despite the panel's finding that the overall risks from Cry9C appear low, it urges agencies to follow up on illness reports and get better data on protein residues in foods. "A thorough assessment" will continue, says an EPA statement. "It's clear that EPA is going to sit on this petition for a while," says Rebecca Goldburg of Environmental Defense. Whatever EPA decides, the agency will likely be cited in lawsuits now proliferating by people who allege allergic reactions from StarLink; some corn growers have also filed a class action suit, claiming they weren't warned about mixing StarLink corn with other corn. Last month, Cry9C did turn up in another variety, for reasons Aventis can't yet explain.

–JOCELYN KAISER

INFECTIOUS DISEASES

Polio Outbreak Raises Questions About Vaccine

The oral vaccine designed to protect children from polio has been fingered as the possible culprit in a recent outbreak of the devastating disease in the Dominican Republic and Haiti. The small cluster of cases marks the first polio outbreak in the Western Hemisphere in more than 9 years. It is also the first reliable report that a vaccine-derived polio strain may have reverted to a virulent form and spread contagiously. Although a massive vaccination campaign already in the works is expected to contain the outbreak, the unusual incident raises troubling questions about a vaccine that has been in widespread use for nearly 40 years.

Three children in a rural area of the Dominican Republic about 80 kilometers from the Haitian border came down with paralytic polio in July and August. A single case has also been confirmed in Haiti, where the disease struck a child who lives 3 hours' hike from the nearest road. None of the children had been vaccinated; that means they acquired the vaccine-derived virus from someone who had. Although both regions are remote, there is enough traffic between them that person-to-person transmission could have occurred, says Ciro de Quadros, who directs the vaccines and immunization program for the Pan American Health Organization (PAHO).

The oral polio vaccine is highly effective and easily administered. But because it employs live but weakened strains of the virus, its use results in vaccine-associated paralytic polio in about 1 of every 750,000 people who receive it, usually those with compromised immune systems. But there has been no evidence that this vaccine-induced form of the disease can be spread from person to