# Food and drink

**Alongside the environmental risks of using genetically modified crops are the public health concerns. These may be easier to assess but are of no lesser importance.**

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Thus far, this debate has focused on the environmental impact of genetically modified crop plants. As my own involvement in gene technology relates more to the safety of its applications in food, I would like to broaden the discussion to include this aspect.

Recently, there has been much debate about the risks associated with genetically manipulated foods. The issues are confused and to a significant extent coloured by a lack of confidence in the regulatory process. A lack of confidence fuelled, at least in Europe, by unrelated food safety concerns such as the bovine spongiform encephalopathy (BSE) and food-borne bacterial pathogen outbreaks.

It is generally accepted that the introduction of new technologies, foodstuffs, and medicines involves some associated risk. Whilst this is minimized by safety evaluation and regulation, we do not expect to eliminate risk completely before moving forward. In this regard, gene technology is no different.

For novel foods, regulatory committees use objective approaches to assess perceived hazards, and come to a conclusion about their safety and acceptability. However, with gene technology, such traditional toxicological approaches based on whole foods are of limited value. In contrast to defined chemicals, whole foods are bulky, complex, chemical mixtures, only limited quantities of which can be fed to animals in trials. Acute effects would are therefore difficult to produce.

Instead, the 'substantial equivalence' approach was developed following an initial Food and Agriculture Organization/World Health Organization (FAO/WHO) consultation exercise,[1] which was further refined by the Organisation for Economic Co-operation and Development (OECD)[2] and WHO/FAO[3].

This approach uses an existing food, with a history of use and an accepted level of safety, as a baseline against which a genetically modified derivative can be compared. Safety is established by demonstrating that there is no significant difference between the two foods over a range of characteristics including both phenotype and composition.

When a new characteristic is the intended product of the genetic manipulation, the safety evaluation can be focused on this particular characteristic. A recent controversy over experimental genetically modified potatoes expressing lectin genes provides a useful illustration of the approach.

Animal feeding experiments established that there was a safety concern over the lectin. On its own, this would be sufficient to prevent the approval of a genetically modified plant producing the same substance without similar experiments being carried out on the plant itself. It is far more effective to use a toxicological approach focused on a new constituent than to rely on the genetically modified plant material itself. Conclusions about the lectin have no bearing on the safety of gene technology *per se*; they simply served to identify the risks associated with one particular novel trait in food.

One of the more difficult aspects of the substantial equivalence approach relates to unintended or secondary effects of genetic modification. The extent

of scientific data required to establish whether or not a secondary effect might create a significant safety hazard is necessarily subjective.

For any established crop plant, toxicological or nutritional concerns relating to natural toxicants will be well known. In conventional plant breeding this is an established safety issue, while in a genetically modified plant, analysis of the levels of any such substances provides reassurances that gene introduction has not created an unexpected change.

Certainly there are examples of conventional plant breeding creating cultivars with unsafe levels of natural toxicants, but there is no reason to suppose that gene technology is any more likely to cause this type of hazard.

Nothing is risk free, but where there is every reason to suppose that products of gene technology are as safe as a natural counterpart, their acceptance seems appropriate. However, it would help to have better numerical expressions of risk so that gene technology issues can be compared to the risks we readily accept in our everyday life. Issues carrying small risks can be difficult to deal with, even for scientifically based regulatory committees.

One controversial issue relates to the presence of genes for ampicillin resistance in some genetically modified plants. Here, the DNA is not actively expressed by the plant, but, rather, is carried over from an early stage of DNA manipulation prior to its introduction into the plant. It is quite possible to remove these sequences before a genetically modified plant is constructed, but for some genetically modified maize lines this has not been done.

Antibiotic resistance is of general concern. The possibility that DNA consisting of an ampicillin resistance gene might find its way from a genetically modified plant to pathogenic bacteria has been extensively debated. There is general agreement that such an event is unlikely, as there is no known mechanism for gene transfer of this type to occur. Also, the consequences are considered of little significance because similar genes are widespread in natural bacterial populations.

Nonetheless, this small risk is readily avoided by preventing the introduction of unnecessary genes during genetically modified plant construction. In my view, this is also an issue of establishing good practise. An argument of convenience is being made to encourage acceptance of these early gene technology products, and the risk is indeed minor, or irrelevant, in the case of processed food products.

For plants destined for consumption by man or farm animals in a fresh state, however, there is no doubt in my mind that a genetically modified plant lacking a bacterial antibiotic resistance plasmid is preferable to an analogous version carrying this DNA. Since the latter is achievable, I question the need to use the former in a fresh state for food.

It certainly seems that safety evaluation is more difficult for environmental concerns than for food safety. The issues are less well supported with scientific data, as is borne out in last week's contribution from Rosie Hails and colleagues. It is clear that once released, the environmental impact of a genetically modified plant introduction may prove difficult to control. It would be surprising for example if the insects subjected to botulinum toxin did not respond to the selective pressure imposed and eventually evolve insensitivity.

However, the control of weeds and pests in agriculture is not a new issue, and the most likely negative environmental consequence of gene technology is to reduce its effectiveness rather than cause some unspecified disaster. Consequently, agricultural systems will doubtless need to be developed hand-in-hand with gene technology in order to ensure its long-term effectiveness.

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**References**

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2. OECD Safety evaluation of foods produced by modern biotechnology - concepts and principles. (OECD, Paris, 1993).

3. FAO/WHO Biotechnology and food safety. (FAO, Rome, 1996).

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