GREENPEACE Briefing

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GE Food: Safe to Eat?

Most genetically engineered (GE) crops are processed into food for humans and animals - but are they safe to eat? Genetic engineering can have unexpected and unintended effects because the process is imprecise and random. Inserted genes may disrupt natural genes, be unstable in their new environment, or function differently than expected. But what does this mean for food safety?

There are two ways in which genetic engineering may affect food safety:

- gene disruption or instability may lead to new toxins being produced;
- the new protein produced by the foreign gene may cause allergies or toxicity.

There is scientific agreement that the potential for such risks does exist and in many countries regulations are in place to examine the safety of GE foods. But how good is the testing system? This briefing examines the regulatory system and the way in which it operates. Disturbingly, it reveals that regulatory authorities use the concept of 'substantial equivalence' even though it has been severely criticised by some of the most respected scientific bodies.

How are GE foods tested?

Although the regulation of GE foodstuffs differs from country to country, the concept of 'substantial equivalence' forms the basis of regulatory assessments worldwide. Essentially, the chemical composition of the GE food is compared to an equivalent non-GE variety – GE soybean would be compared to conventional non-GE soybean, for example. If there is no significant difference detected between the two, the GE variety is pronounced safe. This sounds sensible, but a closer look at the system reveals some serious shortcomings.

The first problem concerns what is actually compared between the GE and non-GE food. The levels of some major and minor nutrients, known toxins and other anti-nutritional factors are measured. In potato, for example, the major nutrients include carbohydrate and protein, the minor nutrients are any vitamins, and known toxins would include solanine (the compound in green potatoes that can cause illness). However, there is no standard list of what must be measured and there is no process to look for unexpected or unintended changes – one of the most important concerns over GE food safety.

The second problem is that the systems to detect allergenicity or toxicity of the GE product have serious limitations. Allergies to proteins found in some foods such as peanuts are already well known. Genetic engineering is designed to produce new proteins not normally present in the plant and these may cause allergies. It may also result in unintended modifications to existing plant proteins, which could make them allergenic. However, it is not possible to predict whether a protein is a potential allergen with any certainty. Tests examining the protein's characteristics and comparing them with known allergens are not foolproof. The proteins may never have been part of humans' diet before so there may be no experience to go on. Questions have also been raised over some GE crops which have already been given safety approval. For example, it has recently been shown that a *Bt*

protein, Cry1A - commonly present in GE insect resistant crops - may have induced allergenic-type responses in mice and the study recommended further safety tests[1,2].

Another problem is that when any food safety testing is performed on GE crops, it is only short-term - over days or a few weeks. There is no long-term testing or testing for chronic effects of toxicity or nutritional changes. Because of this, the French food safety authority, AFSSA, recently concluded that current safety testing is not sufficient to ensure the safety of GE foods[3]. Their report also stated that it was important to research into the possible gradual development of allergic reactions through prolonged exposure to GE foods. This echoes a scientist's comments in the scientific journal, *Nature*, about the long-term effects of GE food that: "*Under current monitoring conditions, any unanticipated health impact of such foods would need to be a 'monumental disaster' to be detectable*" [4].

Because of problems like these, the use of substantial equivalence as a criterion in GE food safety testing has been severely criticised[5] by such respected institutions as The Royal Society of London[6] and Royal Society of Canada[7].

Cause for concern

The criticisms of substantial equivalence are of more than academic interest. There is evidence that unintended effects of genetic engineering are not uncommon, that potential allergens have entered the food chain because of inadequate controls, and that the scientific data supplied to regulatory authorities cannot be trusted.

Unexpected and Unintended Effects

Unexpected and unintended effects in GE crops can be produced in several different ways:

- **By the genetic engineering process itself:** Genetic engineering involves the insertion of a novel gene(s) at random into the DNA of an organism. It is a crude science and small segments of the plant's own DNA may become rearranged or deleted[8,9]. Multiple copies and extra fragments of gene inserts have been found in GE plants, including some commercial varieties of maize and soya[10,11,12]. For example, Monsanto's Roundup Ready soya contains two additional fragments of the inserted gene[10] and a segment of 'unidentified' DNA[9,13]. This was not known at the time of the regulatory approvals for food use in several countries and the discoveries were only made after Roundup Ready soya had been on the market for several years.
- **By alteration of normal function:** A plant's normal metabolism may be affected by genetic engineering if the insertion of a gene disrupts its complex biochemical pathways. It is difficult to predict what the consequences would be and these could be affected by environmental conditions[14].

Examples where genetic engineering has caused unexpected effects in plants and other organisms include:

1) Yeast which had been genetically engineered to improve alcohol fermentation unexpectedly had up to 30 times the concentration of methylglyoxal (a highly toxic compound) compared to the control non-GE strain[15].
2) Researchers at Monsanto who were trying to increase the content of carotenoids (a chemical which is used to form vitamin A) in oilseed rape (canola) found that vitamin E and chlorophyll levels in the seeds were dramatically and inexplicably reduced[16].
3) Other researchers trying to genetically engineer the carotenoid pathways in tomatoes found over-expression of the gene caused unexpected dwarfism in the plant[17].
4) Monsanto's GE Roundup Ready soybeans have suffered unexpected crop losses in hot, dry weather due to stem splitting caused, most probably, by increased lignin[18]. The soybeans' phytoestrogen levels are also 12-14 % less than in conventional soybeans, which may mean that soy-based products

derived from Roundup Ready soybeans would be less useful as sources of phytoestrogens[19].

5) Levels of a potato toxin (glycoalkaloid) increased and decreased unexpectedly in separate genetic engineering experiments when engineered with different genetic inserts that were not intended to alter the toxin content[20].

Allergies

Even if the allergenic potential of a GE crop is recognised by the regulatory authorities, it can still end up in human food. Aventis' StarLink was a type of insect resistant GE corn grown in the USA from 1998, which produced the *Bt* protein, Cry9C. It was only approved for animal feed and industrial purposes as there were concerns that the Cry9C protein could cause allergies because it shares characteristics of other allergens. However, in September 2000, StarLink was found in corn taco shells and other foods, and over 300 corn products had to be withdrawn from the market[21]. Traces of StarLink corn were also found in corn based foods in Japan and Korea. It is not known how StarLink came to be in the human food chain - it may have been inadvertently mixed with other corn at a mill, a conventional crop may have cross-pollinated with a StarLink crop, or a farmer may have sold StarLink corn for human food to get a higher price[22]. Whilst StarLink is not being grown anywhere in the world at the moment, it may have contaminated other maize seed and remain in the food chain. The episode raises questions about the ability of regulatory authorities to control GE crops.

Flawed data

There is disturbing evidence that even the limited data supplied to regulatory authorities is flawed or incomplete:

- Data about plant toxins and anti-nutrients (which interfere with our ability to make use of other nutrients in food) are often missing or show significant differences[5]. For example, in the EU applications for different types of GE maize or corn, the content of trypsin inhibitors and phytate (both important anti-nutrients in maize) were only determined in some, but not all cases[5,23]. Similarly, the content of sinapine - an antinutrient of oilseed rape (canola) - was not determined in all cases, and for Zeneca/Syngenta's GE tomato, TGT7F, data on several inherent tomato toxins were not given[5].
- Many of the trials are based on only one or two seasons of growth and environmental effects are not considered in the dossiers. Deleterious effects of genetic engineering may not be immediately obvious and may only become apparent after several generations[24], and environmental conditions can alter plant composition. Indeed, one study recommended 'special care' when investigating environmental effects on GE crops[23].
- The data accepted for approval of a GE maize known as T25, which was produced by Aventis (then AgrEvo) and approved for cultivation and import in Europe in 1998[25], has been reviewed and found seriously deficient by independent scientists. Although the maize was intended as cattle feed, no feeding or toxicity studies had been performed on cattle. A scientist said: "*I would not drink milk from [cattle fed] the forage with the present stage of knowledge*"[26].
- Chicken feeding studies in support of Aventis' T25 maize have also been criticised by independent scientists, who drew attention to 'suspicious' trends in terms of the weights and mortalities of the birds. The scientists concluded that: "… *this study…is inadequate in terms of providing any evidence or conclusions. It is not of a standard that would be acceptable for publication in a scientific journal. It follows that neither do we consider the study as reported to be adequate for being taken into account as evidence of safety in connection with decisions to approve the use of the relevant GM maize. If anything, the results as reported arouse suspicions of real differences between the treatments*"[27].

Babies and infants most at risk

The Royal Society[6] recently considered the possible effects of GE foods on the health of babies and infants. The report recognised that food allergies are far more common in children than adults, stating that: "*food allergies occur in 1-2 % of adults and 6-8 % of children*". Therefore, children would be most vulnerable to any allergens that may have gone undetected in GE food. In the report, infants are classified as a "*high risk group*" for post marketing surveillance of deleterious effects of GE foods in humans.

The Royal Society[6] also recognised that babies and infants are vulnerable to harmful effects from nutritional changes in their diet. Any changes in the composition of foods made from GE crops could be important when given to infants over a long period of time, especially if it is a food such as infant formula which infants may live off as a complete food. The report recommended that any GE ingredients in foods such as infant formulas "*should be investigated most rigorously*".

Conclusions

Although there are serious concerns about the safety of eating GE foods, the safety testing systems are inadequate. Genetic engineering can produce unintended and unexpected effects but the regulatory processes, which are based on the principle of 'substantial equivalence', are not designed to detect such effects. The systems used to detect allergenicity are incomplete and the data submitted by companies - supposedly demonstrating that their GE foods are safe - is often of poor quality.

The long term implications for human health of eating GE food are also not known (and have not been investigated), but babies and infants are especially vulnerable to allergies and changes in the nutritional composition of their diet. They are classified as a 'high risk group' for post marketing surveillance – but no such monitoring of either adults or children has ever taken place.

Therefore, Greenpeace believes that there is no basis upon which it can be claimed that the GE foods on supermarket shelves are safe to eat.

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