GM crops –
the health effects

Soil Association

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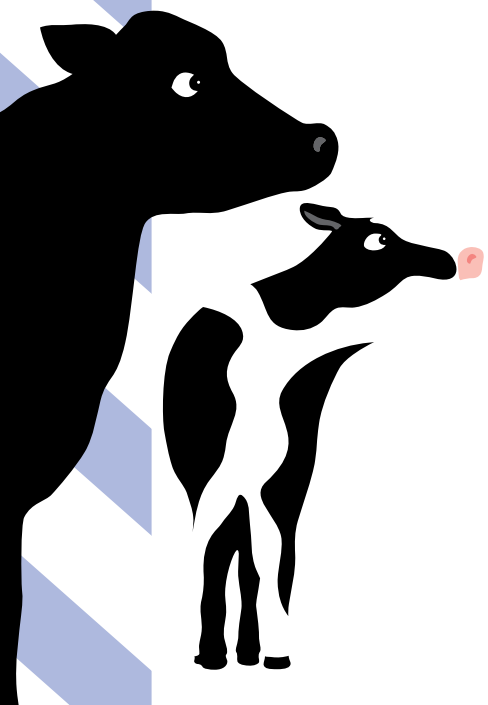

Introduction

One of the main concerns about GM crops is whether they will have negative effects on health. This was initially a theoretical concern. However, considerable scientific evidence has emerged over the last few years that has substantially developed our understanding and shows that there are indeed real health risks from genetic engineering. There is now a worrying body of published, peer-reviewed scientific evidence from controlled animal studies carried out in many countries and by different parties (government, independent and company studies) that demonstrates that GMOs cause a wide range of serious unexpected health impacts. Evidence is also beginning to emerge that if GM crops are fed to animals, small amounts of GM material appear in the resulting meat and dairy products, and this had not been previously identified.

Both of these issues raise serious human and animal health concerns about the use of GMOs in food, and also major ethical concerns about the fact that foods from GM-fed animals remain unlabelled. The findings also raise serious questions about the reliability of the European safety assessment and advisory procedures. With this evidence, the Soil Association believes that GM crops are unsafe and should not be used for food.

Do milk, eggs and meat from GM-fed animals contain GM material?

It was often suggested by the advocates of GM crops that there should be no concerns about this issue because GM crop material is degraded during processing into feed and during digestion. (There are, for instance, significant secretions of nucleases, enzymes which break down DNA, along the gut.)[1] Until a couple of years ago, none of the published studies had detected transgenic (GM) DNA in the milk, eggs or meat of GM-fed animals.[2,3,4,5]

Nevertheless, several of these studies found that plant chloroplast DNA from animal feed is present in milk, eggs and meat.[2,3,4] This plant DNA was not nuclear DNA, the DNA contained in the nuclei of cells which is where the novel genes ('trangenes') are usually inserted for making GM crops. It was instead the DNA that is found in the chloroplasts, the plant 'organelles' that photosynthesise and which are present in large numbers in plant cells. Chloroplast DNA is vastly more abundant than nuclear DNA, since each plant cell can have thousands of copies of chloroplast genes but just two to four copies of each nuclear gene. Plant chloroplast DNA is therefore thought to be more detectable in animal products than nuclear DNA simply because of its greater abundance, not because it is less susceptible to breakdown during processing or digestion.

It is therefore in fact likely that many studies were failing to detect GM crop ('transgenic') DNA in animal products and tissues because of its comparatively low level of presence and limitations in the sensitivity of the analytic methods being used, rather than because transgenic DNA does not actually make its way into animal products and tissues.

Since late 2005, however, three published studies by three different scientific teams and one unpublished study have actually detected transgenic plant DNA in animal tissues and milk.

A Canadian team fed pigs and sheep Roundup Ready oilseed rape and then examined various tissues from the animals. They found that a liver, a kidney and intestinal tissues from the pigs, and intestinal tissues from the sheep contained fractions of the transgenes.[6] In another study, Italian scientists fed piglets for 35 days on Monsanto's GM maize (Mon 810). They subsequently found fragments of a transgene in the blood, liver, spleen and kidney of the animals.[7]

Another Italian research team, from the University of Catania, detected GM soya and GM sequences in shop-bought milk in Italy.[8] An unpublished study, carried out in the year 2000 at the University of Weihenstephan in Germany, also detected GM material (from GM soya and GM maize) in the milk of cows which had been fed large amounts of GM plants. The results of the study were published by Greenpeace in 2004.[9,10] The researcher has suggested that the DNA may have been a result of contamination of the milk by dust from the GM feed in the dairy. Whilst this is unproven, this points to a potential common source of contamination with

the use of GM feed and does not change or undermine the fact that the researcher found GM DNA in the milk.

The Soil Association decided to also investigate this issue. We asked those farmers whose feeds we had found contained high levels of GM soya, if they would also provide samples of their milk or eggs for testing for the presence of GM DNA or GM protein. Two dairy farmers and one egg producer agreed to provide samples. Each farmer provided two samples of milk (from two different cows) or two samples of eggs, as well as another sample of feed to re-check the GM soya level. All samples were tested by Genetic ID in Germany. The soya in all three feed samples was found to be 100% GM. However, our tests did not detect any GM DNA or protein in any of the milk or egg samples. In several of the milk samples, plant DNA, including soya DNA, was detected, indicating the possibility that a very low level of undetected GM DNA may have been present. Subsequently, when we became aware of the Italian research which had detected GM DNA in shop-bought milk, we also carried out a similar, but smaller-scale survey. Milk samples were collected from 10 different leading supermarket or corner shop chains. All of the samples were analysed using the same analytic technique used by the scientists from Catania, as well as by an in-house method. Again, no GM DNA or protein was detected, but several samples contained traces of plant DNA, including soya DNA.

In conclusion, based on the fact that crop chloroplast DNA is commonly found in milk, eggs and animal tissues, and that four research teams now have, between them, detected GM crop DNA in the milk, blood, liver, kidneys and intestinal tissues of GM-fed animals, we conclude that it is likely that people are being frequently exposed to GM DNA by eating milk and meat from GM-fed animals, albeit at very low levels. Further research into this subject is needed.

Do GM foods have health impacts?

Biotechnology companies have claimed that genetic engineering is no more unpredictable and dangerous than traditional cross-breeding, and as a result GM crops should not be subjected to special or extensive safety assessments. In reality, genetic modification differs fundamentally from traditional cross-breeding, and there are very good scientific reasons for being concerned about the safety of GM crops.

Genetic engineering usually involves introducing a package of genetic material derived from one organism (or several) into the DNA of another, often a completely different species. It is never based on the plant's normal reproductive processes, which are used in traditional cross-breeding. Instead, the foreign DNA is inserted into the plants own DNA either by using the infective process of a disease bacteria or by bombarding the cells with fine metal particles coated with the foreign DNA. This artificial DNA insertion breaks down the natural biological mechanisms that normally maintain the genetic integrity of species. At various stages in the process, the number of cells are increased by a laboratory method called a "tissue culture".

The technique has several serious flaws. This means there is a large number of risks inherent in GM crops, which do not apply to plants produced by traditional cross-breeding:

- Since the inserted genes usually come from other organisms such as bacteria or are synthetically produced, the proteins they produce are often new to the animal or human diet. The production of the protein may also involve a new biochemical pathway in the plant or affect an existing one, which can mean the production of other novel protein or biochemical by-products, some of which could be allergenic or toxic. This explains why GMOs have been associated with allergic reactions.

- The technique is highly disruptive to the plant's genes in various ways. The process of inserting the gene is known to damage the plant's own DNA: the gene can integrate right in the middle of another gene, causing it to lose its function.[11] Additionally, the tissue culture stages cause numerous changes to the rest of the plant's DNA. There is well-documented evidence by the FSA and others that genetic engineering causes extensive 'genome-wide' mutations and changes in the activity of very many of the plant's own genes as a result of genetic engineering.[12] These widespread genetic effects are not predictable or controllable.

- Unlike naturally occurring genes which are generally only active at certain times and in certain cells, transgenes are usually active the whole time and in all cells. This means that the gene's products and any by-products are present in all of the plant's tissues. So, for example, unlike normal non-GM maize, the Bt toxin is present in all the cells in Bt maize, the main GM maize used in animal feed.

- It is now known that genes do not operate in isolation or completely dictate to the plant, contrary to the earlier simple scientific concept of genes as building blocks and the 'blueprint' of life. Genes are instead themselves controlled by numerous interactive plant regulatory mechanisms, including other genes and cellular processes, in a complex system which is far from fully understood (the science of 'epigenetics'). The result is that the same gene can behave in 10 different ways in 10 different locations, depending on the regulatory elements it ends up next to.[11] As genetic engineers cannot control where the genes end up in the plant DNA and do not know the effects of the different locations, unpredicted side effects easily occur.

- Scientists have recently found that a harmless protein in one organism can become harmful when inserted into another organism, even if its sequence of amino acids remains completely identical. This is because of a process called "post-translation modification" whereby, depending on the plant species and the type of cell, different sugars, lipids or other molecules attach to the protein and modify its function (an example is 'glycosylation'). This was recently highlighted by Australian scientists who inserted a previously harmless bean protein into a pea, which then caused allergic reactions in mice.[13,14,15] Genetic engineers are unable to accurately predict and control this effect.

- Research commissioned by the FSA and others, on both humans and animals, has now shown that the inserted transgenes can move out of GMOs when they are eaten and enter the bacterial population in the mouth and gut, a process known as 'horizontal gene transfer'.[16,17] There are concerns that this means that there may be instances when, over time, the gut bacteria start to produce the transgenic protein in the animal or human gut, such as antibiotic resistance or Bt toxin production, with health implications.

- The inserted gene is often unstable and, over time, found to rearrange within the plant's genome. In 2003, a French laboratory analysed the inserted genes in five GM varieties, including Monsanto's Roundup Ready soya, and found that in all cases the genetic sequences were different to those that had been described years earlier by the biotechnology companies.[18,19] Subsequently, a Belgian research group also found differences to the companies' genetic sequences, as well as to those found by the French scientists.[19,20] This genetic instability means that the way in which the inserted gene expresses itself in the plant and its impacts on health may change over time.

Official safety assessments are far too narrow

One of the most remarkable facts about the development of GM crops is that, despite years of immense public concern, political controversy and the developing scientific understanding of the risks of GMOs, very few of these risks are actually checked in the official regulatory approval process. There is a long regulatory process that requires the companies to submit considerable amounts of information, but almost none except a small sub-set of the above concerns are routinely investigated in the process.

Those opposed to GM crops generally believe that any overall assessment of the list of risks indicates that GM crops are currently far too risky to be used for food or animal feed. Governments, however, have been persuaded to allow GM crops to be grown and used for food or animal feed as long as there is a 'case-by-case' risk assessment. The problem is that the impacts of the genetic engineering process on the biology of organisms is so complex, and scientific knowledge of plant biochemistry so limited, that it is completely impossible for scientists to model and predict the actual health effects of each genetic engineering attempt. The only way that the risks listed above could be assessed on a case-by-case basis, with some level of accuracy, would be to use animal feeding trials. This is how the safety of medical drugs and pesticides are assessed. However, the biotechnology companies are not normally required

to undertake such animal feeding trials in Europe, the US, or indeed anywhere. Although this was the initial intention of the UK and US Governments, the use of animal feeding trials for risk assessment was quickly abandoned after the first of such trials, on GM tomatoes and potatoes, found unexpected adverse effects on the animals (see later).

Instead, regulators mainly rely on an assessment process that is much more limited. Under this approach (commonly referred to as 'substantial equivalence'), a limited number of comparisons are made with the non-GM equivalent plant. Several of the physical characteristics of the new GM plant are compared with the non-GM variety. Then, a chemical comparison is made. But, although plants have up to 10,000 different biochemicals, the levels of only a small number of the GM plant's biochemicals are checked with the non-GM plant, such as key nutrients and known toxins. If the levels of these are considered 'similar', it is then assumed that the whole chemistry of the GM plant is similar as regards safety in almost every other way. The GM crop is considered 'substantially equivalent' to the non-GM plant, and no further special safety tests have to be carried out. The OECD, for example, suggested that ,"If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety".[21]

Under the EU assessment procedure, some other checks are required beyond this basic comparison, but the 'substantial equivalence' approach still rules. So, the EU usually requires testing to show whether the protein produced by the gene is toxic or allergenic. However, the safety of all the other novel proteins and biochemical by-products produced by the GMO are not usually checked. The stability of the inserted gene has to be checked, but not the stability of the whole genome and thus not the GMO as a whole. These other aspects are essentially just assumed, without any basis, to be safe. No GMO has ever been rejected under this assessment process.

Ever since 'substantial equivalence' was first proposed by the US Government for approving GM crops, there has been strong criticism of this process as fundamentally unscientific and inadequate for safety assessment. In 1992, when the US Government proposed using the concept instead of animal trials, the scientific advisers of the US Food and Drug Administration's (FDA) did not support the Government's policy, arguing that animal feeding trials were needed to identify undesirable effects.[22] The policy was adopted anyway and then taken up by Europe and other countries. In 2001, a review for the Canadian Government by the Royal Society of Canada concluded that, "The Panel finds the use of 'substantial equivalence' as a decision threshold tool to exempt GM agricultural products from rigorous scientific assessment to be scientifically unjustifiable."[23] Other scientists, writing in the eminent scientific journal *Nature* have described substantial equivalence as "a pseudo-scientific concept" which is inherently "anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests". They point out that scientists are not able to reliably predict the effects of a GM food from knowledge of its chemical composition, and so active investigation of the safety and toxicity of GM crops is required.[24] Even the former Chair of the FSA's advisory committee, the Advisory Committee on Novel Foods and Processes (ACNFP), which until 2004 was responsible for carrying out safety assessments of GM foods, has said, "The presumption of safety of novel GM plants on the basis of substantial equivalence lacks scientific credibility."[25]

Poor safety assessment of Roundup Ready soya

Monsanto's Roundup Ready soya (RR soya) is the most widely grown GM crop variety in the world and the most widely used GM crop in commercial animal feed. Its safety assessment is therefore of particular interest. 'Roundup Ready' soya varieties tolerate applications of Monsanto's 'broad spectrum' glyphosate herbicide, Roundup, which destroys all other plants. The summary of the safety data used in the regulatory approval process is available from Monsanto's website.[26] It does not, however, make for reassuring reading for it shows that Monsanto's scientific case is very flimsy.

The new protein which the genetic modification had introduced to the soya was compared with other proteins already in the food chain, and deemed to be 'functionally similar'. Its amino-acid sequence was compared with known protein toxins and allergens, and found to be different. Monsanto then claimed that 'compositional analyses' established that the GM soya (as a whole) was substantially

equivalent to the non-GM parent variety and other soya varieties.

The safety of the novel protein was assessed only in one short-term (acute) feeding trial with mice. The safety of the protein was not tested on any of the species that are now actually eating the novel protein in animal feed. The only feeding tests carried out with the soya were 'nutritional' feeding studies, which assessed growth rate in a variety of animals and milk production in dairy cows. No animal feeding studies were carried out which were specifically designed to determine the safety of the whole GM soya; in particular no toxicological tests were done. No long-term feeding studies were carried out.

In the absence of such basic scientific investigations, it is clear that no objective assessment of Monsanto's evidence could conclude that the safety of RR soya has been determined.

Animal feeding tests show negative effects of GM crops

The biotechnology companies frequently refer to the large number of published animal feeding studies as evidence of the safety of GM feed. However, it is important to stress that the vast majority of these are not safety studies. They are not toxicological studies, which would involve analysing the animal tissue for toxic effects, or studies of other safety aspects such as the rate of horizontal gene transfer. Instead, these studies are mostly of commercial interest, designed to evaluate the effect of the GM crops on commercial feed performance indicators, such as livestock growth rates or milk production. In contrast, if we look at the much smaller number of genuine animal safety studies, some of which were conducted by the companies themselves, a very different and very worrying picture emerges. We summarise below the alarming findings that have now accumulated for the GM crops being used as food and animal feed.

(i) GM soya

Russian rat trial – A Russian scientist, Dr Irina Ermakova, investigated the effects of feeding Roundup Ready soya to rats, with dramatic findings of apparent generational effects. A group of female rats were fed RR soya before mating, during pregnancy and during lactation. Very high mortality rates occurred in the rat pups: 56% died within three weeks of birth, compared with only 9% in the control rats fed non-GM soya. Additionally, stunted growth was observed in the surviving progeny, with some of the organs in the smaller GM-fed pups being tiny in comparison with those from control groups.[27] This study has now been published.[28] Dr Ermakova was shocked by her own results and has called for further detailed investigations to be undertaken.[29]

(The ACNFP reviewed an early draft of Ermakova's work and said it lacked detail, in particular about the geographical origins of the GM and non-GM soya used and whether they contained mycotoxins, and said no conclusions could be drawn.[30] They also claimed that her results were inconsistent with another feeding trial of RR soya which had not found any adverse effects.[31] The ACNFP's comments are seen as biased, however, as the latter study was not a valid comparison since it used male mice, not pregnant rats, and, while the ACNFP called this study "well controlled", it had less nutritional detail than Ermakova's study.[32])

Italian mouse trial – One of the only long-term feeding studies carried out on GM crops was undertaken by scientists from Urbino, in Italy, and found that Roundup Ready soya affects key body organs. Mice were fed RR soya for up to 24 months. A variety of organs and body fluids were then examined. The scientists found significant cellular changes in the liver, pancreas and testes of mice, which involved structural changes and/or functional changes.[33,34,35,36,37] The cellular changes in the liver, which metabolises toxic compounds, suggested that RR soya causes an increased metabolic rate.

FSA human feeding trial – The only published trial of GM foods on humans was carried out by Newcastle University for the Food Standards Agency, and published in 2004. It was designed to study what happens to transgenic DNA in the human gut and whether it could pass out and enter bacteria in the body, a long-standing concern. It found that the entire transgenic gene in GM soya survives the passage through the stomach and small intestine, though not through the colon. The study also discovered that portions of transgenic DNA had 'horizontally' transferred from GM food into the intestinal bacteria of some of the volunteers, which was a shocking discovery with implications for the long-term impacts of GM consumption.[16,38] Just as shocking, however, was the fact that at the time the

FSA chose not to mention this key finding in its communications on the study, thus widely giving the impression that horizontal gene transfer had not been identified in the study.

(ii) GM maize

Monsanto rat trial – In June 2005, after a German court ruling in favour of Greenpeace, Monsanto was forced to release the full details of its safety data for the GM maize, MON 863, which was being evaluated by the European Food Safety Authority (EFSA). The maize had been genetically modified to produce a Bt-toxin which kills the corn rootworm, a maize pest. Monsanto's studies showed that the Bt maize had several statistically significant effects on the rats: increased white blood cells, a drop in immature red blood cells, decreased kidney weight and increased blood sugar levels.[39,40]

The chemical data also showed signs of toxic effects to the liver and kidney systems. Professor Gilles-Eric Séralini, a molecular endocrinologist and member of two French government commissions that evaluate GM food, said that the rats likely suffered a toxic reaction. A full analysis of the chemical data by Professor Séralini and his team was published in May 2007. It states, "with the present data it cannot be concluded that GM corn MON 863 is a safe product".[41]

The EFSA GMO Panel, nonetheless, recommended the GM maize should be approved, accepting Monsanto arguments as to why the statistically significant differences should be ignored. (The Panel has been accused of being pro-GM and having financial links to the industry. For example, according to Friends of the Earth, two of its members have appeared in industry videos promoting biotechnology).[40,42] Despite the EFSA's endorsement, the EU's Council of Ministers voted to not approve the GM maize. However, the vote required a 'qualified majority'. This was not achieved, so the Commission had the final say. It approved MON 863 on the basis of the 'scientific advice' of the GMO Panel, in January 2006.[40,43]

Aventis's chicken and rat trials – Aventis (since purchased by Bayer) carried out two controversial feeding trials of its herbicide-tolerant Chardon 'Liberty Link' (T25) maize, which it submitted for approval at the end of 1995. In a 42-day feeding trial with chickens, there was a 7% mortality rate for chickens fed the T25 maize, twice the rate of the non-GM fed chickens (10 of 140 died versus five of 140 of those fed non-GM maize). Compositional tests revealed a significant difference in the level of fats and carbohydrate between the GM and non-GM maize, suggesting alterations in some biochemical pathways.[44]

Separately, Aventis also tested just the transgenic PAT protein which is produced by the modified maize and which gives resistance to the company's herbicide, glufosinate. In a short-term, 14-day rat feeding study, the effects of the isolated protein were tested on four groups of rats, two of which were fed the PAT protein, one at a low level and one at a high level.

The design of the studies meant that any negative effects that occurred would be obscured, unless they were very dramatic: only five male and five female rats were tested in each group (restricting the chance of establishing statistical significance for any effects), the starting weights varied by +/-20% (rather than the usual +/-2%), and the group receiving the high level of the transgenic PAT protein had the highest starting body weights. Despite this, and the fact that the high PAT protein group showed the highest feed intake, this group ended up with the lowest body weights, significantly less than the group receiving the equivalent non-GM diet and the group receiving the low level of PAT protein. Biochemical differences and measurements of the urine volume indicated an increased metabolic load on the rats fed the PAT protein.[44]

Despite this opposing scientific evidence, T25 maize was approved for consumption by the EU in April 1998. Liberty Link GM maize has been widely marketed in North America by Bayer CropScience.

UK study of gene transfer in sheep – A UK study with sheep, published in 2003, found that when GM maize was eaten, after only eight minutes, some of the inserted transgenes moved out from the maize and 'horizontally' transferred into the bacteria in the mouth. One of the inserted genes coded for resistance to the antibiotic kanamycin.

After the transgenes transferred, the *E.coli* bacteria were found to be resistant to the antibiotic, showing that the transgenes had integrated into the bacteria's own DNA. This proved that 'horizontal gene transfer' of inserted genes can happen relatively easily.[17]

(iii) GM oilseed rape

Monsanto rat trials – The GM oilseed rape, GT73, has been approved in Europe since 2004, although documentation published by the US FDA shows that two of Monsanto's rat feeding studies found statistically significant adverse effects.[45] GT73 is a glyphosate-tolerant 'Roundup Ready' (RR)variety.

The first study, carried out with a mixture of two of Monsanto's glyphosate-tolerant oilseed rape varieties, including GT73, found statistically significant decreases in terminal body weight and cumulative body weight gains in male rats (but not female rats) fed GM rape, compared to rats fed non-GM rape. Monsanto, however, argued that there were 'technical' problems with the study, and repeated it. Interestingly, while the US FDA clearly states that statistically significant differences in the body weights of the male rats were found, the EFSA claimed that the study found no differences in body weights (though they admitted that the GM-fed rats had higher liver to body weight ratios).[46]

The second study, conducted solely with the GT73 variety, found that rats fed this GM rape had relative liver weights that were increased up to 16% compared to those fed the non-GM parental line. Apparently forgetting that there had been 'technical' problems with the first study and that the rats had not been fed exactly the same GM rape in both studies, Monsanto argued that the results of the second study should also be ignored since the results of the two trials were 'inconsistent'. They carried out a third study which did not find any problems.[45] In August 2004, GT73 was approved for food and feed use in the EU.

(iv) GM peas

Australian mice trial – The results of recently published research by Australian scientists on the safety of GM peas raises serious questions about the safety of GM crops in general. The researchers inserted a gene, normally found in kidney beans, to peas to make them resistant to the pea weavil, and then fed the GM peas to mice for four weeks. The peas triggered allergic reactions in the mice: the lung tissue became inflamed. The mice also became sensitive to other substances, reacting to egg white, whereas those fed non-GM peas did not. Even after cooking the peas, the mice still had an allergic reaction.[13,14,15]

This was considered a surprising result as the mice did not have an allergic reaction to non-GM peas or to the kidney beans, and because the new protein being expressed by the introduced gene in the peas was chemically identical to the protein in the kidney beans. Closer examination, however, revealed that although the protein in the GM peas had an identical amino acid sequence to the protein in beans, there were now differences in the sugars attached to it (due to glycosylation).

The scientists concluded that "transgenic expression of non-native proteins in plants may lead to the synthesis of structural variants possessing altered immunogenicity".[13] In other words, a protein which is non-toxic in its native plant cannot be assumed to remain non-toxic when transferred and expressed in a GM plant– yet this is precisely what has been assumed by regulators so far. The 'substantial equivalence' approach does not assess the possibility of such harmful glycosylation occurring.

(v) GM tomatoes

Calgene mice trials – Unpublished trials with GM Flavr Savr tomatoes commissioned by the company Calgene and submitted to the US FDA in order to gain approval for the first GM food, found that mice fed the tomatoes developed lesions in the gut wall. In a 28-day trial, groups of 40 rats were fed GM tomato or a control diet.

Out of 20 female rats fed the GM tomato, lesions were identified in four and seven rats, by two expert groups respectively. No such effects were found in the control rats. The FDA requested another study to be carried out. Lesions occurred again (2 of 15 rats) and, additionally, seven out of 40 (17.5%) of the rats fed the GM tomatoes died within two weeks.[47] Following this, the biotechnology industry and US Government agreed to instead use the 'substantial equivalence' concept for approving GM crops, rather than animal feeding trials. Calgene's Flavr Savr tomato and Zeneca's similar GM tomato variety were approved by the FDA in mid-1994. Both varieties were also cleared for sale in the UK, although only Zeneca's (then AstraZeneca) product was sold, as tomato paste until June 1999.

(vi) GM potatoes

UK rat trials – Similar results to GM tomatoes were found by the first animal feeding trial in the UK, and with the same consequence. GM potatoes were famously found to cause lesions in the gut wall of rats in a controlled trial by Dr Arpad Pusztai, working at the Rowett Research Institute in Scotland. The findings, which were publicised in 1998, caused major controversy and misinformation was widely spread by proponents of GM crops that the trials had not been controlled.

Pusztai's studies had been commissioned by the UK Government in order to develop a protocol for using animal feeding trials for the risk assessment of GM crops, so the findings should have been taken very seriously. Instead, Pusztai was suspended, gagged, and eventually lost his job. The UK Government abandoned its plan to require animal feeding trials and instead followed the US Government's policy of relying primarily on 'substantial equivalence'. Pusztai's study was published in the Lancet medical journal, [48] which recommended that it be repeated. To this day, this has not been done.

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