# FINDING A PATH TO MARKET FOR GENETICALLY MANIPULATED ORGANISMS

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## SUMMARY

The current status of regulation for products derived from genetically modified organisms (GMO) in Australia is discussed, and its further development in the light of issues such as the ethical debate, biosafety and public education is touched upon.

**Keywords**: Genetically modified organisms, government regulation

## INTRODUCTION

It is finally happening – "The Biotechnology Revolution" is upon us and it has a status that many equate to the previous great leaps in scientific and social development, such as the industrial revolution. The cloning of Dolly was a watershed in terms of raising public awareness of the type of biotechnology research that has been going on for the last 30 years. The Genetic Manipulation Advisory Committee (GMAC), and predecessors, have operated in Australia since the mid-1970s, with the brief, to ensure biosafety of GMO experimentation through self-regulation of research. Now the revolution is real, with products entering the market place. We have Bt cotton growing in our paddocks, GM vines to produce our wine, and many foods containing GM soy, not to mention medicines that are the result of foreign DNA "piggy backing" in GM bacteria, all technologies that offer more efficient production or better health. To the community at large, the impact has so far been minimal. Plants lead the way but, as we become able to "modify" animal genomes, public concern will increase (Baghurst *et al.* 1995). This revolution is one in which the general public will participate in an unprecedented manner, because it is about what we eat, how we fight disease and how we choose to reproduce. From the outset, the debate has been polarised; ranging, from unrealistic promises of dramatic increases in productivity of crops and livestock to paranoia about the dangers of the new technology and concepts such as "genetic pollution" (Rifkin 1998).

Why should this issue be of interest to us as scientists and producers? There are two reasons. First, our research activities, and the commercial products they yield, will, in the interests of community safety and confidence, be regulated. Second, our scientific endeavors will be challenged by public debate in a manner we have not seen before.

## THE CASE FOR GMO REGULATION

What do we currently have to do to be able to conduct experiments with GMOs? The major criterion is meeting the requirements of GMAC, whose role is to assess biosafety risks and make recommendations as to whether an experiment should be undertaken or not. GMAC is not a regulatory body; it works in an advisory capacity only and has no statutory powers. GMAC does not assess what many might call the "ethical" considerations of GMOs. For instance, GMAC will ensure that GM sheep are kept secure, with double fencing to prevent uncontrolled matings, but GMAC will not advise on the ethics of transplanting a human gene into another species.

As animal breeders, where do we go from here if we want to participate in the biotechnology revolution? There have been some eloquent examples of what is lacking in terms of being able to market GMOs. Australians were amongst the first in the world to produce transgenic livestock. In the mid 1980s, a research team at Adelaide University inserted a second copy of the porcine growth hormone gene into pigs using a human promoter sequence. This product was marketed by Metrotec (a university-industry joint venture) in the absence of a regulatory framework to approve its sale, with disastrous results (Hindmarsh 1998). Metrotec wanted the government to approve the product as safe for human consumption, but with no regulatory framework, sale of GM pork came to a swift end. The resultant public uproar over "mutant meat" made research and product development commercially very unattractive. Good science, perhaps, but no "path to market" for the little piggies, with the result that their gonads ended up in liquid nitrogen and their bodies in a large pit. This led to a prevailing sense, in the research community and industry, that GM pigs were politically too difficult to work on. There are nervous investors who have seen the pig debacle and want some assurances before they put their dollars into research related to gene technology for meat production.

In contrast, in the US, the first serious GMO ready for eating was a tomato. A tremendous amount of work had been done by the company and the Food and Drug Administration to address the issues of how to market this product (Jim Maryanski, Biotechnology Coordinator FDA, pers. comm.). At the same time, a system was put in place to cope with future products. So far, applications for approval to market food products have all been for GM plants and microorganisms. The emotive animal debate is yet to start, but at least in the US there is a system in place to regulate the sale of GM animal products.

Why do we need to regulate GM products? The reasons are well covered in a draft paper for stakeholder consultation by the Department of Industry, Science and Resources, the Commonwealth department responsible for GMO regulation (Draft Regulation of Gene Technology, DISR 1998). A revised regulatory system for gene technology is now needed urgently for the following reasons:

- To provide researchers, industry and investors with a clear regulatory path to market.
- To protect humans and the environment from potential risks posed by GMOs and GMO products, including accidental releases.
- To engender public confidence in gene technology, by ensuring that development and application will be accompanied by appropriate risk assessment and controls.

## THE REGULATORY FRAMEWORK PROPOSED FOR AUSTRALIA

How will a regulatory framework grow to meet these goals? No doubt you have always wondered how primary school Australian history was going to influence your career as a scientist. Well, here is a very real and current example. The building of an effective regulatory framework will depend on nine independent sets of legislation being passed by nine different governments. This is a legacy of our history; as a federation of states, any nationally agreed framework (which regulation of GMOs needs to be) is actually an agreement of all states and territories including, if appropriate, the federal government. Witness the torturous negotiations, in 1997, for uniform national gun control laws in Australia. Hopefully, national regulation of GMOs will have a smoother path, but it still requires an enormous amount of consultation and negotiation. On top of this, we have the task of ensuring that

our regulatory measures and standards are compatible with relevant international standards to protect our world competitiveness and trade opportunities.

The proposal under discussion by governments is that regulation of GMOs be built on existing legislation for the control of food, therapeutic goods, agricultural and veterinary chemicals, and industrial chemicals. Those GM products that do not fall within the mandate of these systems will be overseen by a proposed new entity, called for the moment, the Gene Technology Office (GTO). The role of the GTO will be to coordinate gene technology product regulation in Australia in concert with existing schemes, to provide regulation for GM products not covered by existing schemes and to provide statutory control of research on GMOs, the role currently undertaken by GMAC.

For research, the main change will be the introduction of statutory control for experiments on GMOs, in contrast to the current GMAC system based on voluntary self-regulation. Hence, GMAC will be replaced by the Gene Technology Advisory Committee, whose role will be to provide expert scientific and technical advice early in the regulatory process, identify potential and unacceptable risks and recommend conditions for final approval. Closer to home for scientists, this will result in the strengthening of the present role of Institutional Biosafety Committees (IBC). The legislative backing behind the GTO means that IBCs will have legal responsibilities to notify activities, to comply with standards and to respond to directions from the GTO. This proposed change is designed to provide public assurance that research is being appropriately monitored and controlled.

The proposed GTO will be the "virtual shop front" for regulating all GM products, and it will coordinate the progress of applications through the appropriate regulatory bodies. This may involve one or more agencies. For example, plants with herbicide resistance genes that are also eaten would fall under the jurisdiction of both the National Registration Authority and the Australia New Zealand Food Authority. Where products fit the responsibility of an existing regulatory body, that agency will give final approval for product distribution. Built into the approval process will be a post-release compliance strategy for products where there are appreciable risks to be managed.

## PUBLIC ACCEPTANCE OF GMOS

Humans have evolved with the various plants and animals that have provided a source of sustenance. Part of that evolution has been a "learning" of which plants and animals are safe to eat. For many in industrial societies, this type of education is now far removed from life and reliance is placed on regulatory systems to ensure food safety. If we swap genes between species we normally eat and those we don't, we are going to have to "relearn" what is safe. In the UK in particular, and there is every sign that this argument will spread to other nations, this issue is raised by those who oppose the introduction of GM foods. In some cases the fears, although genuine, have no scientific basis, because many of the changes - the FlavrSavr tomato, for example - are minor with predictable and innocuous effects. However, there is an increasing trend to introduce gene constructs whose primary function is to affect some agronomic characteristic that has nothing to do with the quality of the food product. Insect and herbicide resistance are the most notable. The argument that these products should be marketed without extensive testing is not sustainable, and any such suggestion is likely to attract adverse reaction. The complexity of public concerns must be acknowledged (Frewer *et al.* 1997; Baghurst *et al* 1995), and these concerns have escalated with recent controversy over

experiments with transgenic potatoes at the Rowett Institute, UK; one week claims in the media that the potatoes were dangerous, next a discrediting of this by scientists, and now fresh allegations of harmful effects (UK Daily Mail 31 January, 1999).

The adverse public reaction in the US to the use of recombinant bovine somatotrophin (rBST), to boost milk production in dairy cows, demonstrates how biotechnology advances with animals can be highly emotive. A campaign, based on a fear that administering rBST to lactating cows would contaminate the "purity" of milk, was used to discourage public acceptance of this product. Now, the debate has a new dimension with the revelation that the use of rBST has animal welfare implications, possibly causing increased mastitis, reproductive disorders and lameness (DesCôteaux *et al.* 1998).

Currently, media from the UK give some graphic examples of why public confidence must be built in GM products if the benefits they offer are to be realised. In January 1999, ASDA (a large UK supermarket chain) was threatened by a pressure group (MAGE Press Release 19 January, 1999) who announced that they would enter the local ASDA superstore to remove GM baked beans that contained Bt maize. The plan was to take the controversial beans to the Food Department of the City Council and demand that they be disposed of as hazardous waste. ASDA's response, the next day, was to announce that all their own brand products would be certified free of GM products and their suppliers had until the end of March to respond (MAGE Press Release 20 January, 1999).

The incident with ASDA beans has not occurred in isolation. GM trial crops have been burned and there have been accusations of "BSE type" cover-ups in the UK. For the Australian public to accept GM products they need some understanding of the technology and to have confidence in the safety of what they are being asked to consume, both from a human health and environmental safety point of view. Various proposals, such as consensus conferences, ethics committees and food labelling, are being considered to build public confidence. But the difficulty of the task should not be under-estimated and nor should genuine public concern be dismissed arrogantly by scientists.

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