BIOTECHNOLOGY POLICY

2014

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INTRODUCTION

What is SAFEMEAT?

SAFEMEAT is a partnership between the red meat and livestock industry and the state and federal governments of Australia.

The partnership ensures that Australian red meat and livestock products achieve the highest standard of safety and hygiene from the farm to the consumer. SAFEMEAT initiates research and development, develops communication linkages, monitors the status of Australia's products, reviews standard and examines emerging issues that could have an impact on the industry in the future.

Australia's red meat industry

Australia is among the world's largest and most successful and efficient producers of commercial livestock and a leader in the export of red meat and livestock. According to MLA (2013), the total value of Australia's off-farm beef and sheep meat industry is A$16.2 billion.

Australia is a world leader in the export of commercial livestock. The live trade is a significant contributor to the Australian rural economy and has provided an important market for Australian cattle, sheep and goat producers for more than 30 years.

The national sheep flock, now at around 68.1 million head, is down on the historical highs of 1960 when it reached 170 million. This reflects a more competitive international fibre market, land use changes in the agricultural sector and, more recently, drought.

Similarly, the beef cattle herd size is down to 28.5 million head from the 1970's high of 30 million (source: ABS - *Agricultural Commodities,* 2011). Dairy cattle contribute an additional 2.6 million head to the cattle herd, and the national goat flock stands at three million.

On the domestic front, Australians consume an average of 46.5kg of red meat each year. This is made up of 33.7 kilograms of beef, 10.8 kilograms of lamb and two kilograms of mutton.

To maintain and grow this competitive position in the market, the Australian red meat industry is investing in research and development programs which utilise innovative technology. Biotechnology is one of these important investments.

BIOTECHNOLOGY - THE SCIENCE

Just as consumers have enjoyed technological advances in areas like telecommunications and transport, plant and animals scientists have been using new tools and techniques to develop better outputs. Plant and animal science, like medical science, utilises a whole suite of technologies including molecular biology and genomics.

CSIRO defines biotechnology as "the use of biological systems — living things — to make or change products". Biotechnology has been used for centuries in traditional activities like baking bread, making cheese and brewing beer. Traditional animal and plant breeding techniques, which involves 'crossing' individual animals or plants with desirable characteristics and selecting those from the new generation with the desired characteristics for further breeding, are also early techniques of biotechnology. These processes saw wild plants and animals become domesticated and shaped into the species that exist in agriculture today.

Animal biotechnology today is focused on four key areas:

- Advancing human health - Animals have been used for years to produce medicines for humans. Animals have been used as production centres to produce therapeutic proteins in their milk, eggs and blood which can be used in the development of pharmaceuticals.

- Improving animal health and welfare - Biotechnology can enhance breeding, resulting in healthier herds. Additionally, the animal health industry has developed treatments that can prevent and treat disease. New vaccines, diagnostic tests and practices can help farmers treat animal diseases, while reducing food borne pathogens at the farm level.

- Enhancing animal products - Improved animal health conditions from vaccines, medicines and diagnostic tests result in safer foods for consumers. In addition, food quality may be improved through the introduction of desirable traits from new genes. In the future, meat, milk and egg products from animals could be nutritionally enriched utilising biotechnology.

- Reducing environmental impact - Biotechnology can help produce environmentally friendly animals, as well as conserve endangered species. Farm animals and their feeds have been improved through biotechnology to reduce animal wastes, minimizing the impact on the environment. Today's reproductive and cloning techniques offer the possibility of preserving the genetics of endangered species. Genetic studies of endangered animals can also result in increased genetic diversity which can result in healthier populations of species.

An increasing understanding of how living things function, grow and reproduce allows modern biotechnology to be utilised to create new opportunities for food and fibre production.

Modern biotechnology includes the discovery of genes (genomics), understanding how genes function and interact (functional genomics), the discovery of natural DNA markers which can be used in conventional breeding to select for more efficient plants and animals, and as the starting information leading to genetic modification. (For more detailed definitions see Attachment 1).

Biotechnology

Biotechnology provides new tools for improving animal health and welfare and increasing livestock productivity. Biotechnology can reduce an animal's impact on the environment and enhance the ability to detect, treat and prevent disease. Livestock cloning has the potential to improve breeding programs through the selection of healthier or better quality offspring.

While the focus of this review is the red meat industry, animal biotechnology extends to all animals including livestock, poultry, fish, insects, companion animals and laboratory animals. Currently, three key scientific areas of animal biotechnology have emerged:

- Animal genomics - the defining and characterisation of the complete genetic make-up of an animal. Understanding animal genomes provides a basis for disease resistance, disease susceptibility, weight gain, and determinants of nutritional value.

- Animal cloning - cloning does not manipulate the animal's genetic make-up or change its DNA. Cloning creates an exact genetic copy of an existing animal, essentially an identical twin, using somatic cell nuclear transfer.

- Genetically modified (GM) animals - the creation of an animal which has had genetic material from the same or from another species added to its DNA, with the aim of improving the original animal.

Meat and Livestock Australia invests in biotechnology research, as follows:

	Research and Development spend	**Project aims**
Beef genetics	$3.5 million per annum	• Genomic enhanced breeding cattle. • Development of phenotypic benchmarking of EBVs. • Design and analysis of Beef Information Nucleus (BIN) schemes. • Enhancements to breeding objectives for multiple trait selection. • Genotyping of industry bulls, research station female and key sires with the latest dense SNP chips breeding cattle.
Sheep genomics	$2.5 million per annum	• Genomic enhanced breeding. • Tools for current breeding program analysis. • Development of ASBVs for new traits which improve the specification of breeding objectives.
Plant genomics	$750,000 per annum	• Marker assisted breeding for key plant species.
Vaccine development	$2 million per annum (approximately)	• New generation OJD vaccine (to replace existing vaccines). • Bovine respiratory disease - development of a GM vaccine. • Salmonella - Development of a salmonellosis vaccine for registration in Australia to prevent disease in commercial livestock production, particular for sheep in live export.
Animal cloning	N/A	• Cloning is used as a research and development tool only. It has the potential in the future to distribute elite genetics however prior to proceeding with such research industry consultation would be required.

Meat and Livestock Australia currently has no investment in the development of GM animals.

Gene technology
Gene technology has been around for over twenty years and underpins a number of fields of biological research. It allows researchers to understand the functions of different genes and to modify these functions to improve the end product. For example, in plants, research has focussed on modifying the genes of a plant to help its root system access nutrients more efficiently, and to provide a plant with its own in-built system to protect against disease or insect attack.

In Australia, most agriculture commodities have an investment in gene technology research. Australian scientists currently have regulatory approvals to conduct field trials of genetically modified banana, barley, canola, cotton, lupin, pineapple, ryegrass, safflower, sugarcane, wheat and white clover. Some specific examples of this work are:

- Increasing the oleic acid profile in safflower.
- Increasing the grain composition and nutrient utilisation efficiency of wheat.
- Improving cotton varieties to deliver increased fibre.
- Enhancing the nutritional content of banana.
- Developing sugarcane varieties with tolerance to drought.

The most scientifically advanced GM crops undergoing field trials/assessment in Australia at present are as follows:

Research agency	OGTR licence number	Project details
Wheat/barley		
Vic DEPI	DIR 122 (2013)	Abiotic stress tolerance, yield
CSIRO	DIR 117 (2012)	Wheat - altered grain composition, enhanced nutrient utilisation efficiency Barley - enhanced nutrient utilisation efficiency
CSIRO	DIR 112 (2012)	Altered grain composition and nutrient utilisation efficiency
CSIRO	DIR 111 (2012)	Altered grain composition, nutrient utilisation efficiency, disease resistance or stress tolerance
Adelaide University	DIR 102 (2010)	Enhanced nutrient utilization & abiotic stress tolerance
CSIRO	DIR 99 (2010)	Growth & yield characteristics
CSIRO	DIR 94 (2009)	Enhanced nutrient efficiency
CSIRO	DIR 93 (2009)	Altered starch
CSIRO	DIR 92 (2009)	Altered grain
Vic DEPI	DIR 80 (2008)	Modified for drought tolerance
Adelaide University	DIR 77 (2008)	Enhanced tolerance to environmental stress or increased dietary fibre
Sugarcane		
SRA (BSES)	DIR 95 (2009)	Altered plant growth, enhanced drought tolerance, enhanced nitrogen use efficiency, altered sucrose accumulation, and improved cellulosic ethanol production from sugarcane biomass
University of Queensland	DIR 78 (2008)	Altered sugar production
University of Queensland	DIR 51 (2005)	Expressing sucrose isomerase
Pasture		
Vic DEPI	DIR 89 (2008)	White clover - AMV resistant
Vic DEPI	DIR 82 (2007)	Ryegrass and tall fescue - Improved forage qualities
Vic DEPI	DIR 47 (2003)	White clover - AMV resitant

Genetically Modified animals
No GM trials of production animals are currently approved in Australia. However, research focused on developing GM animals continues around the world, with the most advanced project - a GM salmon - currently seeking regulatory approval in the USA (For further information see 'In the Marketplace').

In New Zealand, researchers announced in 2012, that they had produced a GM cow which produced high protein hypo-allergenic milk. The researchers indicated that their approach to this research could have potential to be used to alter other livestock traits. The scientists used a technique known as RNA interference (see Attachment) to block the production of the protein beta-lactoglobulin (BLG) - a protein found in cows and other ruminants but not found in human milk which is known to cause allergies in humans.

Beyond this region, considerable work is also underway globally to develop GM livestock models to assist in human disease prevention. Some of this research includes:

- Inserting human antibody genes into cattle - research that could have a role in preventing infectious disease.
- Developing GM goats for studying cardiac arrhythmia - large animals have organ sizes similar to humans.
- Using pigs as 'models' to understand human disease - including cystic fibrosis, liver disease, heart disease, cardiac arrhythmia, cancer, neurodegenerative disease and muscular dystrophy.

Researchers note that this medically-focused research does have challenges in terms of cost and market acceptance, however, while the cost of the research is greater in animals, the cost of human clinical trials may be less due to a more robust research model being utilised.

Biotechnology

As products of biotechnology are wide-ranging and not subject to the same regulatory scrutiny as products of gene technology, it is difficult to track the utilisation of biotechnology in the marketplace. Evidence suggests that biotechnology is being used extensively around the world and new tools are constantly being identified and their potential explored.

Australia's key red meat markets span a large area of the globe and include:

- Japan
- Korea
- North America - Canada, Mexico, USA
- Europe - United Kingdom, Italy, Belgium, Luxembourg, Germany
- Middle East - United Arab Emirates, Bahrain, Libya
- North Africa
- South Asia - China, Hong Kong, Taiwan, Indonesia, Singapore, the Philippines, Malaysia, Vietnam and Thailand.

Some of these countries and regions have embraced gene technology, while others have adopted a more cautious approach, although caution predominately applies to the planting of GM crops, rather than the import of GM food and crops which may include GM animal feed. Interestingly, Australia's major market competitors, with the exception of New Zealand, have largely all embraced gene technology and specifically the planting of GM crops. These include South America, the USA and India.

GM crops

In 2013, 175.2 million hectares of GM crops were planted in 27 countries - 19 developing and eight industrial countries.

A record 18 million farmers grew GM crops in 2013. Over 90 per cent of these, or 16.5 million farmers, are in resource-poor countries – including 7.5 million farmers in China, 7.3 million in India and 400,000 in Philippines.

Soy, corn, cotton and canola are the most common GM crops, but varieties of sugarbeet, papaya and lucerne (alfalfa) are also grown around the world. More than 25 per cent of these crop were those with "stacked traits" - containing more than one new trait.

Five European Union countries (Spain, Portugal, Czechia, Slovakia and Romania) planted GM insect resistant corn and the first GM drought tolerant corn was planted in the US by 2000 farmers.

In the United States of America, a total of 165 GM crop 'events' in 19 plant species have been approved to 2013 although not all of these are grown commercially and no GM animals have yet been approved for food consumption.

GM crop events approved in the USA					
alfalfa	2	canola	20	chicory	3
corn	38	cotton	27	creeping bentgrass	1
flax	1	melon	2	papaya	3
plum	1	potato	28	rice	3
rose	2	soybean	19	squash	2
sugar beet	3	tobacco	1	tomato	8
wheat	1				

Australia has been growing GM cotton since 1996 and it now accounts for almost 100 per cent of cotton production, which generates fibre for clothing and textiles, oil for cooking and feed for livestock. Genetically modified cotton has seen the cotton industry reduce its insecticide use by over 85 per cent per year.

Australian farmers have also been growing GM canola since 2008 in some states and the uptake is steadily growing, with seed sales increasing by 22 per cent in 2013. Canola is grown for its oil and canola meal is used for animal feed.

Global GM crop growth 2013 - top 20 countries

No.	Country	Area (million hectares)	Crops
1	USA	70.1	Corn, soybean, cotton, canola, sugar beet, alfalfa (lucerne), papaya, squash
2	Brazil	40.3	Soybean, corn, cotton
3	Argentina	24.4	Soybean, corn, cotton
4	India	11.0	Cotton
5	Canada	10.8	Canola, corn, soybean, sugar beet
6	China	4.2	Cotton, papaya, poplar, tomato, sweet pepper
7	Paraguay	3.6	Soybean, corn, cotton
8	South Africa	2.9	Corn, soybean, cotton
9	Pakistan	2.8	Cotton
10	Uruguay	1.5	Soybean, corn
11	Bolivia	1.0	Soybean
12	Philippines	0.8	Corn
13	Australia	0.6	Cotton, canola (and carnations)
14	Burkino Faso	0.5	Cotton
15	Myanmar	0.3	Cotton
16	Spain	0.1	Corn
17	Mexico	0.1	Cotton, soybean
18	Columbia	0.1	Cotton, corn
19	Sudan	0.1	Cotton
20	Chile	<0.1	Corn, soybean, canola

Animal feed

Animals around the world have been fed GM crops – including soy, canola, cotton and corn – since 1996 when they were first introduced.

Livestock feeds such as GM corn and GM soy have been compared with conventional feeds to measure any changes in feed composition. The research shows that levels of nutrients – such as protein, carbohydrates, fat, energy, amino acids, fatty acids, minerals, vitamins and other components are substantially equivalent in GM and conventional feeds.

The Federation of Animal Science Societies – a professional organisation comprised of 10,000 scientists in academia, government and industry – has concluded that:

- "The safety of meat, milk and eggs is assured by the science-based risk assessment procedures used by government agencies and developers;
- The DNA introduced in GM plants and the proteins encoded by this DNA have not been detected in the meat, milk or eggs from animal fed this products; and
- Meat, milk and eggs from animals fed GM feeds are safe for human consumption".

Hundreds of peer reviewed feeding studies have been conducted with numerous animals - rodents, chickens, quail, pigs, sheep, dairy cows, beef cattle, goats, rabbits, buffalo and fish - measuring feed intake, nutrient digestion and health, with the vast majority, some of which have spanned multiple generations, showing no detrimental impacts from the consumption of the available GM crops. In addition, no differences in the composition of animal products including meat, milk and eggs, have been observed between animal fed conventional and those feed GM crops.

Genetically Modified animals

There are no GM animals commercialised anywhere in the world at present, however, much attention is focussed on the USA where an application to approve a GM salmon is currently before US regulator, the Food and Drug Administration (FDA).

The FDA's preliminary finding is that the approval of this salmon would not have a significant impact on the environment, however, the regulatory assessment/approval process appears to be taking an extended period of time. The salmon, referred to as "AquAdvantage Salmon" is designed to exhibit a rapid-growth phenotype which allows it to reach 'market size' (two to five kilograms) more rapidly that other farmed Atlantic salmon. It is unclear at this time as to when the FDA will make its final recommendation. If approved, this will be the first GM animal to be commercialised in the world.

REGULATION AND PATH-TO-MARKET

Regulation

In most regions of the world, gene technology research and development and products of gene technology are subject to specific regulation. In Australia, all gene technology research and end products (including products entering the food chain), must be approved by the relevant national regulatory authorities. These regulatory authorities ensure GM products are safe, prior to them being permitted.

In Australia, the main federal regulatory agency responsible for gene technology is the Office of the Gene Technology Regulator (OGTR). The role of this authority is to assess GM technology to ensure it is safe for human health and safe for the environment. The OGTR works with other relevant authorities including Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Therapeutic Goods Administration (TGA). For example the use of GM products in food for human consumption is regulated by FSANZ, the use of GM products as human therapeutics is regulated by the TGA and the use of GM products as veterinary therapeutics is regulated by the APVMA.

As indicated, GM food safety is the responsibility of FSANZ. Standard 1.5.2 of the Australia New Zealand Food Code requires that all GM foods or ingredients to be sold in Australia undergo a mandatory pre-market safety assessment to ensure they are safe for human consumption. In addition, since December 2001, Australia has had in place a mandatory labelling regime that requires all GM food sold in Australia to be labelled as such if novel DNA or protein is present in the final product.

Under Australia's national scheme, all states and territories recognise approvals made by the OGTR in respect of risk to human health and safety and the environment. However, during the development of the federal regulatory system, state governments expressed concern about the impacts the commercial release of a GM crop may have on local trade and export markets. As a result in 2003, a policy principle was issued 'for the purpose of recognising areas (if any) designated under a State law for the purpose of preserving the identity of GM crops, non-GM crops or both GM and non-GM crops for marketing purposes'.

This policy principle has resulted in several states enacting GM crop moratorium legislation consistent with the principle. To date, it has prevented the commercialisation of GM canola in a number of states. It also presents an unclear path-to-market for current projects in the research and development phase and some would also argue that it acts as a disincentive for attracting investment and developing commercial partnerships.

Path-to-market

While regulatory approval is key to taking a GM product to the market place, given the global focus on gene technology, considerable work is also required outside the regulatory area. Those developing GM products are also required to focus on market and trade aspects in order to ensure a predictable path-to-market. This work requires extensive communication and working in partnership with internal stakeholders, the broader supply chain, other research agencies and possibly global competitors. It also requires an extensive analysis and understanding of key overseas markets and customers within these to understand, key elements including:

- Regulatory frameworks - for cultivation, import and food.
- Government and industry standards.
- Customer views.
- Country (government and community) perceptions of GM products.

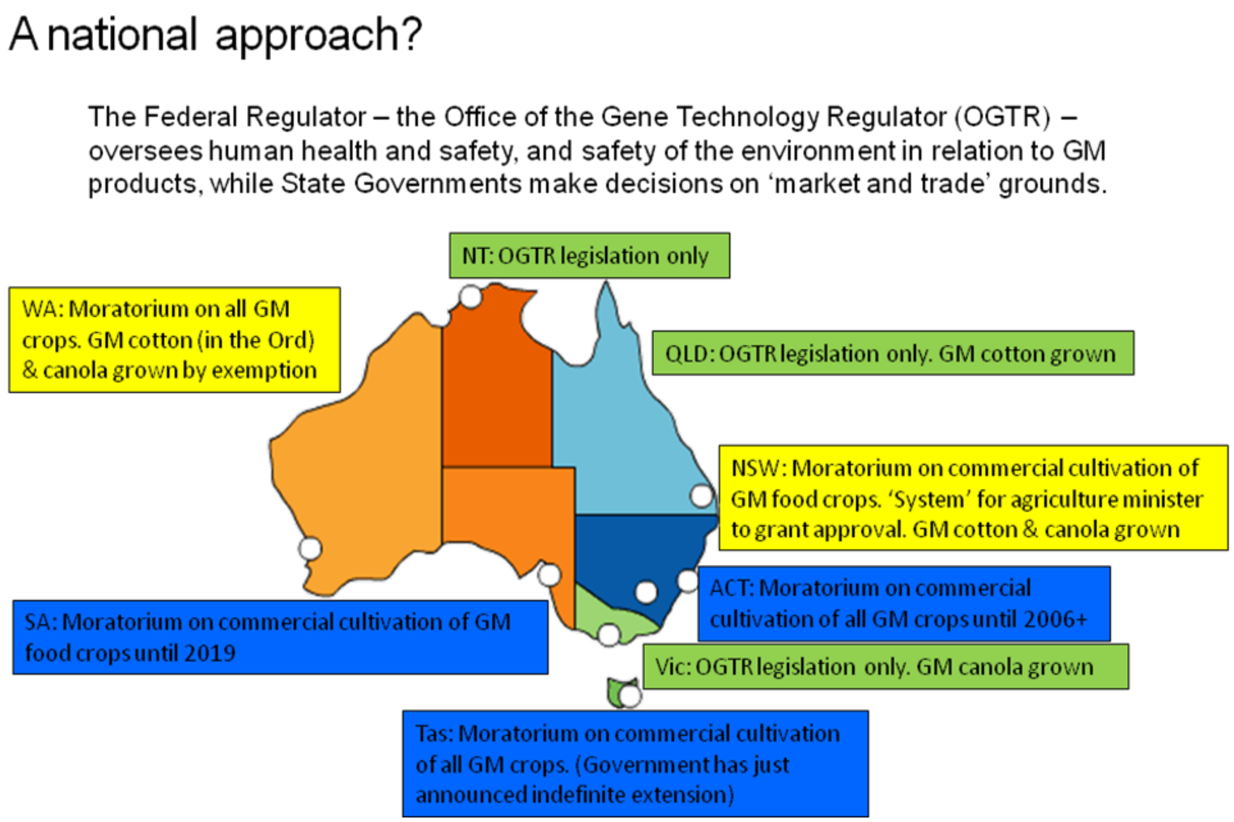
Coexistence
In recent years, considerable focus has been placed on the concept of coexistence - that is, the concurrent cultivation of conventional, organic, IP (identity preserved) and GM crops consistent with supply chain preferences. Despite the recent attention given to coexistence in the GM context, it is not unique to GM farming. In fact, it could be argued that all humans have examples of coexistence in their lives.

Agriculture operates in nature – wind blows, birds fly – this is the reality of the environment in which crops and food are produced. In agricultural communities, farmers producing different crops and animals via different production methods coexist with each other, through segregations and with tolerance thresholds for a range of things. Agriculture achieves coexistence through segregation and the establishment of thresholds/tolerances.

Thresholds/tolerances allow for small amounts of unintended comingling, to account for crop/food production in an open environment. The smaller these thresholds, the greater the cost of food production. Different forms of agriculture production and products have coexisted in Australia for hundreds of years.

During the development of GM products, specifically GM crops, it is important that practical standards for coexistence are developed - to ensure realistic or achievable requirements on producers and the supply chain.

Australian state government approaches to OGTR-approved GM crops



CONSUMER PERCEPTIONS

Around the world numerous studies have been undertaken to assess consumer attitudes to biotechnology including medical and agricultural biotechnologies. According to the Council for Agricultural Science and Technology (CAST) two key questions can be gleaned from public opinion studies on agricultural biotechnology generally, and on animal biotechnology particularly. These questions underlie the views for many publics:

- What is the purpose for the specific application?
- How is the work carried out?

Many public opinion studies reveal a fairly consistent hierarchy of purpose, according to CAST: Applications intended to generate health and medical benefits are viewed most positively, followed by applications with environmental benefits. European surveys have found a consistent ordering, in decreasing favourability for "genetic testing for heritable diseases; drug production using bacteria modified to contain human genes; bioremediation using GM bacteria; medicinal human cell or tissue cloning; use of plant genes in GM crops; animal cloning to product drugs in their milk; and for producing foods to make them high in protein, keep long or change the taste".

Work on microorganisms appears to generate the least concern, followed by research on plants. More concern is raised about the genetic modification of animals.

In the USA, where the largest amount of GM crops are grown, consumers appear to have been largely unengaged on the subject of genetic modification, however, over the last 18 months, a substantial campaign to introduce GM food labelling has emerged. While it is too early to predict the outcome of the campaign, it will be interesting to see if this increased attention on GM crop production has an impact on consumer attitudes to gene technology in the USA.

Australia

In Australia, the federal government supported GM consumer attitude studies from 1999 to 2012. The last of these studies, undertaken in 2012 showed that:

- Males, younger people and those who live in capital cities are more likely to support GM foods.
- People are more supportive of GM foods that have health outcomes or are cheaper, and find lasting longer or tasting better only of minor benefit.
- Support for GM foods and crops has remained fairly consistent over the past few years, with about 60 per cent of the population willing to eat most GM foods, and about 25 per cent not willing. However this figure changes depending on the type of food being modified, whether there are benefits to the consumer and the perception of effective regulation.
- There are differences in attitudes to GM foods by gender, age and attitude to science and technology, with males scoring an average of 5.2 on a ten point scale of support for various GM foods and females scoring 4.0; people under 30 consistently rated a full point higher than those over 30; and those with had a high support for science scored 6.6, while those who generally mistrusted science scored 4.0.
- The study also found that almost nine in ten Australians had heard of modifying genes in plants to produce food, and half felt the benefits of doing this outweighed the risks while one in six felt the risks outweighed the benefits.
- Just over half (52 per cent) of the population were in favour of growing GM crops in their state and a third (32 per cent) were opposed – but about six in ten of those opposed would change their mind if the crops could demonstrate positive outcomes for the environment, provide benefits to health or pass stringent regulations.
- Conversely, many of those who supported growing GM crops in their state would change their position if benefits were not proven or it diminished farmers' competitiveness.

Other key findings included:

- There was a much stronger belief that applications of biotechnology such as stem cells would improve our way of life in the future (90 per cent) compared with the cloning of animals (39 per cent) or the cloning of human embryos (30 per cent).
- There was moderate agreement that '*regulations on the use of GM in agriculture and food production are sufficiently rigorous*'.
- A majority (54 per cent) felt the benefits of using GM to grown human tissues or organs in animals for human transplants outweighed the risks (19 per cent).
- A strong majority agree that not vaccinating children puts others at risk and that human activities have a significant impact on the planet.

Thirteen years of Australian consumer attitudes to biotechnology studies provides data to predict attitudes to biotechnology based on other criteria. The table below provides a snapshot of several segments of the community.

Predictors of attitude		
	More likely to be supportive of GM and other biotechnologies	**Less likely to be supportive of GM and other biotechnologies**
Gender	Male	Female
Age	16-30	51-75
Awareness and knowledge	Had heard of biotechnology Knew enough to explain it to a friend	Had not heard of the term biotechnology
Employment	Student or employed	Retired or home duties
Higher agreement with	Science is such a big part of our lives that we should all take an interest. New technologies excite me more than they concern me Not vaccinating children puts others at risk.	Scientific advances tend to benefit the rich more than they benefit the poor. Technological change happens too fast to keep up with. We should use more natural ways of farming. People shouldn't tamper with nature.

SAFEMEAT BIOTECHNOLOGY POLICY PRINCIPLES

SAFEMEAT SUPPORTS THE FOLLOWING POLICY PRINCIPLES:

The science and its terminology

1. Biotechnology is broad ranging - The Australian red meat industry agrees to act to raise awareness of, and gather support for, the broad aspects of biotechnology, including outcomes already in the marketplace and those more likely to enter the marketplace in the future.

2. Recognise potential benefits - The Australian red meat industry recognises significant potential benefits from the use of some forms of biotechnology along the entire supply chain, and the need for its development and application in an integrated systems approach. This will require investment in R&D, commercialisation of intellectual property, and the development of strategic research and commercial relationships.

3. Recognise potential risks - The Australian red meat industry recognises that applications of biotechnology in livestock and red meat production may also pose some risks that need to be thoroughly researched and understood from the perspective of consumers, the environment and participants in the supply chain.

4. Use consistent language - As part of a great industry and consumer education and communication initiative, the red meat industry agrees to use consistent language and definitions relating to the science involved in biotechnology in discussions with stakeholders and the general public.

Regulation

5. Safety and environmental obligations - The industry recognises its obligations with biotechnology to provide products that meet appropriate animal safety, food safety and quality requirements, and have community acceptance in terms of sound and environmentally appropriate production and processing practices.

6. Transparent, science-based regulation - The industry agrees that a clear and transparent regulatory system is required for the confidence of all stakeholders, and supports *the Gene Technology Act 2000* and the Office of Gene Technology Regulator and other regulatory instruments governing the use of facets of biotechnology. Further, as a matter of urgency, the industry agrees to work with government to address the issue of regulatory requirements for cloning, to ensure the industry is positioned to capture the benefits and address the risks before the technology becomes a major tool for the red meat sector.

7. Access to approved products - The industry supports investment in biotechnology research and access to regulatory approved products without unnecessary impediments, including unreasonable compliance costs.

8. International standards - The industry will collaborate with other countries and international standard setting bodies regarding biotechnology to ensure robust safeguards and transparency of decision-making which does not create artificial barriers or disincentives to innovation or trade.

Markets

9. Ethical and social considerations - The industry recognises the need to be aware of the ethical and social issues surrounding the use of biotechnology, and the animal welfare and health considerations, particularly in the development of GM and cloned animals.

10. Supply chain choice - The industry recognises that producers, processors and retailers have choice in the application, or otherwise, of biotechnology and encourages the investigation of options to support this choice. However, the industry also recognises that if biotechnology adoption continues this choice may be reduced, particularly in relation to animal health and animal feed options.

11. Market intelligence - The industry recognises the potential diversity in technology and market positions that may arise, and the need for the industry to reasonably cater for such diversity and associated outcomes where feasible. The industry supports the proactive monitoring and regular gathering of market intelligence and public perception data – both nationally and internationally – which impact the elements of this policy.

12. Changing commercial environment - The industry recognises that community and market expectations are undergoing change and that a high level of uncertainty currently exists in relation to commercial returns on investment in research and development in this area, and that such investments should be subject to rigorous technical and commercial evaluation prior to approval. Further, the industry agrees to maintain sound knowledge about the research effort underway globally in order to maintain a competitive approach in the development of these key technologies.

An informed industry

13. Proactive communication/education - The industry recognises the need to proactively inform and educate stakeholders about biotechnology and to develop an industry communication strategy, to ensure a rational and informed debate.

ATTACHMENT 1

DEFINITIONS IN DETAIL

Genomics

All the genes in an individual or species are known as the genome. The study of large numbers of genes simultaneously is called genomics. Genomics is the key to a greater understanding of gene function that can lead to further large-scale improvements in the performance of animals.

While animals have been improved using conventional means, a large number of characteristics cannot be improved via conventional means either because the methods are too expensive or slow, or selection occurs in the wrong sex, or the animal has to be killed to obtain the measurement. The main focus of genomics in livestock is to study genes in order to understand and/or predict their relationship to the resulting physical body of the animal, with a focus on traits which cannot be improved as effectively by conventional methods.

Genes act in regulated networks, and their regulation can be affected by events elsewhere in the body and outside the body, including diet and stress. Animals have between 20,000-25,000 genes, which is why genomic approaches are needed to:

- find the function of relevant genes;
- better understand the complex interactions between genes and the environment
- relate gene activity to animal performance
- identify new features of an animal because the number of interactions between so many genes is exceedingly complex.

One of the primary tools in the genomic analysis of a species is the production of the genome sequence of the animal. A genome sequence is the DNA sequence of the entire genetic material of the animal. A genome sequence that is in the draft phase will allow the identification and the ability to study all genes using the methods of genomics. A genome sequence is an important tool for studying the genome.

In livestock, the key focus is identifying genes involved in resistance to parasites or diseases and those responsible for features such as growth rate, muscle size or fat composition. Animals with these desired features can then be used in breeding programs.

With the gene sequences for several organisms now known, it is possible to prepare whole arrays of genes, groups of genes or pieces of genes by a variety of technologies. Such collections of genes are being used as a way of finding out which genes are doing what at each particular moment of time.

Functional genomics

Functional genomics is the study of gene function and is often considered to be synonymous with studies of gene expression. Gene expression refers to the process by which the coded information of a gene is transcribed into RNA, and many genes are translated from RNA into protein.

Phenomics

The phenotype is the sum of the observable characteristics of an individual. The expression of these characteristics results from the interaction of genetic and environmental factors. Phenomics is the study of the range of variation in measurable traits, or phenotypes, within a species.

Proteomics
Genes work by expression into the myriad of proteins that make up the structure and function of an organism. Proteomics is the study of genes through studying the activities, interactions and quantities of many proteins simultaneously in the tissues of a plant or animal.

One approach to proteomics is to analyse all the proteins being produced at various times and see how they vary. That way, it is possible to find out which proteins are basic 'house-keeping' ones, and which are produced as part of a developmental stage or in response to a particular situation, such as infection. Protein analysis can be compared to genetic activity in related cells to determine which proteins might be produced by particular genetic sequences.

This science depends on separation, isolation and characterisation of large numbers of proteins.

Metabolomics
Metabolomics is the study of all the small molecules produced in the animal body. While the proteome can be studied by looking at the proteins that are active in a cell, the action of those proteins in total can only be studied indirectly by looking at proteins. To be able to study protein action directly, the fluctuations of all of the small molecules that are produced by proteins (metabolites), must be able to be tracked. Genetic differences between genes that influence proteins either directly by protein sequence or indirectly through regulation of the amount of protein can be tracked in this way.

Quantification of these outcomes and their relationship to the proteins made and the genes expressed is the challenge for bioinformatics.

Bioinformatics
Bioinformatics is the use of computers and information technology to analyse biological information. Given the complexity of genetic systems bioinformatics is an increasingly important tool in biotechnology. It is important in the study of DNA sequences of the genome, including the assembly of the DNA sequence, the identification of unknown genes directly from sequence information, the prediction of gene function for unknown genes, and the prediction of gene networks.

Nanotechnology
Because atoms and small molecules are nano-sized in diameter, nanotechnology is often defined as the building of materials and machines from atoms. This technology is most developed in cosmetic and coating industries.

Molecular markers (marker assisted selection)
Marker assisted selection allows genes with significant effects to be targeted specifically for selection in breeding programs. Some characteristics are controlled by a single gene, but most of those of economic importance are quantitative traits that are likely controlled by a larger number of genes. These genes, usually called quantitative trait loci (QTL) are not uniform in their size of effects, some are too small to be individually of commercial importance, while others are so large they can cause the phenotype to be classified into two or more classes. These latter sort are also referred to as major genes, and examples are double muscling in cattle and callipyge in sheep – an abnormal increase in muscular tissue caused entirely by enlargement of existing cells.

Genetic markers can be used in breeding and have potential to enable faster genetic progress in livestock breeding programs. Prior to the use of markers, the performance of animals and their relatives was the only way of measuring the genetic potential of their genes. Characteristics such as those listed below may benefit from marker- assisted selection:

- Simply inherited characteristics (coat colour, genetic defects).
- Carcass quality and palatability attributes.
- Fertility and reproductive efficiency.
- Carcass quantity and yield.
- Milk production and maternal ability.
- Growth performance.

Gene technology

The use of gene technology to produce genetically modified organisms (GMOs) is currently one of the most controversial applications of biotechnology. Gene technology is also referred to as genetic engineering and genetic modification. Using gene technology, scientists aim to introduce, enhance or delete particular genes of a living thing, thereby permanently changing its characteristics.

Genes are made of DNA. They contain coded instructions for proteins, which give living things their particular characteristics like hair and eye colour. Most living organisms use DNA as the genetic code. Gene technology or genetic modification allows researchers to insert a copy of a gene from organism into the DNA of another organism, including from one species to another. The resulting organism is genetically modified or transgenic.

Gene technology is defined by the Australian *Gene Technology Act 2000* as “any technique for the modification of genes or other genetic material, but does not include sexual reproduction, homologous recombination or any other techniques specified in the Regulations.”

Gene silencing refers to the processes that allow researchers to switch off the activity of a targeted gene, so that it is possible to determine the impact of the loss of the particular gene on the phenotype.

Proteins derived from ribonucleic acid (RNA) make up the structures and perform the functions of living things. Most messenger RNA (mRNA) acts as an intermediate stage between the gene and its proteins. Gene silencing works to degrade the RNA instructions of a specific gene and it is composed of several technologies.

Gene silencing is a tool that:

- May allow the function of many genes to be investigated.
- Could silence genes throughout an organism or in specific tissues.
- Offers the versatility of partially silencing or completely turning off particular genes.
- May selectively silence genes at particular stages in an organism's life cycle.

Gene silencing may help researchers find out what specific genes do, produce new pharmaceuticals and develop disease resistant plants and animals.

Cloning

Cloning is the production of genetically exact duplicates (clones) of an organism by means other than sexual reproduction.

Cloning naturally occurs in plants, however in animals and people it is rarer and only occurs at the embryo stage. Identical twins are natural clones. While clones can be readily produced in some organisms, especially in some plants where even a small cutting will give an identical plant, cloning in mammals is more difficult. A less controversial cloning technique called embryo splitting in mammalian species resembles the natural process that results in twins (twinning), which occurs when a fertilised egg splits during development and forms two embryos instead of one. This feature of the egg has been used by researchers to split embryos artificially and implant the resulting clones into recipient females.

To clone an adult mammal is far more difficult, and requires that the nuclear DNA from a donor cell be reset to the embryonic state, that a recipient egg be found and its nuclear DNA removed and be replaced by that from the recipient cell. This was achieved in 1996 with the production of "Dolly" the lamb in Scotland, who was cloned from a cell of an adult sheep. The cloning technique used to create Dolly is called somatic cell cloning. The donor DNA can be deliberately modified during the process of cloning and the resulting offspring can be genetically modified as well as cloned.

Individuals of all the major livestock species have been cloned, but animal cloning technology is still considered to be in the early stages of development.

There are four main drivers of cloning technology:

- Improving productivity - farmer and economy.
- Improving the end product - consumer.
- Improving human health.
- Enhancing knowledge in cell biology - what makes cells tick?

Potential uses of livestock cloning include:

- Multiplying animals which are outstanding performers in a particular environment - dairy cows, beef and dairy bulls.
- Allowing breeders to take a small number of animals with superior genetics and rapidly produce more.
- Duplicating valuable animals nearing the end of their lives so that their genetic value can continue to be accessed.
- Using cloned bulls to disseminate genetics in remote and vast locations where other reproductive technologies such as artificial insemination are impractical.

Xenotransplantation

Research involving GM animal clones is underway for xenotransplantation purposes. Xenotransplantation is defined as transplantation from one species to another; for example, from a pig to a human. The term covers transplantation of organs, tissues or clusters of specialised cells. Xenotransplantation requires genetic modification to incorporate human genes into donor animals that will cause transplanted tissue to be recognised as human thus eliminating the usual adverse tissue reactions.