Bt-maize (corn) during pollination, may trigger disease in people living near the cornfield.

Virtually an entire village of thirty-nine people living adjacent to a large field of *Bt*-maize (Dekalb 818 YG) on the island of Mindanao in the Philippines were stricken by a disease with respiratory, intestinal, and skin reactions, and fever. The symptoms occurred during the period when the maize was producing airborne pollen. The residents, some of whom lived only a few meters from the plants, certainly inhaled the pollen. The maize was genetically engineered to produce the insecticide called *Bacillus thuringiensis* (*Bt)*. In response to *Bt*-toxin, IgA, IgG, and IgM antibodies were detected in their blood samples, indicating an immune reaction to GM maize pollen.

Local authorities had proposed that the disease was infectious, but could not identify the cause. The symptoms of four families, however, subsided after they left the area to stay with friends or relatives. Upon returning, the members of all four families once again exhibited the symptoms. Such a response contradicts the claim that the disease was infectious, and points to environmental causes.

The Norwegian Institute for Gene Ecology learned about the incident during the fall of 2003 and arranged for blood samples to be taken in October. The IgA and IgM reactions in their serum indicate a recent exposure to *Bt* within the previous three months and are consistent with an interpretation that the disease might have been created by inhalation of the *Bt*-pollen from the field.

The maize variety Dekalb 818 was popular in the area. According to members of the village, seed representatives offered them an improved version of Dekalb 818, called Dekalb 818 YG. This is a hybrid between Mon 810, a *Bt*-crop from Monsanto, and the conventional Dekalb 818 variety. This past year was the first time that Bt maize was planted in the region. Some villagers said they were never told it was a genetically engineered variety, and did not know that it was creating its own pesticide.

An additional finding from the study showed that the level of expression of the *Bt*-toxin Cry1AB varied considerably in the corn kernels, even from the same plant. The levels ranged from 0.014 ug to 0.9 ug, with other kernels expressing levels both above and below the limits of detection of the study.

Implications for human health

There has been great concern that genetically engineered crops might increase allergies or immune sensitivity in the population. Soon after Monsanto's genetically engineered soy was imported into the UK, for example, soy allergies skyrocketed by 50 percent. (No follow-up studies were conducted to confirm a link.) At a Russian press conference held on 11 December 2003, a group of scientists announced that the number of people with symptoms of allergy increased by three times over the past three years, and that the increased consumption of genetically engineered foods by the population might be the

cause. Allergies are similarly on the rise in the U.S., where genetically engineered foods are eaten regularly.

Many scientists are concerned that crops genetically engineered to create the *Bt*-toxin may, in particular, have adverse immune and allergenic effects on humans.

A U.S. government-funded study published in 1999 confirmed that farm workers exposed to *Bt* insecticide sprays exhibited skin sensitization and the presence of IgE and IgG antibodies, both considered part of an allergic response. The workers with a greater reaction were those with more exposure to the spray—another allergy signal. While the workers did not exhibit respiratory symptoms, the period of exposure was relatively short, and the amount of *Bt* that they were exposed to from the spray was quite small. *Bt*-crops, on the other hand, create 10 to 100 times the amount of exposure. And the seeds of some of those *Bt*-crops have yet another 10 to 100 times that amount.

Three mouse studies were conducted on a *Bt*-toxin, Cry1Ac, similar to that found in GM cotton and maize varieties. Two of these mouse studies showed that the *Bt*-toxin triggers an antibody response in the blood and mucous membranes of mice; the third demonstrated that Cry1Ac boosts the immune response to other antigens as powerfully as cholera toxin. This study verified that *Bt* also acts as an adjuvant. An adjuvant is an enabling agent, which increases a person's susceptibility to other allergens and immunogens. In other words, allergic reactions as a whole might theoretically increase in a population that is exposed to an adjuvant. This might explain the increased rate of allergies described above.

In a study published in *Natural Toxins*, mice were fed a diet spiked a natural *Bt*-protein. When the researchers analyzed tissue sections from the ileum (the lower part of the small intestine) by electron microscopy, they found significant structural disturbances and intestinal growth.

All of these animal studies conclude that *Bt* is active in mammals, doesn't degrade, may bind to the intestines, and therefore may pose a threat to human health. These studies suggest that feeding the *Bt*-crops to humans and animals may be premature.

_Bt_-corn would not pass the FAO/WHO recommended tests

In spite of the evidence that *Bt* creates reactions in mice, regulatory authorities such as the U.S. Environmental Protection Agency (EPA) have stated that *Bt*-toxin is not supposed to survive long enough to even get into the small intestine. It's supposed to be degraded in the stomach. They base their claim on test tube experiments conducted by the biotech companies. The *Bt*-protein is put into a test tube containing simulated gastric fluid—a mixture of hydrochloric acid and pepsin, a digestive enzyme—which, they claim, mimics the act of digestion in the stomach. The longer the protein stays intact, the greater the opportunity for it to elicit the antibody response associated with allergy.

The FAO/WHO likewise propose a test-tube evaluation of protein stability. Although Monsanto's test on its own *Bt*-maize protein (Cry1Ab) resulted in over 90 percent degradation after just two minutes, critics point out that the strength of the acid and the relative amounts of enzyme and Cry1Ab Monsanto used in their test tube was unrealistic and specifically designed to destroy the protein as quickly as possible. Monsanto used a pH of 1.2, as compared to the considerably milder 2.0 recommended by the FAO/WHO. Also the ratio of pepsin to Cry1Ab used was about 1,250 times greater than the FAO/WHO standard. When that same Cry1Ab was independently tested using a different solution, 10 percent of Monsanto's *Bt*-toxin protein lasted one to two hours, not two minutes. If the researchers had used the FAO/WHO guidelines, however, more of the protein would have lasted even longer. Furthermore, another test tube study showed that Cry1Ab only breaks down to sizeable fragments—large enough to remain potentially allergenic and larger than the maximum size specified by the FAO/WHO. (In any case, many scientists have pointed out that the test-tube studies as a whole are flawed, as they do not approximate actual conditions, and survival of *Bt*-protein has already been confirmed in animal models.)

A second method for investigating allergenicity recommended by the FAO/WHO and others involves comparing the structure of the foreign protein to those of known allergens. The reasoning is that if a section of the GM protein's amino acid sequence is similar or identical to that of a known allergen, it might trigger a reaction. A researcher at the U.S. Food and Drug Administration (FDA) discovered such a similarity between Cry1Ab and an egg yolk allergen.

Genetic instability makes allergy testing even more problematic

The finding that corn kernels express different levels of the *Bt*-toxin make existing allergy safeguards much more problematic. The level of protein that is tested by scientists may not represent the actual level the public is exposed to.

Contact
New findings: Terje Traavik PhD, +47 9581 7537, terjet@genok.org
Further discussion: Jeffrey Smith in KL, 012-333-7495