Crop Biotechnology and Food Safety

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Crop Biotechnology and Food Safety

Introduction

Scientists and regulators have more detailed knowledge about approved biotech food crops – herbicide tolerant soya or insect resistant maize, for example – than any of the other fruit, vegetables, or animal products we eat regularly without thinking. Not only this, but hundreds of millions of people in North America have eaten these foods for the past six years, with not a single incident of harm. To quote the European Commission: "The use of more precise technology and the greater regulatory scrutiny probably makes them even safer than conventional plants and foods."

On the other hand, when scientists are asked whether something is safe, they will never give an unequivocal, black-and-white "yes" as an answer. Nothing can ever be proved to be 100% safe. And yet, in a society which increasingly demands reassurance, where "accidents" become "preventable incidents" and where someone is always held to blame, such apparent lack of clarity makes some people worried.

Some of those concerned about the use of modern biotechnology in food production point to this inability to be completely certain as evidence that it is therefore unsafe and to be avoided. In reality, nothing could be further from the truth. Foods and ingredients derived from genetically modified crops are the most studied things we have ever eaten.

In this paper, we will look at some of the questions about safety, and the evidence produced to answer them. We will see that every application is thoroughly studied on a case-by-case basis before a decision is made by the authorities. We hope you will agree that this class of foods – highly regulated and exhaustively studied – presents no cause for concern.

This is the fourth in a series of papers about aspects of modern biotechnology produced by ABE. We value your feedback and criticism, and would be pleased to have suggestions for further topics to be included.

The social context: risk avoidance

The point has been made before that people's basic attitudes to new technology in general, and modern biotechnology in particular, are remarkably similar across Europe and America[1]. And yet there are clear differences in the reactions of societies as a whole to GM foods: very little real concern about their safety in the USA, and more positive attitudes in Spain, the Netherlands and Scandinavia than the EU on average, for example.

The major reasons for the differences observed on the two sides of the Atlantic are quite easy to see; in particular:

1. The United States has not had the series of high-profile food safety incidents experienced in Europe, BSE being the biggest.
2. Europeans in general, and many of the Member States in particular, have little confidence in their governments' ability to protect them from problems with food. We do not have the experience of an established, trusted EU-wide body equivalent to the Food and Drug Administration, although the setting up of the European Food Safety Authority will hopefully be the first step to correct this.

With this background, and in societies where environmental activists still command attention, it is easy to put doubts into people's minds about the safety of new and complex technology applied to something as personal as food. Little wonder then, that, in consumer surveys, a significant proportion of Europeans express concerns about the safety of biotech foods[2].

Food safety: how is it assessed?

A number of concerns have been raised about the safety of foods derived from modern biotechnology. The main ones, which we will cover in more detail below, are:

- Potential to induce new allergies
- Unintended effects, such as toxicity
- Possible transfer of genetic material to animals and people
- Antibiotic resistance marker genes

Allergenicity

Allergies and their causes

Allergies are caused by a range of substances: pollen, house-dust and food being the most common. In all cases, the allergy is to a particular protein, to which the body reacts. This reaction is, for most people, just annoying: a runny nose, itchy skin etc. However, for a few sensitive individuals, contact with even a very small quantity of the allergen (the protein responsible) can cause a severe reaction, called anaphylaxis or "toxic shock". In extreme cases, death can result.

The great majority of cases are caused by common items in most people's diets, in particular dairy products, shellfish, soya and nuts. Certain allergens have a greater effect than others on susceptible individuals; tree nuts and peanuts are a particular case in point.

A similar condition to allergy is celiac disease, in which wheat and related cereals causes inflammation of the digestive system and other problems. This is caused by a major component of the gluten protein in certain genetically-predisposed individuals. In the case of both allergies and celiac disease, sufferers have to steer clear of the food component they are sensitive to if they are to avoid all symptoms.

There is a feeling amongst the public at large that allergies are on the rise: a trend associated in many people's minds with modern living. For example, according to the British Nutrition Foundation, 20% of people believe they are allergic to one or more foods. In fact, based on a number of reports from round the world, the real incidence of food allergy is only 1-2 % in children, falling to less than 1% in adults. Of these, fortunately only a small percentage suffer from severe or even life-threatening reactions. In the case of celiac disease, the proportion of sufferers across Europe is estimated to be only about 1 in 5000, although there are locally higher incidences (up to 1 in 300 in parts of Ireland, for example).

Food intolerance (which is completely unrelated to allergy) is something which affects a larger number of people, although still well below 10% of the European population.

1 See the second paper in this series (Public Attitudes) for more details
2 Note that consumers are actually more positive when in a position to buy real products rather than answer theoretical questions

It is a reaction – indigestion, for example – to a particular food which leads some people to avoid the food in question. However, this does not cause specific, severe reactions as allergies can, and is not life-threatening.

Could biotech foods make a difference?

Against this background, many people are understandably concerned about possible new allergens, and this is why some have questioned the safety of GM foods. Since genes code for the production of proteins, and proteins are potential allergens, doesn't the introduction of different proteins create problems? This is exactly the question asked by the regulatory authorities when assessing the safety of a new food (whether or not produced by use of modern biotechnology).

Not surprisingly, there is a rational, stepwise approach to the problem[3]:

- The source of the inserted gene is, of course, known. If it is from a source known to cause allergies, the new protein must be presumed to be allergenic. This presumption can be confirmed by further testing, for example by doing skin tests on allergic individuals.
- Any new food shown to cause an allergic reaction in this way would not be allowed for human consumption.
- If the gene is not from a source commonly causing allergies, testing is more complex. For new proteins, the structure is compared with that of all known allergens to look for similarities. They are also subjected to a laboratory test for speed of digestion: those causing allergies are normally relatively slowly digested (since they must have time to cause a reaction). If the protein is dissimilar to known allergens, and is rapidly digested, it is unlikely to cause allergic reactions.

It is never possible to be 100% certain that something will not cause an allergy in some individuals: more than 160 foods have been associated with allergic reactions. However, we can be a lot more certain about newly-introduced biotech foods than other new additions to our diet. By way of comparison, many of us will remember kiwi fruit first becoming available in Europe. No testing was required, and some individuals do indeed have a mild allergic reaction to them.

In practice, the regulatory regime has ensured that the public has not been exposed to new allergens from biotech food. The best-known example of this was a modified soyabean in development in the USA. This had a gene from Brazil nut added to increase the quality of the protein and improve its value as an animal feed. This was achieved, but at the laboratory testing stage it was shown that people allergic to Brazil nuts might also show a reaction to the modified soyabean. Because of this, development was stopped, and the improved soya never commercialised. It is now extremely unlikely that any company would choose to incorporate a gene from a known allergenic source in any new development. If – for whatever reason – such a gene was used and the benefits were thought likely to outweigh the risks, the proven regulatory processes would assure the safety of anything which reached the market.

Of course, in most cases, modern biotechnology will make no difference to existing allergies. Sensitive individuals will still have a reaction to some foods, whether modified or not. However, some groups of scientists are now working on **reducing** the allergenicity of common foods using the tools of modern biotechnology. There is even the possibility of a non-allergenic peanut being developed.

Further safety assessment: looking for unexpected problems

Despite the scientific consensus on the basic safety of biotech foods, questions continue to be raised about potential long-term effects caused by regular consumption. Such potential problems can be assessed by feeding trials. However, it is one thing to test individual compounds (pharmaceuticals, for example) in this way, but how do we properly assess the safety of whole foods?

The safety of pharmaceuticals and other highly bioactive compounds is assessed by means of animal studies, using far higher quantities than would be eaten in practice, to establish a clear level having a harmful effect. Classically, a safety level is then set at 100-fold lower intake (on a body-weight basis) than the maximum level for which no effect was observed. However, in the case of whole foods, which are complex mixtures of tens of thousands of compounds, it is usually impossible to feed high enough quantities to measure any effect.

3 For more details, see the joint FAO/WHO Expert Consultation report; 2001

In principle, a test diet containing artificially high levels of a novel protein could be devised, if this can be achieved without compromising the overall balance. Nevertheless, testing isolated components is not necessarily the same as eating the same component as part of a whole food, and care has to be taken to construct a meaningful experiment. Animals must be fed a palatable and nutritious diet, containing all necessary micronutrients. To assess the effect of a particular food component fairly, all other dietary components must be the same.

The difficulties associated with such experiments are covered in detail in the FAO/WHO Expert Consultation report (2000). The Pusztai affair – covered in more detail below – is a perfect illustration of the way that a poorly-designed experiment can lead to incorrect conclusions.

In any case, there is a clear scientific consensus that it is simply unnecessary to do such tests in the large majority of cases. Where it is necessary, an example of how this problem can be approached in a meaningful way was reported by a Dutch group (see Noteborn et al, 1995). They wanted to test the safety of tomatoes modified to produce a protein which controls certain insect pests (Bt tomatoes). First, they did a detailed analysis of all key nutrient and natural toxins and contaminants. Then, they freeze-dried conventional and modified tomatoes and fed rats over a 90-day period with a standard diet containing 10% of the tomato powder. This was the equivalent of an average person eating 13 kilos of fresh tomatoes every day! At the end of the test period, no adverse effects were found for either the trial or control group. If – in exceptional cases – the regulatory authorities deemed it necessary, it could be possible to take a similar approach for other foodstuffs.

For the major biotech crops now in commercial production (soya, maize and oilseed rape) there have been numerous feeding trials using more conventionally-formulated diets reported on both laboratory and farm animals. Since the primary use of these crops is to feed animals, the authorities required clear evidence of their safety before authorising their use, and further trials have also been done since. No adverse effects have ever been reported for approved biotech crops.

We should note again that testing requirements are determined by the regulatory authorities on a case-by-case basis, and that feeding trials are not necessary for all applications.

We should also remember that hundreds of millions of ordinary people in North America and other countries have been eating these products on a regular basis for several years. There have been no cases at all of harm: surely the best evidence we have that these products are safe.

The Pusztai affair

In 1998, Dr Arpad Pusztai, a respected researcher on plant lectins working at the Rowett Institute in Aberdeen, made statements on UK television about his concerns over the safety of GM foods. These were based on experiments in which rats were fed raw potatoes, some of which were genetically modified. This was seized on by anti-GM campaigners as evidence that their concerns were scientifically justified. In the meantime, Pusztai's results were reviewed, and he was dismissed from the Institute. In the ensuing furore, he became the hero of the activists, who perceived him as a victimised whistle-blower on the scientific establishment.

However, when expert independent scientists reviewed his evidence (made public on the Internet) they overwhelming came to the view that wrong conclusions had been drawn from flawed experiments. For example, the animals were fed a diet based on raw potato, which they cannot digest properly, and the modified potato had a lower protein content than the control. As importantly, despite the tremendous publicity, no-one in succeeding years has been able to perform any experiments in which animals suffered any adverse effect when fed GM food tested and approved under existing legislation.

The Royal Society, the UK's most senior and prestigious scientific organisation, set up a team to evaluate Pusztai's evidence and claims, and in its report stated:

"We found no convincing evidence of adverse effects from GM potatoes. Where the data seemed to show slight differences between rats fed predominantly on GM and on non-GM potatoes, the differences were uninterpretable because of the technical limitations of the experiments and the incorrect use of statistical tests."

The Lancet, the UK medical journal, eventually published a paper written by Dr Pusztai and his co-worker, Professor Stanley Ewen. This paper was defended by the editor of the Lancet as a way of putting the evidence into the mainstream of scientific debate. However, once again it was criticised by leading scientists. Sir Aaron Klug, then President of the Royal Society said:

"The Royal Society would not have published this paper by Professor Stanley Ewen and Dr Arpad Pusztai since it confirms the Society's original judgement that the experiments on which this paper is based were flawed."

Although this work will doubtless continue to be brought out as evidence of safety problems, the overwhelming scientific consensus is that there is no evidence to indicate any problems.

Can genetic material be transferred to animals and people?

Foods produced through modern biotechnology will not only have some (usually very minor) modification to the protein they contain, but will also have, by definition, some small change to their genetic makeup. We therefore also have to consider possible safety aspects of this.

DNA (deoxyribonucleic acid) is the molecule which genes are made from. Whatever the gene or source, DNA is essentially the same: a long sugar chain, with four different bases attached in varying positions and proportions. The different patterns formed by these four bases are sometimes referred to as the "letters" of the genetic "alphabet". Combinations of these "letters" form individual genes which provide cells with instructions to make particular proteins.

Because of the common structure of DNA in all life-forms, it becomes very difficult to say what is a "foreign" gene in a particular crop. A specific gene associated with a useful trait may first be identified in a certain organism: an unrelated plant, for example. However, the genetic material which is incorporated in a modified crop plant is not used directly from that source. The particular DNA sequence is first copied thousands of times by incorporating it in a harmless bacterium. The copies of the gene are then isolated and inserted into cells of the target crop to enable it to express the same trait.

Similarly, because all living things have ultimately evolved from the same early primitive forms of life, it is not surprising to learn that our genetic makeup has much in common with distantly related animals, plants and even bacteria. Basic cellular processes which define life are very similar, although different life forms have specialised in different directions: for example, unlike animals, plants photosynthesise but don't need muscles.

So, ultimately, DNA is DNA. Whether "natural" or modified, the long chains are made up of exactly the same simple molecules. Animals (including humans) safely consume it every day. Our digestive systems treat it all the same: DNA is only biochemically active in cells. Once eaten, it is just another food component. In the words of the World Health Organisation: "The DNA from all living organisms is structurally similar. For this reason, the presence of transferred DNA in produce in itself poses no health impact to the consumers."

So, how much DNA is eaten, what happens to it in the digestive system, and what is the effect of modifying genes?

In the case of humans, a large proportion of our diet is cooked, and this process already denatures DNA. The only functional DNA we eat is in raw food: mainly fruits, vegetables and nuts. However, animals typically eat a diet of raw food, and therefore consume higher levels of native DNA.

By way of example, it has been estimated (see Beever and Kemp) that DNA represents about 0.02% of the dry matter of most crops, with every single cell containing about 10^{10}-10^{12} base pairs of DNA. A 600 kg dairy cow, fed on rations containing 60% GM maize, is estimated to

eat just over 600 mg of DNA a day (less than one gram). For a typical single gene insert (4000 base pairs), the total amount of "foreign" DNA in the diet would be only 0.0004% of the total: just 4 parts in 1 million.

Over 90% of DNA is fully digested by the range of enzymes in the guts of animals. Any fragments which cross the gut wall must be highly degraded, as large molecules cannot pass this barrier. It is a normal, though minor, constituent of the diet of all animals, and there is no evidence that the genomes of humans or other animals have ever incorporated functional DNA from food.

Don't forget that there is not only DNA in the food consumed by animals and Man. In the digestive systems of all animals, there is a vast range of bacteria, with their own particular genes. We are constantly exposed to this "foreign" DNA throughout our lifetimes, with no ill-effect or take-up of genetic material.

Antibiotic Resistance Marker genes

When plant cells have new genetic material introduced into them (are "transformed") only a proportion of them actually receive and incorporate the introduced gene into their existing DNA. There has to be a way of finding out which ones have the new gene and which ones don't, before they are grown on as plants. In some cases, this is relatively easy: only cells modified to tolerate a particular herbicide will grow in the presence of that compound, for instance. In other cases, the cells have to be distinguished using an additional "marker gene".

Genes commonly used in the development of the first generation of biotech crops included those which give resistance to particular antibiotics. Plant cells which had been subjected to treatment to introduce a new gene were then grown on media containing the antibiotic. The transformed cells, containing the antibiotic resistance marker gene (or AR marker gene) were able to grow, and non-transformed cells were not. So, the plantlets taken forward to grow on were known to have the desired additional gene.

From this point on, the AR marker gene serves no useful purpose, but remains part of the plant's genome. The question is then whether there are any possible negative effects from the presence of the gene or its products. In some instances, there have been concerns that the resistance might be transferred to gut bacteria which, in the presence of the antibiotic in question, could survive selectively. They in turn could theoretically pass this resistance gene on to disease-causing bacteria, with possible health consequences.

In the rare cases that the AR gene is transferred to bacteria, this theoretical possibility only exists if the gene is still able to produce the protein conferring the particular antibiotic resistance and is under the control of a bacterial promoter (ie, is able to function in bacteria). This is not the case for all applications of AR marker genes.

In practice, a large percentage of harmful bacteria in the environment are already resistant to one or more antibiotics. There are several reasons for this, not least over-liberal prescribing, patients failing to complete the course of treatment, and low-level use of antibiotics in animal feed. This has led to the preferential selection of resistant bacteria, making some infections very difficult to treat effectively.

The theoretical risk associated with AR marker genes is very small indeed. They are, in the first case, chosen to confer resistance to antibiotics which are not commonly used in human or veterinary medicine. Then, the functional resistance gene must be transferred to bacteria in the gut of an animal (a rather unlikely event), and this gene must again be transferred in a fully working state to a bacterium harmful to humans. The potential additional hazard created by this is tiny compared to the present situation, but the EU authorities have taken the extremely precautionary position in the new legislation (Directive 2001/18) to phase out over the next few years the use of those AR marker genes which may represent a risk (however small) to human health or the environment.

For an interesting insight into how one particular advisory committee approached this issue in a real case, see Professor Derek Burke's chapter in "GM Foods: understanding the issues".

Are there intrinsic problems with modern biotechnology?

Despite the enormous volume of work on safety assessment, there are still those who suggest

that the very processes of modern biotechnology are in some way dangerous. One or two authors (see, for example, Mae-Wan Ho) have put forward theoretical concerns, in particular:

- So-called "promoter" sequences of DNA, incorporated with genes to make them function properly, are often derived from plant viruses. It has been suggested that this can result in uncontrolled transfer of new genetic material into other plants, bacteria and animals. In fact, plants are very commonly infected with such viruses, which have evolved to enter cells in order to reproduce themselves. The additional transgenic sequences are identical to material which plants, animals and bacteria are exposed to in much higher levels on a continual basis. The "35S" promoter (derived from Cauliflower Mosaic Virus), the main object of the criticism, in any case does not function in bacteria.
- The process is also said to cause "genome instability", with sections of DNA rearranging themselves in an uncontrolled fashion. Actually, the genome is not fixed and inflexible, but is subject to constant change in its natural state. The position of a particular gene in the genome can alter the way in which it works, but individual transformation "events" are thoroughly characterised and checked for insert stability.
- The genome has a holistic nature, and incorporating additional single genes will not have the claimed deterministic effect, but in some way disrupt the whole organism. This is clearly more of a philosophical than a scientific view.

None of these criticisms has ever been considered credible by biological scientists, and no experimental evidence has ever been put forward in support of the arguments. Of course, this doesn't mean we should be dismissive of legitimate concerns, but criticisms such as these do not have a scientific basis.

The role of the EU

The EU is a major sponsor of research, and this applies as much to biotechnology as other areas. In 2001, the European Commission published a report summarising the range of EU funded projects being undertaken on safety issues in the biotechnology area. This covers 81 projects, carried out over fifteen years (including those still in progress), involving over 400 research teams and costing some €70 million. As stated by Philippe Busquin, EU Research Commissioner, in his introduction:

> "The results of the research and growing practical experience, feeding into regulatory and risk management policies, have enabled these to be regularly adapted to facilitate safe innovation, thus contributing to the excellent safety record to date, and providing a basis for continuing public confidence in the technology and its products."

The projects cover many safety-related issues, from detection methods to microbes used for cleaning contaminated ground. In the specific case of food, nine major collaborative projects are listed. These cover such issues as improved standardised evaluation frameworks, possible gene transfer from foods to gut bacteria, and approaches to look at the unintended effects of gene insertion. Perhaps most importantly, there is a major project bringing together a wide range of safety assessment experts in a network designed to exchange information, discuss new issues of possible concern, and continually improve and share safety assessment protocols.

Reports such as this give the lie to criticisms that too little is known about safety issues. To quote from Professor Sir John Berringer's foreword:

> "One of the 'best kept secrets' during the last few years of acrimonious discussion about GMOs has been the enormous body of research being conducted in Europe and elsewhere that is directly relevant to risk assessments."

Of course, the fact that there is no evidence of any safety problems associated with food produced by agricultural biotechnology does not mean that we conclude all applications are safe and that no further safety assessment work need be done. For every new application under the Deliberate Release directive or Novel Foods regulation, the independent experts giving their opinion will raise specific issues and require evidence from well-designed, reproducible experiments to confirm that no problems exist. The particular data required is determined on a case-by-case basis. The

continuing EU-funded research projects will improve still further the methods for collecting this evidence.

The scientific consensus

To date, there have been no serious doubts raised about the safety of biotech crops for animals or people. Theoretical concerns have been expressed, but after careful study have never been given credence by expert scientists.

Numerous statements have been made by august scientific bodies in support of the technology: the EU Scientific Advisory Committees on Plants and Foods, the Royal Society, the US National Academy of Sciences and many others. Despite this, in today's society it is relatively easy to get concerns raised in the media, and the average person takes more heed of these than of the body of scientific information.

Public perceptions: now and in the future

There are numerous reasons which contribute to the perceived public unease about biotech foods, some of which have already been covered above. The fact is that a significant proportion of the European population are suspicious of the use of modern biotechnology in their food[4]. These suspicions often surface as concerns about safety.

And yet, the answer is not just to "educate" people about the facts. A full understanding of science and technology is to be encouraged, but we know that only a small proportion of the public will be sufficiently interested to get such knowledge. For the majority, it's a question of being reassured by those they trust. To put it simply, when the majority of people put more faith in government agencies than in environmentalists, the climate of opinion will be much more positive.

But government has to earn this trust, and building it is a slow process. The current approach at EU level is to tighten even further existing regulations in an attempt to address all the criticisms and concerns raised by the green lobby. Well thought-out, science-based legislation which inspires public confidence is clearly a good thing, but the present EU situation has the makings of a downward spiral. As new regulations are passed, further concerns are raised which are the subject of yet more proposed legislation. The reality is that those implacably opposed to crop biotechnology for political reasons will never be satisfied, and the result could be highly stringent regulations which stifle innovation without ever fully satisfying the critics.

Biotech foods: the most thoroughly studied foods ever

Foods derived from biotech crops have been studied more intensively and in more depth than anything else we consume. None have been released on the market without meeting all safety criteria devised by the relevant authorities. There have been no incidences of food safety problems attributable in any way to GM foods. This despite the fact that hundreds of millions of people, in North America in particular, have consumed these foods routinely over the past six years as part of their normal diet.

We should also remember that enzymes (particularly chymosin for cheese-making and amylases for use in the starch industry) produced from GM micro-organisms have been used for many years in an entirely safe and uncontroversial way.

In Europe (as well as America) the majority of farm animals regularly eat feed containing biotech soya. There have been no incidences of health problems for these animals. The products derived from them – meat, eggs, milk – are indistinguishable from those produced from non-GM fed animals.

To quote once more from the European Commission report: "The use of more precise technology and the greater regulatory scrutiny probably makes them even safer than conventional plants and foods."

4 See the second paper in this series (Public Attitudes) for more information

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Who we are

The companies involved with the development of agricultural biotechnology believe strongly that biotechnology has the potential to enrich our lives in many ways. We recognise, however, that the introduction of genetically modified crops and foods has raised concerns in many European countries. Our industry has an ongoing commitment to scientific research and testing, and to ensuring that products are developed and commercialised in a responsible and safe manner. We also recognise that the success of any new technology in Europe needs to be based on respect for people's viewpoints. The biotechnology industry believes that consumers should be as informed as possible. The agricultural biotechnology industry is therefore working with various organisations across Europe to improve transparency and to foster a useful dialogue on agricultural biotechnology. Our efforts focus on broad and serious communication to a range of audiences – media, NGOs, policy-makers, retailers and others – with the aim of listening to and respectfully addressing the concerns of European citizens as well as making information available about our industry and this technology.

The following companies are participating in this effort:

BASF
Bayer CropScience
Dow Agrosciences
DuPont
Monsanto
Syngenta

Our aim is to increase the dissemination of information and contribute to an informed debate about crop biotechnology. If you are interested in receiving more information about agricultural biotechnology, please contact; Peter Wynne Davies at:

info@ABEurope.info or consult the ABE website at www.ABEurope.info

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