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IS GM FOOD SAFE TO EAT?

Judy Carman

The safety of genetically modified (GM) food is a central issue driving the genetic engineering controversy today. This chapter explores the potentially harmful effects of GM foods on human health and - in doing so - focuses upon the most commonly eaten GM foods in Australia. I look first at how GM foods are made and then consider some of the potential risks that inform a safety evaluation of these foods, especially in relation to the safety testing that has been done.

SOME BACKGROUND ON GENE TECHNOLOGY

Essentially, living tissue is made up of cells, each cell has a nucleus, each nucleus has chromosomes, and chromosomes contain most of the organism's DNA. Some of the DNA is in the form of genes that code for proteins, enzymes and other biochemical substances that organisms need to function. Traditional plant breeders take a plant with a desired characteristic, such as high yield, and cross-pollinate it with another plant with another desired characteristic, such as disease resistance. Progeny with both characteristics can then be chosen and used. In contrast, genetic engineers take a section of DNA from an organism that expresses a desired characteristic, join it with other sections of DNA such as viral promoters, and insert the resultant *gene cassette* into the plant.

It is possible to contest the claims of genetic engineers that their methods of insertion are precise (see also Traavik's points discussed in Chapter 3). The biolistics process, for example, takes gold or tungsten particles, coats them with the desired DNA and fires them into the plant. As the cells repair, the new DNA is integrated into the plant's genome. As the inserts are placed where they may not normally be found in nature, some inserts may affect the expression of the plant's genes. This may turn genes off or on, affect the function of other genes, produce new toxins or allergens, or produce a *wild characteristic*, such as higher levels of toxins found in a wild ancestor.

Partial copies may also be inserted. For example, seven years after the release of Roundup Ready soy, Monsanto has found that it contains two DNA segments about which they were previously unaware.¹ Another concern is that the insert may not be stable over many generations, resulting in the insert degrading, changing, or moving. That concern is exacerbated by the use of viral promoter sequences in inserts, such as the cauliflower mosaic virus, reputed to be prone to high rates of recombining with DNA. Furthermore, sections of inserted DNA can come from plants not normally eaten (for example, petunias), bacteria (for example, *Bacillus thuringiensis*), animals (for example, fish genes in tomatoes), or viruses, (for example, cauliflower mosaic virus). Another concern centres on the use of DNA that codes for antibiotic resistance in GM plants. One GM potato has DNA coding for resistance to five antibiotics.² Resistance to antibiotics used in humans is frequently encoded. There are concerns that if these DNA sequences cross into gut bacteria, our current problems with antibiotic resistant bacteria may worsen considerably.

Proponents and critics of GM food have very different views about GM plants. Proponents argue that the GM plant has changed insignificantly and that the rest of the plant will behave as before. Therefore the plant is *substantially equivalent* to the parent plant and does not need safety testing. Critics argue that these are untested hypotheses, and with the technology in its infancy, unknown and unintended consequences may result. In keeping with the precautionary principle (see Chapter 3), thorough safety testing should be undertaken before feeding GM food to millions of people.³

CURRENT GM FOODS IN AUSTRALIA

GM versions of soya bean, canola, corn, potato, sugarbeet and cotton have been approved for sale in Australia by Food Standards Australia New Zealand (FSANZ), formerly the Australia

New Zealand Food Authority (ANZFA). The foods are widely present in breads, pastries, snack foods, baked products, oils, fried foods, confectionary, soft drinks, and sausage skins. Labelling laws were introduced in December 2001, but do not cover foods that are made from animals fed with GM feed (for example, meat, milk, eggs, honey), that are highly refined (for example, cooking oils, sugars, starches), or that are prepared at bakeries, restaurants and takeaways. These laws also exclude foods 'unintentionally' contaminated by up to one per cent per ingredient, that have been processed before 7 December 2002, that are made with processing aids or food additives using GM microbes, or that contain GM flavours present at less than one per cent.

Most GM foods eaten in Australia are from plants genetically engineered to express either a protein that degrades a specific herbicide so that spraying a field of crop and weeds with the herbicide saves the crop and kills the weeds, or a protein that when eaten by a grub, ruptures the grub's gut, killing it. Some GM plants do both.

WHAT COULD GO WRONG?

One concern is that novel DNA from GM food could be taken up by microbes in the gut or tissues of the body. GM advocates and FSANZ have stated this as unlikely, as any DNA would be quickly degraded.⁴ Others argue that transgenic DNA is specifically designed to cross species barriers and to jump into other genomes.⁵ In fact, human simulations indicate that transgenes in GM food may survive in the human stomach and small bowel for up to four hours.⁶ Furthermore, an oral bacterium was found to take-up and express free exogenous DNA within a minute.⁷ In addition, foreign DNA ingested by mice can reach peripheral leukocytes (a type of white blood cell), spleen and liver via the intestinal wall mucosa and can be found in B and T cells of the immune system and covalently linked to mouse DNA.⁸ Other work has indicated that short DNA fragments from plant chloroplasts can be found in the lymphocytes of cows, and possibly in their milk, while muscle, liver, spleen, and kidney tissues from chickens were found not only to contain, but to amplify, certain gene fragments.⁹

In addition, in the only GM food study that could be found on humans, seven people - who had previously had their lower intestine removed and consequently used colostomy bags - were fed a single meal of a burger and milkshake, both containing GM soy. It was found that 'a relatively large proportion of genetically modified DNA survived the passage through the small bowel'.¹⁰ There was also evidence of genes being transferred from the GM soy to intestinal microbes.¹¹ Yet, because no GM transgenes were detected in bacteria from faeces in people with entire gastrointestinal tracts, the authors sweepingly suggested that these bacteria did not survive passage through the human colon.¹² Another interpretation is that the transgenic DNA may have entered intestinal cells and/or passed into the bloodstream.¹³ This went unassessed, even though several bacteria can invade intestinal cells and transfer genes into mammalian cells.¹⁴ Critics also pointed out that the experimental design allowed for only a tiny fraction of the GM DNA transfers to be detected.¹⁵ This may explain why GM DNA was not found in those faeces but, in a different experiment, was found in rat faeces for up to seventy-nine hours after feeding the rats ingested GM DNA.¹⁶

A further concern involves proteins that the GM plant has been engineered to produce that are not normally found in the human diet, or not in the human diet in such high concentrations. Particular concerns have been expressed about the grub-killing (insect protected) GM plants containing Bt toxin. This toxin is produced by a soil bacterium called *Bacillus thuringiensis* (Bt). In organic agriculture, an emergency insecticidal spray containing the whole bacterium is used, and this can be washed off by the consumer. A plant that has been genetically engineered with a Bt toxin gene, however, constantly makes the toxin internally and the toxins cannot be washed off. FSANZ regards Bt GM foods as safe because Bt has previously been used in agriculture without known harmful effects, the grub gut is alkaline whereas the human stomach is acidic, and there are no receptors on the surface of mammalian intestinal cells for the proteins expressed.¹⁷ However, Bt proteins have never occurred before in such high concentrations in food, and protein degradation is known to be incomplete in the stomach, after which the meal passes into the much more alkaline duodenum - the first part of the small intestine. In addition, adverse effects have been found in animals eating these proteins. For example, researchers fed mice potatoes containing a Bt toxin approved for human

consumption in some countries. To another group of mice, they fed potatoes treated with the δ -endotoxin believed to have the insecticidal properties of that GM potato. Both types of potato caused damage to the microscopic structure of the ileum (part of the small intestine).¹⁸ Mice fed the δ -endotoxin had hyperplasia and other changes often considered precursors to cancer.

Yet another concern is about the potential for GM plants to unexpectedly produce substances that are novel for that plant. Specifically, there are concerns that such unexpected substances may be dangerous, especially novel proteins. Advocates of GM technology and FSANZ have argued that any novel proteins would be quickly degraded so that they wouldn't enter bodily tissues.¹⁹ Yet, it is well known that proteins can cross the gut wall into bodily tissues to create toxicological and other health problems. Food allergies - for example, to peanuts - can kill susceptible people,²⁰ and eating meat from cattle with bovine spongiform encephalopathy (BSE, or mad cow disease) can kill people by causing variant Creutzfeldt-Jakob disease.

Of particular concern is the case of the Showa Denko KK company, which produced tryptophan, an amino acid used as a dietary supplement, from a GM strain of the bacterium *Bacillus amyloliquefaciens*. It resulted in an epidemic of eosinophilia-myalgia syndrome in the United States and Europe.²¹ Although the product was 99.6 per cent pure,²² thirty-seven people died within months and 1500 were permanently disabled before governments stopped counting.²³ Proponents of GM food have argued that cost-cutting procedures and reduced purification were at fault, rather than the GM organism. Investigations, however, concluded that these two factors could not be separated because both events happened at a similar time.²⁴ Thus, a new GM strain of the bacterium produced contaminating substances, which were then not sufficiently removed due to less stringent purification. Further investigation of the manufacturing process proved impossible, as the company quickly destroyed all batches of the GM bacteria.²⁵

There are three important points about the tryptophan example. First, a GM organism produced one or more dangerous substances. Second, the sold product, at 99.6 per cent pure, was much more substantially equivalent in its chemical composition to pure tryptophan than products of GM crops are to their non-GM counterparts (see 'Further problems: compositional analyses', below). This shows how dangerous the 'substantially equivalent means its safe' argument is, yet it was used by various government regulators to decide that GM food was safe, and some groups still use it. Third, even if insufficient purification had a role to play, the product had still been greatly purified. Most GM products are not even slightly purified before entering our food, making them potentially more dangerous than this company's tryptophan.

THE SAFETY TESTING THAT HAS BEEN DONE

In science, results of new work are published in peer-reviewed scientific and medical journals, so that others can repeat and extend the experiments and hence build-up a picture-in-progress of the area. Yet, rather incredibly, a recent literature search of the safety assessments of GM foods currently available in Australia yielded safety assessments of only one food: Monsanto's Roundup Ready soy. Furthermore, it was written by Monsanto-paid scientists. So how can we be satisfied that GM foods are safe when independent scientists cannot easily verify the accuracy and veracity of the results of existing safety assessments? The only effective way to assess data is to review documents written by FSANZ when it is asked by an applicant company to approve a GM food for consumption. Yet, this government watchdog agency does none of its own safety testing, instead relying on the company data. It has, however, produced a document describing its guidelines for assessing safety of GM foods,²⁶ which are best described as safe until proven harmful, the opposite of a precautionary approach. Perhaps the agency is constricted by its mandate, which is to both protect public health and safety and to promote fair trade, trade and commerce, and consistency between domestic and international regulations.

Whenever FSANZ reviews the safety of a GM food, it reviews the information presented to it and generates a report of about seventy pages per application. A review of twelve reports covering twenty-eight GM crops - four soy, three corn, ten potatoes, eight canola, one sugarbeet and two cotton - revealed no feeding trials on people. In addition, one of the GM corn varieties had gone untested on animals. Some seventeen foods involved testing with only a single oral gavage (a type of forced-feeding), with observation for seven to fourteen days, and only of the

substance that had been genetically engineered to appear, not the whole food. Such testing assumes that the only new substance that will appear in the food is the one genetically engineered to appear, that the GM plant-produced substance will act in the same manner as the tested substance that was obtained from another source, and that the substance will create disease within a few days. All are untested hypotheses and make a mockery of GM proponents' claims that the risk assessment of GM foods is based on sound science.

Furthermore, where the whole food was given to animals to eat, sample sizes were often very low - for example, five to six cows per group for Roundup Ready soy²⁷ - and they were fed for only four weeks. Moreover, some of these experiments used some very unusual animal models for human health, such as chickens, cows and trout. Some of the measurements taken from these animals are also unusual measures of human health, such as abdominal fat pad weight, total de-boned breast meat yield, and milk production. So it would appear that many of these tests have not been designed to measure human health at all, but rather to reassure primary producers that GM feed will permit farm animals to grow sufficiently to get a reasonable price at market. In its safety assessments, FSANZ uses these kinds of experiments as evidence that these foods are safe for human consumption. Even worse is that often the only results given from these experiments were the death of experimental animals. If other information was given, it was usually only body weights, with possibly some organ weights. If gross pathology was examined, there was no description of what was involved. Certainly, biochemistry, immunology, tissue pathology, and gut, liver and kidney function and microscopy results were not given, and were therefore probably not done when they should have been done and the results disseminated. In addition, animals were not fed for long enough for cancer studies, or studies into the effect of offspring, to be done. Consequently, those experiments could be regarded as initial experiments in what should have been a long series, starting with several thorough animal experiments and finishing with several detailed human experiments, yet they remain the only ones done.

Even more disturbing is that, even with these existing experiments, which are limited in their ability to pick up health problems, some adverse effects were found. For example, rats fed canola meal from GM canola GT73 had liver weights increased by twelve to sixteen per cent.²⁸ However, rather than being investigated further, these results were attributed to a higher level of glucosinolates (a known toxin in canola) in the GM canola compared to controls. Yet the level of glucosinolates was only about a third of the official level of concern as measured by the Codex Alimentarius Commission,²⁹ a global United Nations agency for setting food standards. This indicates that this substance may be innocent of these adverse effects. Consequently, a different substance may have caused the adverse effects, and, if it is oil-soluble, it may be in the oil fraction that people eat. However, there appear to be no feeding studies on canola oil to check this potential.

In another example, in addition to their normal diet, one group of rats was fed control potatoes while another was fed a Bt GM potato line. After a month, a 'number' of abnormal findings were noted, such as enlarged lymph nodes, hydronephrosis, and enlarged adrenal glands.³⁰ It was reasoned that, because at least some of these results were also found in the control rats, no statistical difference was found between the two groups, and so FSANZ decided that the GM potatoes were safe for eating. Control rats are supposed to remain healthy; that they did not indicates either that rats are an inappropriate animal model for safety testing of potatoes, or that something unusual was happening with all the rats. A virus, for example, may have infected the rats, masking any effect of the GM food, or the controls may have been inadvertently fed the GM food. Put simply, the experiment should have been repeated and expanded to determine what was occurring and why, followed by extensive human experiments, before the food was considered safe.

FURTHER PROBLEMS: COMPOSITIONAL ANALYSES

Another notable problem with the FSANZ reports is that often only the concentrations of amino acids - the building-blocks of proteins - are given in the reports, rarely the fatty acids (the components of fat) or anti-nutrients. Moreover, the type of statistical detail required by a scientific journal is not given for any analyses,³¹ thereby preventing others from properly reviewing the data and doing sample size calculations.³² The sample sizes are very small indeed,

usually about five to seven, and as low as two.³³ This allows the applicant company to too-easily find no statistical difference between the composition of the GM food under assessment and its control. This is profoundly inadequate to assess what may occur in the real world.³⁴ Even so, some significant differences were found with some GM foods. For example, eight of the eighteen amino acids (forty-four per cent) measured in corn line MON 810 were significantly different to the control corn.³⁵ Yet, those differences were ascribed to natural variation and were not investigated further, even though such significant amino acid differences could also signal the production of potentially harmful novel proteins. Adding weight to that possibility is that the amino acid differences could not be explained by the production of the proteins that were genetically engineered to appear, for any of those foods.

Such results have led the Royal Society of Canada to describe the notion of substantial equivalence as 'scientifically unjustifiable and inconsistent with precautionary regulation of the technology',³⁶ and the American National Academy of Sciences to describe human health safety testing procedures to be 'woefully inadequate'. The Royal Society in London has also weighed into the argument, describing the current system of safety screening, developed in the United States, as flawed, subjective and inadequate and that manufacturers' tests on such foods should be tightened and opened to independent scrutiny.³⁷

BEST PRACTICE HUMAN HEALTH SAFETY TESTING

Safety testing for GM foods is far below the best practice of human safety testing involved in the clinical trial of, for example, of a new pharmaceutical drug. Before a clinical trial is even begun, thorough animal testing is undertaken to determine adverse and therapeutic effects of the treatment in those animals. If the tests are passed, the four phases of the clinical trial begin. Phase I tests for adverse effects in a small number of healthy volunteers, Phase II tests for the therapeutic effect in a small number of volunteers, and Phase III is the randomised controlled trial (RCT). This is where a large number of people are randomly assigned to one of two groups. One group is the control. It takes a placebo (for example, a sugar pill) or the existing therapy, while the experimental group takes the new treatment. Neither the participants nor those involved with the participants know who is taking which. After a suitable period the results are analysed. If the new treatment passes, it is then monitored in the community (Phase IV). As a result of the push towards evidence-based medicine a further step is often undertaken - the meta-analysis. This process statistically sums the results of a number of randomised controlled trials to get a better picture. It is championed by an international collaboration of scientists known as the Cochrane Collaboration.

For this procedure to apply to GM foods, animals should be fed each GM food - one food per experiment - under investigation, and the results compared with results in animals fed the equivalent non-GM food. Animals should be fed for long enough to determine any cancer risk. Foods should also be fed to pregnant animals to determine any effect in new-born animals. At a minimum, biochemistry, immunology, tissue pathology, microscopy, and gut, liver and kidney function should be measured. If the food passes these tests, then the four phases of a clinical trial should be undertaken. This is where volunteers would be fed the foods for at least several months. However, even these studies cannot determine the long-term health effects of GM foods on humans. To do this, long-term cohort studies are required, where people's current self-selected exposure to various GM foods are measured over future years and any diseases noted as they arise. In addition, specific surveillance systems would be required to pick-up any ill-health effects in the general population.

BUT, WHERE ARE ALL THE SICK PEOPLE?

People are worried that GM food could make them ill. However, the proponents of GM food and FSANZ argue that, because no-one has found any documented cases of people who have become ill from eating GM food, GM food must be safe. To see whether this statement makes sense, let's assume for a moment that GM food is making people ill and see how easy it would be to find the proof that GM food is causing the illness.

The first problem is to recognise that there is a new health problem in the community. Without full animal testing, we don't even know which diseases to look for in people. If the resultant disease is an existing disease, for example, cancer, that has a registry or effective surveillance system established for it, we will be alerted to an increase in that disease if people are paid to look for it. If the disease has no effective surveillance system, either because it is a new disease and therefore cannot be under surveillance, or because it is an existing disease without a surveillance system, the problem may go completely unnoticed. Most diseases have no surveillance system, including diseases that kill many Australians each year, such as asthma.

Consequently, we are likely to be unaware of any problem until a critical mass of clinicians begins to individually recognise that they have been seeing a lot of syndrome X, start asking their colleagues if they have seen the same, and push for an investigation. If this does not happen, we may never know there is a problem. The HIV/AIDS epidemic went unnoticed for decades, even though it created memorable secondary infections, such as those obtained from cats, and had a focus in young gay men who tended to cluster geographically and see the same doctors. It was largely picked-up by chance, because record-keeping of one pharmaceutical drug, pentamidine, indicated an unusually high number of patients with a rare pneumonia,³⁸ even though there were by then thousands of HIV/AIDS cases worldwide. We still do not know how many people are infected, even in Australia, which has one of the best surveillance systems in the world. It is also important to note that, by the time some surveillance data are collected and made available for analysis, several years can elapse. This can lead to a lag of several years between the cases occurring and appearing in a surveillance system.

Finding cases of illness is however only the first step. Then we would need to prove that GM food was the cause by mounting an investigation, because surveillance only indicates there is a disease. It does not inform us of the cause. Anything that looks like an infectious disease usually results in an investigation by a state or local health authority. Anything else, for example, an increase in cancer, relies on someone, usually an academic, having an interest in the disease and applying in a competitive medical research grant system, for funding to do the investigation. Applicants to one of the main sources of medical research funding, the National Health and Medical Research Council, can expect on average an eighty per cent failure rate overall - often higher for public health-related work such as this - resulting in a possible delay of many years before an investigation could begin.

If funding is secured, various causes of the disease would be suggested and tested by different investigating teams. For an existing disease, existing hypotheses would be considered and tested before GM foods. For example, for immune function problems, infectious diseases would first be considered. For diseases where food is traditionally suspected, for example, gut cancers, food consumption would likely concentrate on existing hypotheses such as fat or fibre content rather than GM, leading to another potential lag time of several years. Moreover, investigations involving food eaten over several years are fraught with difficulty. Most people cannot even remember everything they ate the day before. Try it. Now, try to quantify, for example, the amount of chocolate you have consumed in the last five years, in all its food combinations. Consumption of GM food components are even harder to quantify, as many manufacturers still do not know whether they are using ingredients derived from GM sources, or they do not label the food as containing these. So how can the consumer or investigator determine the amount or types of GM foods eaten in a group of ill people? It therefore becomes almost impossible to prove that a GM food has caused a disease, even if there are thousands of cases.

Let's continue this exercise by asking: what would happen if a link were found between a GM food and human ill-health? It would be reasonable to expect that the public would want this food removed from the food supply. However, experience with the tobacco industry indicates that affected industries tend to argue and lobby against evidence for lucrative plant products. This would be compounded by the political considerations and lobbying of many thousands of disaffected farmers whose livelihoods depended on growing the crops. Action becomes even harder the weaker the link is between exposure and the disease. One of the strongest relationships between an exposure and a chronic disease ever found, and repeatedly found, is the relationship between smoking and lung cancer. The chance of smokers getting lung cancer is about twelve times that of non-smokers. Even so, public health action to reduce smoking such as banning advertising and smoking in some buildings, has taken decades. Risks for other

exposures, particularly food, and their cancers tend to be much lower. Therefore, obtaining sufficient proof and getting action tends to be much harder for these. So, even if a GM food is found to cause harm, it may take many years of effort to remove it from the food supply.

Even if immediate action were instigated and the GM food were banned, our previous experience of the release of live organisms into the environment, such as cane toads, indicates that we would not be able to effectively recall it, but that it could continue to spread its genes through the non-GM equivalent plant population (as Chapter 4 also recognises). Furthermore, even if a recall were effective, any 'incubation period' - that is, the delay between exposure and disease - could see cases appearing long after the recall. Any incubation period could also result in a lag time of many years before cases even begin to appear in the population.

In short, with the level of current safety testing, if GM foods do cause human health problems, it will be very difficult to determine this, even though there may be many many cases, and finding the cause and doing something about it may take decades.

CONCLUSION: RISK AND THE FUTURE

Scientists tend to measure risk as a combination of the probability of something happening and the consequences if it does. A useful analogy is a footpath, where the narrower the footpath, the greater the probability of falling off, and the higher the footpath, the greater the consequence of falling off. It is unlikely that many people would take a challenge of walking along even a wide footpath strung between two tall buildings, because even if the probability of falling off is low, the consequence could be awful. Similarly, even if the probability of GM foods causing adverse health effects is low, the consequences of exposing a billion people to it, including the whole of the Australian population, could be dire. If only one person in a thousand became seriously ill, then with about a billion people currently exposed worldwide, the result would be a million people seriously ill worldwide, and about 19 000 in Australia.

In conclusion, there is an urgent need for the full labelling of GM foods, comprehensive safety testing by independent researchers of all GM foods currently in the marketplace and of all subsequent GM foods before they enter the marketplace. Until these measures are adopted, a statement needs to be placed on GM foods that human safety testing has not been done. Finally, a dedicated long-term national surveillance system for the potential health effects of GM foods is long overdue.

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