MEAT & LIVESTOCK
AUSTRALIA

on farm

Gene Technology Strategic Review December 2001

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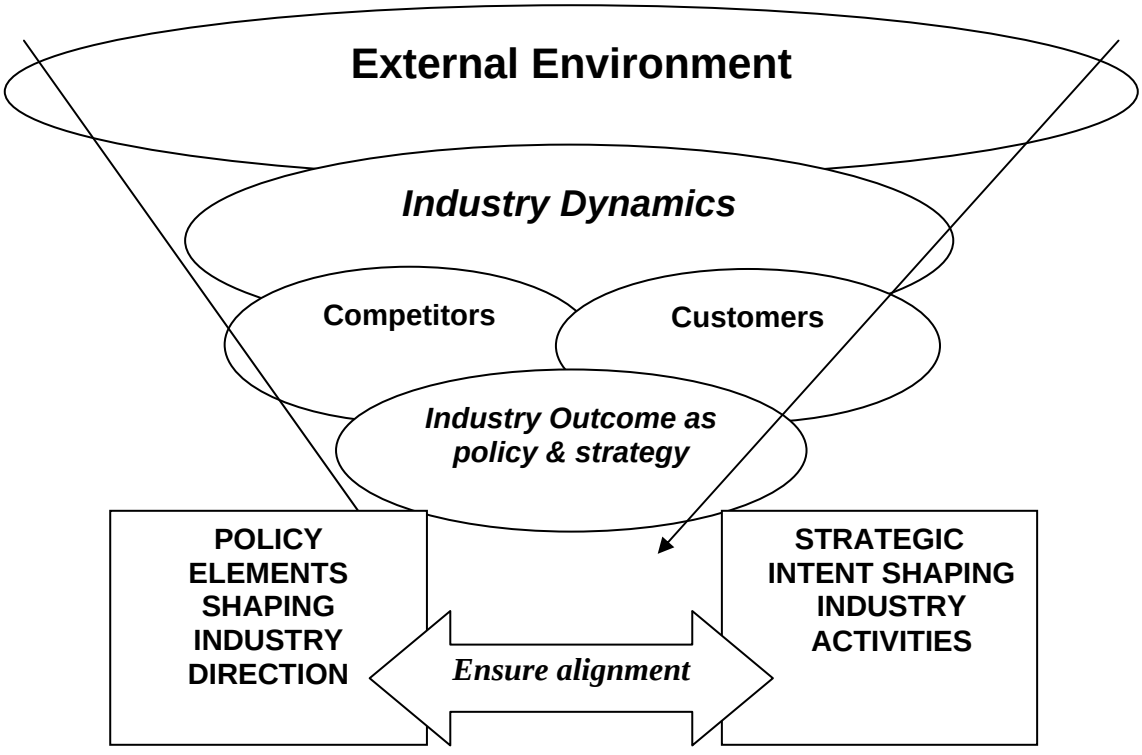
1. INTRODUCTION

This paper progresses from the 2000 SAFEMEAT Policy Paper on Gene Technology and reviews subsequent strategic developments impacting the livestock and red meat industry, and overall implications for the industry in terms of further policy implementation. Since the policy was approved in late 2000, two initiatives have been implemented which are reported briefly in this paper.

This paper updates, in particular, developments in the public policy and regulatory fields, both domestically and internationally, combined with an overview of global strategic developments particularly following the BIO 2001 International Conference in the USA (Mid-year). It also highlights the key areas for activity by the SAFEMEAT Gene Technology Sub-committee.

1.1 2000 Policy and Industry Strategic Framework

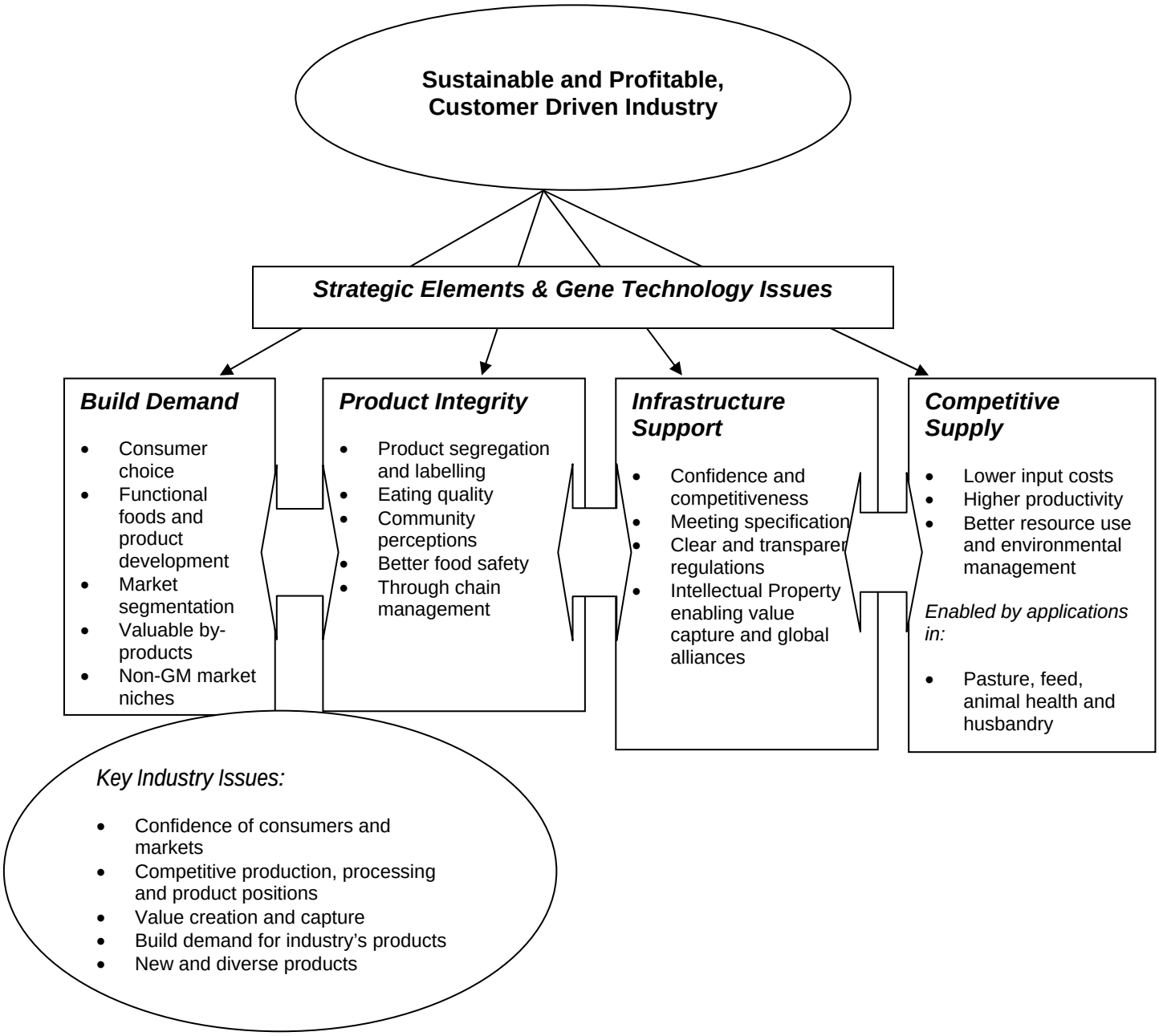
In 2000, a policy document on the use of gene technology in red meat production and manufacture was prepared with industry stakeholder involvement through a SAFEMEAT sub-committee process. This was based on the following assessment of the strategic framework in which the industry operates. Since the development of the policy document, industry feedback and potential changes in the external environment and customer attitudes necessitate a further review. This section will broadly highlight these issues.



The overall industry strategic intent was proposed in the 2000 Policy as **'a sustainable and profitable customer driven red meat and livestock industry**'. The key elements enabling the industry to meet this intent relate to:

- the building of demand for red meat and associated products,
- product integrity – both quality and safety,
- infrastructure support to and within the industry, and
- the ability of the industry to be a competitive supplier.

Gene technologies potentially impact these elements as shown on the following page.



Major developments, externally and within the industry, over the last year impacting the key industry issues above are summarised in the following section, and are covered in more detail as required in Section 2.

Building Demand

Over the last year in Australia, public attitudes to biotechnology appear to have stabilised based on Biotechnology Australia's surveying. It is also now widely accepted the GM food labelling is essential – see later regarding the introduction of labelling in Australia from December 2001. In Europe and North America, attitudes have not altered dramatically with continuing resistance to GM food in Europe and overall market acceptance in North America. See later for regulatory factors impacting the European position.

More recently, in Asia both Japan and Korea have introduced GM food labelling which is shaping public attitude, as is the fallout from the Starlink corn issue, described later in Section 2. These developments have translated into greater enquiry to Australian red meat suppliers for assurance of their GM-free status, not only related to meat products but also to their livestock feeding and other process related practices. This represents the major GM related issue facing the industry currently.

Product Integrity

While GM meat and related products are not yet available, developments in the grain area are having spillover effects. The Starlink corn issue in the USA (see Section 2) has resulted in the realisation that bulk grain Identity Preservation and Segregation systems are currently generally insufficient to ensure non-GM grains, including for feed. This has flowed on to the realisation of the difficulty of supplying non-GM feed to intensively managed livestock in major northern hemisphere markets, again with spillover implications for Australia. While locally produced GM grains are not present to any appreciable amount in the stockfeed supply in Australia, cottonseed meal is an issue due to the use of GM cotton (insect and herbicide tolerant) for currently 30% of the industry's planted area. The expected introduction of GM canola (herbicide tolerant and hybrids) from 2003 will also result in related feed meal issues.

One initiative that has been progressed by MLA related to this area in 2001 has been a review (by the Bureau of Rural Sciences) of the impact of GM feed and pasture on livestock specifically addressing:

- Description of all known GM feed and pasture.
- Estimation of present and potential levels of exposure of Australian livestock to GM feed and pasture.
- Estimation of present and potential levels of exposure of livestock in Europe and North America to GM feed and pasture.
- Description of current and planned European and North American quality systems implemented.
- Summary and critique of scientific evidence on the impact of feeding GM pasture and feed to livestock related to animal health, welfare and production, and the environment.

- Summary and critique of scientific evidence on the movement of DNA, retroviruses and related matter through the food chain.

- Identification and prioritisation of knowledge gaps that may form the basis of future research.

General conclusions drawn from this review are:

1. Some Australian livestock are currently being fed GM feed. While *Bt* and Roundup Ready cotton are the only locally grown GM crops currently which could be used in animal feed, some GM crops that are grown overseas are being imported into Australia and are probably being used in animal feed. New GM crops, such as canola, are also likely within the next few years.

2. The use of GM crops in animal feed has the potential to raise a number of issues for Australia's livestock industries. The use of GM feed has caused concern in some markets, such as the UK and Europe, and some retailers have responded to public sentiment by ensuring they move towards non-GM fed meat. Assurances that these requirements are being met may also be needed.

3. Australian farmers will have to consider whether or not to use the new GM crops as they become available over the next few years. They are seeking information to help them decide what they should do. The factors they consider may include examining the market for their products, the costs and yields of the crops, environmental benefits and risks and if there are any additional requirements in growing GM crops, such as compulsory management plans or contracts with seed suppliers.

4. The use of GM crops and pastures in agriculture will change the way agricultural chemicals such as pesticides and herbicides are used. While the GM crops are designed to reduce chemical use or to move towards safer chemicals, there is the potential that the changed way the chemicals are used will change the pattern of residue and metabolite detection. While any safety issues are thoroughly assessed before approval to change chemical use is given, other countries may use any changes in residues and metabolites as a trade issue.

5. A number of health issues have been raised about GM crops. They are usually about human health issues but many are also potential animal health issues. The issues include the safety of using antibiotic resistance markers in GM constructs and the feeding of GM crops to people (or animals) because they are unsafe. Different reasons are often given for the GM crops being unsafe, such as the GM construct entering human (or animal) tissue and harming the person (or animal); the potential for the GM to have allergic, toxic or carcinogenic potential; the use of particular constructs (for example the cauliflower mosaic virus promoter) and questions about possible long term effects. In most countries, including Australia, the safety of GM food and GM feed are assessed by government before they are allowed to be sold, usually following internationally established assessment procedures. However, in some countries there is a lack of trust in governments in this respect. This must be considered in any decision to introduce changes to current production practice.

6. There are a number of novel gene technologies available or being developed to provide the same kinds of improvements to crops and pastures that existing techniques can bring. Public reaction to these technologies could potentially be more accepting.

7. The USA, Canada, Argentina and Australia currently commingle most crops, i.e. mix GM and non-GM crops throughout the supply chain. The US Department of Agriculture is currently investigating whether it should become involved in quality assurance or other programs to facilitate the marketing of products. Given the likelihood of the need to segregate GM from non-GM foodstuffs, at least for some markets, it may be prudent for the industry to explore segregation options to be able to service both GM and GM-free markets.

The review by BRS has now been converted into an eight page brochure that has been widely distributed throughout the red meat and livestock industry, as well as other livestock industries and those involved in feed production. In October 2001, MLA coordinated a meeting between all livestock and feedbase stakeholder organisations with relevant government bodies to address the issue of cross industry coordination and consistency especially in relation to vendor declaration and Quality Assurance requirements. This will be progressed further in 2002.

At a broader scale, a review of the issues related to segregating gene technology products across all major agrifood industry chains was completed for the Federal Government (Agriculture Fisheries and Forestry - Australia) in 2002. Relevant aspects of this review are referred to in Section 2 addressing strategic drivers. An overall observation from this review was that the Red Meat industry has, through its strong supply chain management focus, developed a sound platform of Quality Assurance and associated management practices for the implementation of Identity Preservation and Segregation systems.

Subsequent to this study, the Federal Government recently announced a three-year project to examine the feasibility of segregating genetically modified products across their entire production chains, as part of an overall supply chain management approach to agrifood industries.

Infrastructure Support

New regulatory systems covering gene technology and food become effective in 2001.

From June 21, 2001 the new (Federal) Gene Technology Act became effective through the Office of Gene Technology Regulator (OGTR); with a national framework of regulation and licensing established, an extension of the principles of scientific assessment of risk as developed by GMAC, recognition of the ‘precautionary principle’ in risk assessment, and provision for community involvement through a consultative approach. Developments at the State level require complimentary legislation and regulatory processes under a Federal/State Ministerial Council approach. Field trials of GM crops continued over the last year under interim guidelines, with considerable publicity over alleged and substantiated breaches of field trial guidelines for GM canola by both Aventis and Monsanto in Tasmania and South Australia. All field trials are now regulated by OGTR under the new Act.

Beyond regulation of GMOs above, the other major development has been the enforcement of ANZFA Standard A18 covering the labelling of GM food from December 7, 2001. Another initiative implemented by MLA in 2001 was the development of a simplified User Guide for

use throughout the industry supply chain to enable education and compliance with the new standards. This was modelled on a generic draft compliance guide developed by ANZFA which had been customised to address the red meat industry and likely product scenarios involving potential GM labelling (especially smallgoods based on GM ingredients etc), with worked examples. This guide was distributed widely throughout the industry in the October - November 2001 timeframe.

Competitive Supply

MLA maintains its support of a range of gene technology developments through its investment in GM pasture projects with CSIRO, and animal genomics projects with the CRC for Cattle and Beef Quality. A new CRC for Innovative Dairy Products commenced operations in the second half of 2001 with a much stronger focus on bovine animal genomics, with programs that will be of relevance to MLA's interest. MLA also decided to progress its investment in sheep genomics with a joint approach with Australian Wool Innovation (AWI) and potentially New Zealand R&D investors (Meat NZ, NZ Wool Board, AgResearch). A review of relevant genomics developments and a recommended R&D program was submitted to MLA and AWI December 2001. The role of the proposed Sheep CRC is yet to be defined given the current uncertainty over its establishment.

1.2 Strategic Developments Impacting the Industry

1.2.1 Technology Developments

Major Australian technology developments relevant to the red meat industry were reviewed in the 2000 Policy Document, summarised below as:

- Agriculture Victoria programs covering enhanced pasture genetics (white clover virus resistance, ryegrass quality and performance) and animal genomics (molecular marker based animal breeding).

- CSIRO Division of Livestock Industries programs covering bovine gene mapping and animal improvement, with outcomes at the production, processor, exporter and wholesale/retail levels of the industry.

- CSIRO Division of Plant Industries programs covering plant genetics and development, specifically pasture species attributes such as virus resistance, grazing quality and utilisation, and phosphorus uptake efficiency.

Beyond these developments, the following plant based developments have been identified as most likely to impact the red meat industry in Australia through the feed base, as either pasture or stockfeed, over the next decade:

GM crop or pasture – attributes	**Likely commercialisation**
Cotton - Insect and Herbicide tolerance	Already commercial
Canola – Herbicide tolerance, Hybrid Vigour and yield	2003
Field Peas – Improved S-amino acid profile	2003
Cotton – Enhanced Insect tolerance	2003-06
Canola and Cotton – Modified oil qualities	2006
White Clover – Virus resistance	2006-07
Wheat – Herbicide tolerance, Starch modification	2007

GM crop or pasture – attributes	Likely commercialisation
Lupins – Increased methionine	2007
Pasture spp. – Lignin biosynthesis and fructan metabolism	2010
Rice – Herbicide tolerance	2011

(Note that all future developments above require regulatory approval for release of the GMO on a commercial basis, and where appropriate for use in food systems.)

Beyond the predominantly input and agronomic traits in the above table, strategic plant based GM developments are shifting to output traits that are considered to be of higher value and of more attraction to the consumer and markets.

A recent review by the USDA Economic Research Service (early 2001) has highlighted the following areas of current GM technology development likely to be developed towards commercialisation over the next 5-15 years:

Plants - Input Traits

- Herbicide tolerance (range of herbicide chemistries) in a wide range of field and horticultural crops.
- Insect tolerance based on both B.t. and other novel toxins in a wide range of row and specialty crops.
- Disease resistance (viral, bacterial, fungal) in a wide range of field and horticultural crops.
- Agronomic traits related to stress tolerance and enhanced plant performance.

Plants - Output Traits

- Quality of animal feed through altered protein and/or oil levels and quality in soybean and corn, low-phytate corn.
- Food quality for human consumption (nutraceuticals) including oil quality, antioxidant content, anti-cancer compounds, increased mineral and vitamin content, and optimised amino acid profiles.
- Processing related aids such as cotton colour and fibre quality, solids content in tomatoes and potatoes, delayed fruit ripening, and altered cereal starch profiles.
- Speciality chemicals produced in plants as bioreactors, such as pharmaceuticals, antibodies, vaccines, and fine chemicals.

Animals

- Transgenic livestock (cows, pigs, sheep) using milk to produce therapeutic and pharmaceutical proteins.
- Transgenic and cloned livestock (dairy cow, pig) with greater animal productivity, and meat or milk quality.
- Transgenic pigs for potential Xenotransplantation of organs into humans.

Beyond the above applied developments, more fundamental developments such as the sequencing of the bovine genome (project led by USDA) and *Medicago* genome (University of Oklahoma) highlight the strategic importance for the Australian livestock industries to develop capabilities and 'tradeable' Intellectual Property in this area.

1.2.2 Regulatory and Freedom to Operate Issues

The issues associated with the introduction of new GMO and GM Food regulations in Australia have been covered in Section 1. While the Australian domestic situation will be addressed by these regulatory changes, export market impacts of regulatory and freedom to operate issues are also relevant for the export focussed red meat industry.

International Perspectives

Market based drivers vary considerably between North America, Europe, Asia and Australia. These have been influenced by attitudes to food safety and integrity, often due to other non-GMO factors such as BSE and other forms of food contamination in Europe, and attitudes to the roles of government and the market place in regulation. European attitudes have been influenced by a heritage of food security and safety resulting in conservative and restrictive measures based on the 'precautionary principle'. These attitudes have been exacerbated by protectionist trade related issues, activities of NGOs and Green political parties, and commercial moves to secure differentiated market positions beyond regulatory requirements.

North American attitudes are more open and progressive in terms of the role of government in providing a thorough and trusted basis of agriculture, food and environmental regulation; complemented by competitive market environments. There is some difference between USA and Canada (tending to be more conservative), and more recently the impact of concerns elsewhere combined with the Starlink corn issue (see later) has resulted in the issues of consumer information and choice becoming more prevalent. This has resulted in a voluntary approach to food labelling and pre-notification of GMO release. The Asian focus has generally been on accessing the benefits of new technologies while managing the risks.

Global developments in the key drivers are summarised below, condensing widely varying information sources into an overview of the major drivers. Individual references highlight considerable variation in both base data (especially consumer surveys) and the interpretation of the data (e.g. EC vs USDA).

Drivers	Australia	North America	Europe	Asia
Market – food safety and product integrity	Consumer information and choice required. Receptive to GM and non-GM food based on risk and benefit information.	Little overall consumer objection to date, based on trust in food supply system. Some evidence of erosion of this position, mixed views on food labelling.	High overall consumer concerns underpinned by lack of confidence in the food supply system. Requirement for more information on risks and benefits.	Consumer reliance on government regulation for food safety and supply system. Spillover of European fears, esp. into Japan, plus impact of US Starlink corn.
Market – value based product differentiation and	No market recognition currently with	Strategic industry focus on value based output	Current focus is on perceived dangers of input	Similar non-GM focus on input traits to Europe,

Drivers	Australia	North America	Europe	Asia
market segmentation	focus on input traits. Awareness at R&D and industry level of future output traits.	traits, building on broad adoption of input traits. Significant developments already underway commercially with soybean and corn.	trait GMOs, hence non-GMO and IP/segregation focus. Strategic tension developing with awareness of North American developments.	esp. in Japan and Korea. Key countries aware of future potential of input traits to improve agriculture, and output traits of higher value.
Regulatory – release of GMOs	OGTR effective from mid-2001 extending current GMAC system. Focus on protecting human health and environmental safety.	USDA and EPA focus mainly on environmental safety – FDA covers human health, Environment Canada oversees releases.	EC Dir. 90/220/EEC amended to balance protection of human health and environment with economic benefits. Precautionary principle applies*.	Essentially voluntary controls. GMO use overseen by MAFF in Japan. Regulatory processes still developing in most countries.
Regulatory – food standards and labelling**	Food Standard A18 from Dec 2001 introducing food labelling based on new or introduced DNA or protein, with exemptions related to highly refined foods, processing aids and food additives, flavours present at <0.1%, and 1% threshold for 'unintended' GM ingredients.	USFDA covers food and feed safety, based on tolerances set by EPA. System relies on rigorous assessment and due diligence compliance. No specific labelling unless allergens or substantial changes to nutritional content. Pre-release notification likely to be required soon.	Mandatory labelling required based on genetic modification status and presence of foreign protein or genetic material. Recognises potential for 'inadvertent or adventitious contamination' in 'non-GM' food with 1% threshold.	Ministry for Health & Welfare covers food in Japan. Food labelling introduced into Japan and Korea April 2001, with 5% threshold for 'unintended GM content. '
Regulatory – international trade	Not currently supporting Biosafety Protocol. Sensitive to international volatility.	USA not supportive of Biosafety Protocol. Trade issues related to EU and Japan.	Food labelling significantly impacting imports, Biosafety Protocol driver.	Has used Starlink corn imports from USA to leverage trade position.

* While the EU has a regulatory process in place for release of GMOs, there is a current moratorium on general releases. The situation also varies between individual countries.

** The Codex Alimentarius Commission (Codex) operating under the United Nations FAO and WHO has three committees covering GMOs (Food Labelling, General Principles and Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology), which are seeking to establish guidelines for regulation and labelling of GMOs, including derived foods. Current developments are affected by the diversity of views from committee members, with final guidelines (expected in 2003) likely to cater for acceptance of the concept of 'substantial equivalence', but also addressing varying levels of risk management and regulatory requirements. Nevertheless, the Codex Commission

announced in early July that 'in principle agreement' had been reached on foods derived from GMOs requiring pre-market testing and approval, especially in relation to potential allergenicity.

Similarly an OECD Task Force for the Safety of Novel Foods and Feeds has recognised the need to address animal feedstuffs derived from GM plants. A meeting in May 2001 of participant countries, including Australia, agreed on the need to develop a future consensus (or guidance) document and clarify the next steps and schedule (for implementation). Key issues to be covered in such a document are:

- GM plant use as animal feed,
- assessment of GM feedstuffs,
- fate of DNA and protein in animal feeding,
- animal feeding studies as part of a safety assessment,
- post-market surveillance and monitoring,
- industrial by-products,
- agronomic vs Quality Traits (future of GM feedstuffs), and
- current legislative process applied to GM feed.

Action already undertaken by MLA with the review of GM feeds (see Section 1) under the current policy is addressing this area in a proactive rather than reactive mode. It is important to establish an industry position on the GM feed issue based on sound science and a balanced risk assessment, before market responses establish defacto positions based on perception rather than fact.

European Perspectives

Developments in the European Union (EU) are guided by the regulations and directives of the European Commission (EC), and the European Parliament. Given the profile and significance of the EU as a trading bloc, its regulatory and policy philosophy is influencing regional approaches elsewhere in terms of either exporter compliance, or trade and regulatory policies – both operationally and developmentally. Developments in Asia in particular appear to be influenced more by European developments than the USA, which is of relevance to Australia's export industries including the meat and livestock industry. The fundamental difference between the EU and USA approaches is that while they both seek to meet similar objectives, the USA focuses on regulating the end product while the EU focuses on the whole process.

A short review of EU regulatory developments highlights the potential impact on agrifood trade, both operationally and directionally. The original EC Directive 90/220/EEC introduced in October 1991 provided a regulatory framework for health and environmental risk assessment of GMOs and GMO derived products, with 18 GMOs (individual crop varieties with varying traits) originally authorised for release. Since 1998, no further approvals have been granted (effectively the current moratorium) with a further 14 applications pending. The EC Directive 90/220/EEC has been overhauled into a new Directive 2001/18/EC, which was passed by the European Parliament in February 2001 to enter into force from October 2002. These new regulations have the intent of increased transparency and efficiency in the decision making process, the harmonization of risk assessment, and the introduction of clear labelling requirements for all GMOs.

The new Directive 2001/18/EC on the release of GMOs will specifically address:

- gradual elimination of antibiotic resistance marker genes in GMOs, by the end of 2004 for commercial releases, and the end of 2008 for research purposes,
- a 10 year time limit on approvals, with provision for extension to a further 10 years,
- environmental liability with a full proposal expected by the end of 2001,
- interaction effects between GMOs in the environment to be considered in the risk assessment for authorisation,
- recognition of the 'precautionary principle' and the Cartagena Protocol on Biodiversity,
- use of public registers to enable public information on the details of GMO release, and
- labelling and traceability of GMOs, and products derived from them.

The regulation of GM foods is covered separately under EC Regulation 258/97 on Novel Foods and Novel Food Ingredients, which covers food products containing, consisting or produced from GMOs. Originally, a GM soybean and GM corn variety were each approved under 90/220/EEC before 258/97 came into force. Since then, no products have been authorised, with eleven applications currently undergoing the approval process, and others claimed as being substantially equivalent. The 258/97 Regulation also required the mandatory labelling of GM foods, with subsequent EC Regulations covering additives and flavourings (50/2000) and a 1% GM adventitious threshold (49/2000). Australia's new GM food labelling requirements, introduced at the end of 2001, largely reflect the EU position outlined above in concept.

In July 2001, the EC announced new proposed rules on the labelling and tracking of GM foods and the establishment of a European Food Authority that will operate similarly to the US FDA, which will require final approval by the EU Council and the European Parliament. The new rules propose that all foods and animal feed derived from GMOs be labelled, and that full traceability systems be implemented throughout the supply chain. Further changes related to the process rather than the product, e.g. labelling of highly refined sugars and oils of GM origin, are also proposed. Currently, this is not proposed to apply to animal products derived from animals fed GM feedstuffs. The EC has claimed that these new rules are aimed at restarting the EU's approval process for GMOs, which is also consistent with the intent of providing more clarity in the 2001/18/EC Directive on the release of GMOs. International agricultural trade response to the new food labelling proposals from both Australia and the USA has been unfavourable due to the extra costs that will be associated with enforcement of traceability.

The European regulatory and policy framework will unfold further, especially as they engage in trade negotiations with the USA in particular, and as international working groups such as Codex, OECD and the WTO influence their thinking. Late in 2001, the EC attempted to restart the approval process for GM crops prior to the existing moratorium expiring in 2002, based on its assessment of the strategic need for Europe to stay competitive with the technology as well as trade related issues, e.g. WTO obligations. EU member states however resisted this initiative in October 2001 citing continuing reservations about 'accidental contamination' issues with GMOs.

Even with the current conservative position, the EC has recognised its need to increase strategic R&D investment in genomics and biotechnology overall, earmarking 1.1B Euros (US$968M) in its 2002-06 program, up from virtually zero in the 1998-2002 budget. Further insights into the European thinking, as presented at BIO 2001, are covered in Section 4.

International Adoption and Use of Transgenic Crops

Approvals of GM crops in the USA and EU as at May 1999 are summarised below:

Crop	USA approvals	USA % area	EU approved	EU pending
Corn	11	30	4	5
Soybean	3	60	1	0
Canola	3	15	4	3

Source: EC Directorate General of Agriculture, Working Document, 2000.

While the adoption and use of GM crops in the USA is higher, as also shown below, Europe is placed to progress with GM crops once the current moratorium is resolved. Part of this resolution requires the issues of Identity Preservation and Segregation to be addressed – see later.

Over 44M ha were sown worldwide to GM crops in 2000, with herbicide tolerant soybean (53%), insect resistant corn (27%), insect resistant and herbicide tolerant cotton (9%) and herbicide tolerant canola (8%) predominant. Crop areas (2000) by country are summarised below:

Country	2000 area M ha	% of Total
USA	30.3	68
Argentina	10.0	23
Canada	3.0	7
China	0.5	1
Australia	0.15	<1
South Africa	0.1	<1
Uruguay	<0.1	<1
Mexico	<0.1	<1
Bulgaria	<0.1	<1
France	<0.1	<1
Germany	<0.1	<1
Romania	<0.1	<1
Spain	<0.1	<1
TOTAL	44.2	100.0

Source: James (2000) http://www.isaaa.org/briefs/Brief21.htm

Preliminary estimates for 2001 indicate that this area globally has increased to ~50M ha.

Australia's use of GM crops is limited currently to insect resistant and herbicide tolerant cotton, with the introduction of herbicide tolerant and hybrid canola expected from 2003. The current impact of approved GM crop production on Australian agrifood industries is related to:

- Domestic cottonseed meal and oil entering agrifood chains as either meal (stockfeed) or oil (food ingredient and/or additive).

- Imported soybean meal and isolates entering agrifood chains as either meal (stockfeed) or soy flour and lecithin (food ingredients and additives).

- Imported corn flour and oil that may be used as food ingredients.

Domestically produced canola meal and oil is likely to enter the Australian agrifood chain from 2003 with both Monsanto and Aventis announcing their intention to submit for OGTR approval in late 2001.

Soybean and corn are prevalent throughout the global food and feed supply, with the USA accounting for 56% of soybean exports and 76% of corn exports. Most corn and soybean production in the USA is undifferentiated with GM and non-GM commodities being mixed in the supply chain. USDA estimates approximately 2% of US soybean production is based on market demand for non-GM associated with pure seed production, specialty soybean exports to Japan and some EU niche markets. The corn situation is impacted more by some regulatory restrictions on the import of certain corn varieties into the EU (approvals pending). Since GM corn was introduced, US export share of corn to the EU has decreased from 4.5% to <1%.

Canada is the major world exporter of canola (44%), with 75% of its production as GM canola. Canadian exports are, with the exception of some minor niches, undifferentiated due to their major export markets (Japan, China, other Asian countries) not being prepared to pay for costs of segregation.

Recent announcements of the likely introduction of (herbicide tolerant) GM wheat in the USA in the 2003-2005 timeframe have caused reactions both in the USA and its export markets. The general reaction has been to consider Identity Preservation and Segregation as essential to ensure integrity to meet perceived consumer requirements in addition to regulatory requirements, especially in Japan. This will impact global thinking on the overall issue.

GM Testing

Regulatory and supply chain management initiatives such as Identity Preservation and Segregation will require some form of testing for GM and non-GM products and/or ingredients. It is preferable that rapid and economical testing methods are available for use within operational confines.

Testing methods currently available reflect tools that have arisen mainly from research areas, with attempts to now apply them in commercial situations.

PCR (polymerase chain reaction) testing is a very sophisticated test used to detect specific DNA fragments on a gel using chromatographic principles. It is not easily adaptable for rapid on-site testing requiring 2-10 days and costing US$200-$450 per test. Such tests are currently provided by analytical laboratories. Sample size and procedures are issues that impact the representative nature of a parcel of the commodity, e.g. 30kg per 1,500 t grain parcel or 0.002%. The test is very sensitive and can detect to 0.1% DNA content, with the advantage of being readily adaptable to specific gene constructs (and promoter/marker

genes). PCR tests are susceptible to errors however due to contaminants or DNA breakdown, with 'false positives' being a problem area.

ELISA (enzyme linked immunosorbent assay) testing detects for specific antibody reactions that mark the presence of new proteins derived from foreign DNA. ELISA based kits can be used to quantitatively detect foreign protein within 2 hours and at a cost of approximately US$10 per test. This method has been developed by SDI in the USA for a range of major traits such as glyphosate tolerance (soybean) and B.t. (corn). Subsequent developments by SDI has resulted in a rapid dipstick type test that can detect down to 0.1% content in Roundup Ready soybeans in 5-10 minutes at a cost of US$3.50 per test. This test is used to provide a 'yes-no' indicator of GM presence. This approach is being evaluated in both the EU and Japan for use in detecting GM presence in grain and food ingredients. ELISA and dipstick type tests must be developed for each individual gene construct, and are currently commercially limited to B.t. corn (although they are being evaluated in Australia for use in B.t. cotton detection).

NIR *(*near infrared) spectroscopy techniques utilise the absorption and reflectance of light wavelengths to identify and measure the quantity of materials such as oils, starches, and proteins in both whole seeds and processed grains. Tests are rapid and relatively inexpensive where an NIR unit already exists, as is the case in many grain receival and handling points. NIR has the potential for application in this area to detect and measure GM content either directly at the DNA level, or through the downstream protein. Australia uses NIR extensively in its agricultural industries, and has strong technical expertise in this area with the potential to develop this approach further. Iowa State University has reportedly filed a patent application in 2000 to apply NIR technology to the detection and measurement of GM traits.

In Australia, the focus to date has been on developing local commercial PCR capabilities, beyond use in R&D organisations. Originally, a small commercial laboratory based at Murdoch University (***Biotest***) provided a commercial service, and such capabilities are now available from ***AGAL*** (limited basis) and ***GeneScan***.

AGAL is developing PCR testing capabilities with the major life sciences companies (Monsanto, Aventis, DuPont) and AQIS to provide an independent testing capability, plus has been participating in a series of ring tests with laboratories in Europe, USA, Canada, Japan and New Zealand. This latter initiative is being coordinated by Aventis using Liberty Link (herbicide tolerant) corn as the test material to develop standardised processes and procedures globally.

GeneScan is a German company with experience in GM testing since 1994, with operations in Germany, France, USA, Austria, Italy, Sweden, Denmark and Australia. Its Australian operations are quality certified to ISO9001, DIN EN45001 and the Food Chemical Association for PCR laboratories. They have also applied to NATA for Australian certification, although there is no current local standard for PCR. The company has developed a range of testing services covering GM crop identification, quantification of levels in food and feed, and advancing screening systems; plus has also expanded its business into the provision of turnkey Identity Preservation systems. More recently, they have formed an alliance with Earthmark Institute (an organisation recently established to provide independent third party certification for a variety of attributes, including non-GM). The Earthmark alliance also includes an audit based approach to the development of Identity Preservation systems with Arthur Andersen providing this component of the service.

Other PCR developments include the establishment of a dedicated laboratory, which will be used for cotton breeding line typing at Cotton Seed Distributors, Wee Waa; and food companies such as Nestle developing an Asia Pacific laboratory in Singapore, which will complement local testing in their Identity Preservation monitoring programs for ingredients.

Beyond PCR testing, lower cost and faster methods are also being tested for application, particularly in cotton. ELISA techniques are being used as a cotton research tool (for cotton line identification), and may be altered for in-field use. A commercial kit based on the USA Envirologics B.t. protein test (corn based) is being tested for commercial use in cotton, and the Monsanto QuickTest B.t. indicator test is also being used but is not considered suitable for IP monitoring. These developments have occurred primarily after commercialisation of transgenic cotton, and the view in the oilseed industry is that testing methods need to be in place before transgenic canola commercialisation in the near future.

While the above testing techniques will be commercially applied, most likely under some form of government or industry accreditation, there is scope also for novel testing and monitoring methods to be developed for use in a supply chain management approach. MLA potentially has a role here with other RDCs in the evaluation of novel technologies, such as reflectance technologies (NIR etc), for real time and lower cost application in industry supply chains as part of an integrated approach to Identity Preservation and Segregation.

1.2.3 Market and Public Attitudes

The latest information available from Biotechnology Australia surveys shows generally increased consumer acceptance of GM foods, particularly when they are labelled. While this does not indicate that consumers are no longer concerned about GM foods, it supports the experience with new technologies that concerns often settle as more is learned about the technology. Mid-2001 Australian survey results show that the major concerns about food safety are, in descending order of importance:

- food poisoning (72%),
- pesticide use (68%),
- human tampering in the manufacturing process (65%), and
- GM foods (58%).

A separate survey of Australian grocery buyers by RIRDC in 2001 showed that GMOs ranked 11 out of 15 separate issues of concern; with specific issues such as human disease transfer, antibiotics and pesticide residues more important; and general quality of life issues predominating. The RIRDC study also highlighted erratic attitudes to GM foods reflecting poorly informed positions – see below.

Recent comparative studies in the UK and USA found that GM foods rated 43% and 2%, respectively amongst other food safety issues, with higher order issues in the UK being food poisoning (63%), mad cow disease (61%), growth hormones (47%) and pesticides (46%). USA results were generally lower and were related to packaging, food handling, contamination or disease and pesticides above GM foods. Survey trends internationally show a tendency to increased acceptance of GM products, where information is available to the consumer, e.g. UK consumer willingness to eat GM food has risen from 46% in 2000 to 48% in 2001, while two-thirds of French consumers surveyed said they would not be against GM foods if they were labelled. The most recent Eurobarometer survey shows that EU consumers want more information (~85%) and the right to choose (~95%) on GM or non-GM food.

Biotechnology Australia's survey results (like RIRDC's) also show that the community does not feel well informed on many biotechnology issues, highlighting the need to provide more factual and balanced information. Ethical concerns appear very influential in attitude formation, often being based upon whether genetic modification is developed to benefit society or to provide a specific product or production benefit. ***It is clear that ongoing monitoring of public attitudes is required to determine the likely overall and specific responses to gene technology developments that may impact the red meat and livestock industries. This is proposed as an ongoing area of focus in the implementation of the Gene Technology Policy.***

A February 2001 comprehensive review of the "Economic Issues in Agricultural Biotechnology" by the USDA Economic Research Service has highlighted a number of 'supply' and 'demand' side factors impacting the current and projected situation in relation to GMOs in AgriFood Industries.

Supply Side Factors are summarised as:

- **Increasing Private Sector Investment in R&D** – especially led by major Life Science Companies such as Monsanto, Syngenta (Novartis and Zeneca), Aventis, DuPont, Dow and BASF.

- **Increasing Private – Public Sector R&D Collaboration** – especially related to technology transfer and intellectual property commercialisation of public sector developed technology.

- **Consolidation in the Agricultural Input Industry** – combined with vertical integration opportunities to link technology based input and/or output traits with value capture in the finished product as a food or ingredient.

- **Advances in Science and Technology** – enabling the development of input and/or output traits and greater value capture by 'closing the loop' on the output side of the AgriFood Industry chain.

- **Intellectual Property Rights** – extension to cover most forms of biotechnology invention and subsequent commercial positions of 'freedom to operate' based on such property rights.

- **Globalisation of Agricultural Input (and Output) Markets** – enabling global economies of scale to be achieved in terms of technology development, and recouping of investment across larger markets.

- **Shift from Input to Output Traits** – reflecting the maturing of the industry as Life Science Companies in particular transition from their original crop protection heritage to being truly agrifood focussed in their future developments.

Demand Side Factors on the other hand are summarised as:

- Initial Demand for Agricultural GMOs at the Farm Production Level – effectively limiting 'perceived' benefits to the production end of the AgriFood chain, even when based on production and environmental benefits such as more effective pest and weed control, reduced pesticide use, and improved soil conservation. It is now

recognised by the biotechnology industry that it has not identified and communicated the benefits of the first wave of agricultural biotechnology innovations to the general community.

- Negative Consumer and Activist Perceptions – based on concerns relating to food safety, environmental management, ethical and product stewardship issues. The extent of these negative perceptions vary considerably, and are addressed in the next Section relating to Global Developments.

- Food Company and Retailer Attitudes influenced by Consumers and Activists – essentially reacting to market and public perceptions, and usually not based on sound science.

International Trade Issues – reflecting the aggregation of the above factors into 'non-tariff' barriers to trade in commodities that contain GMOs, which is an extension of current protectionist – free trade tensions surrounding trade in agricultural commodities and food products. Recent developments in the development of the Cartegana Convention on Biodiversity have resulted in an International Biosafety Protocol that is proposed to regulate trade and movement of Live Modified Organisms related to potential environmental and biosafety impacts combined with application of the 'precautionary principle' concept. This development has the potential to significantly impact trade flows.

These factors have been described in a recent European Commission Directorate – General for Agriculture working document "Economic Impacts of Genetically Modified Crops on the Agri-Food Sector" as '*the supply-oriented approach of both biotech companies and farmers has been quickly confronted with reactions stemming from the downstream side of the food chain…..citizen and consumer concerns on biotechnology have been echoed and amplified by NGOs and retailers…..their reactions provoked a cascading effect back to the upstream side of the food chain…..several initiatives to segregate GM and non-GM crops and to introduce Identity Preservation along the food chain developed*.'.

The linkage of such conclusions with the recent developments in European regulations, outlined earlier, is obvious. The challenge will be to develop practical and workable solutions to meeting regulatory and community requirements, while also enabling economic supply of agrifood products.

2.1 Government Policy Developments

Federally, the Government has focused on the implementation of the National Biotechnology Strategy released in 2000, specifically through activities to:

- raise the public awareness and encourage a community dialogue, especially through the communication and coordinating activities of Biotechnology Australia,

- ensure effective regulation through the establishment of the OGTR and implementation of the Gene Technology Act from June 2001, and the introduction of GM food labelling by ANZFA from December 2001,

- address economic development aspects of biotechnology, especially through elements of the Innovation Action Plan (see below), especially the Biotechnology Innovation Fund effective from June 2001,

- assessing and assisting the position of Australian biotechnology in the global market through trade, investment and collaboration initiatives, and

- providing resources for biotechnology through aspects of the Innovation Action Plan (see below).

A specific initiative over the last year has been an investigation of the issues associated with Identity Preservation and Segregation of gene technology products in agrifood industries conducted for AFFA, as referred to earlier.
The Federal Government's Innovation Action Plan, 'Backing Australia's Ability' which provides $2.9B over five years to 2005-06, announced in early 2001 contained significant elements for biotechnology, specifically:

- an increase in ARC competitive grants, which will include biotechnology projects,

- increased project and university infrastructure, which will include biotechnology,

- establishment of a world class Centre of Excellence in biotechnology (and IT),

- investment in major national research facilities, which will include biotechnology,

- an extension of the R&D Start funding scheme, which includes biotechnology developments,

- premium rate tax concessions and streamlining the R&D tax concessions to encourage investment in new ventures, including biotechnology,

- expansion of CRC's, including the new CRC for Innovative Dairy Products, and

- innovation and investment programs such as the expansion of the COMET (early stage R&D) funding program, development of pre-seed capital fund initiatives, implementation of the Biotechnology Innovation Fund, and an Innovation Access Program.

Overall the Federal Government policy position developed over the last three years provides a significant platform for scientific and commercial developments in a range of biotechnology areas, including agrifood industries.
Beyond the Federal level, political and economic drivers in the States have resulted in the following regulatory, 'freedom to operate' and policy developments:

Tasmania – An initial twelve month moratorium on field trials and GMO releases into the environment expired in June 2001, and has subsequently been extended for a further two years following a Parliamentary Select Committee on Gene Technology. This committee has recommended a cautious approach be adopted by the government while longer term issues such as market acceptance, environmental risks, perceived threats to Tasmania's 'clean and green' positioning (including organic production), co-existence of GM and non-GM production systems (including Identity Preservation and Segregation), and ethical and community concerns are further assessed.

Western Australia – The newly elected Labor government went into the election with a five year moratorium on GM releases as part of its policy platform. Recently the WA Minister for Agriculture announced an interim policy allowing for the regulated introduction of GMO crops, but with a default position to the five year moratorium in the event that it believes that the GM evaluation protocol process is not working. GM canola trials in WA have drawn some criticism from farmer groups and local councils concerned about the potential trade impact. Grain deregulation issues are also contributing to the issue as grain handlers and marketers use the non-GM issue as a point of potential differentiation based on their QA systems capabilities. The Western Canola Working Group (involving all stakeholders) has prepared a paper for the WA Minister for Agriculture on the overall issue to guide policy development.

South Australia – A Parliamentary Enquiry into Biotechnology was conducted through 2001. A number of biotechnology related breakthroughs by Adelaide based biotechnology companies in the biomedical and animal area (e.g. pig cloning by Bresagen) have highlighted the potential economic development dilemma. The SA Government has recently announced a supportive policy for biotechnology through its "Bright is the Future" strategic plan, combined with its 'Bio Innovation SA' initiative announced in 2000. A number of Eyre Peninsula councils have, similar to in WA, called for their area to be GM free, based on a perception of 'clean and green' market image. The minority parties in the South Australian upper house introduced proposed legislation in 2001 to enable GM free zones, however this does not have government support in the lower house.

Victoria – In its second year of office, the Government launched a comprehensive biotechnology strategy addressing development of the State's biotechnology skill base, developing its biotechnology research base, commercialising Victoria's investment in biotechnology, building a corporate base and marketing the State's biotechnology capabilities, and government providing leadership and support. The focus in Victoria is across biomedical, agrifood and environmental applications of biotechnology, with the agrifood commitment reinforced in the Government's 2001 budget funding of a number of key agrifood related biotechnology developments, balanced by the need to address ethical and community issues. Through 2000 and 2001, a number of local councils in Victoria have declared themselves GM free, without any statutory authority. The Victorian Government released a discussion paper on the issue of GM free zones, with public consultation and a subsequent decision late in the year not to proceed due to the impracticality of implementing such zones. Victoria was also represented with a large delegation at the major international BIO2001 Conference in June, comprising political, government, research and commercial leaders, where the Premier formally launched the state's biotechnology strategy.

New South Wales – The major stimulatory approach to biotechnology in NSW continues to be through economic and industry development activities of state government departments, and in particular development of biomedical R&D capabilities and associated commercialisation. The NSW Government provided for a number of bio-medical based cluster developments in its 2001-02 budget. Agrifood developments have not appeared to be an area of high priority, despite capabilities within the state in the Department of Agriculture and CSIRO, although recent announcements in the NSW budget will see a focus on exploiting these capabilities.

Queensland – Recognising the need to develop 'new economy' industries, Queensland has aggressively promoted the development of a biotechnology industry with major investment in both infrastructure and capability development through a $270M ten year plan. This focuses on the development of infrastructure, especially the new Institute for Molecular Bioscience, human resource development, supporting early stage funding, assisting commercialisation,

communications for community acceptance, and globally positioning Queensland as a major centre of Australian biotechnology. Like Victoria, a large delegation attended the BIO2001 Conference, and the two states have begun to cooperate on the development of national positions of collaboration and joint effort.

New Zealand – The NZ Royal Commission on Genetic Modification delivered its report and findings on July 30 following a year long process that received wide and varied input not only from within NZ, but globally. While the various environmental, technical and market risks of genetic modification were acknowledged, the major theme of the report was one of 'preserving opportunities' and encouraging the co-existence of all forms of agriculture and their associated production systems. Beyond specific initiatives related to ethical and Maori matters, the Royal Commission also encouraged NZ to develop an overall biotechnology strategy. The NZ Government decided in October to progress with contained and field testing of GMOs, under strict regulation, while placing a two year period of restraint on commercial release although exceptions will be allowed for GM animal and human vaccines.

2.2 Commercial Developments

Developments of relevance to the meat industry primarily involve animal genomics; transgenic animals and cloning for improved animal products and productivity, and specialised protein (therapeutics etc) production in animal organs and milk. Genetic marker developments for improved beef line selection, involving marbling and tenderness characteristics, are already occurring through the CRC for Cattle and Beef Quality resulting in commercial testing services. A current project between MLA, AWI and a NZ consortium is developing a business plan to guide investment in the area of sheep genomics and related technologies.

Companies such as Genzyme (USA), PPL (UK), and Pharming (Netherlands) are all active in the production of therapeutic proteins in either cow, sheep or goat milk for example. PPL and AgResearch in New Zealand have developed transgenic calves with the intent of producing the myelin protein in their milk as a potential treatment for Multiple Sclerosis. Pharming are known to be interested in establishing a transgenic dairy herd in Australia, potentially with the new Dairy CRC to produce therapeutic proteins in a similar manner although this may be influenced by their current acquisition by Genzyme.

Bresagen, based in Adelaide, is developing a range of animal therapeutic products, as well as transgenic pigs as potential organ sources for Xenotransplantation. Basic animal pathogen genomics research, especially in Victorian institutions, has the potential to support a stream of novel animal vaccines and therapeutics.

2.3 Supply Chain Issues

The major supply chain issues relate to the requirement for traceability, Identity Preservation and Segregation in the agrifood system. Safety and quality requirements, as well as specific customer requirements, have resulted in various methods designed to track commodities and ingredients through the food and feed chain. A basic distinction exists between traceability systems designed to record safety and quality-based information, and Identity Preservation systems designed to ensure products meet customer requirements and specifications.

Traceability

This refers to mechanisms that enable the retrieval of information as to the history of a product or ingredient at any point in the food and feed chain, requiring systems of record keeping and documentation that enable retroactive tracking. This extends beyond record keeping of transactions and process actions to measurement or analysis at critical points to check for compliance with specifications. Such approaches have also been termed as the application of 'due diligence' practices consistent with sound corporate operations and governance.

Existing food and feed supply systems generally have traceability systems in place to meet the requirements of the individual supply chain. Recent developments within the European Commission have identified that Traceability Systems should address the following elements:

- Application to all food and feed ingredients, regardless of market destination.
- Ability to rapidly trace back to the source of a problem at any stage in the chain, to meet safety requirements.
- Food and feed ingredients must pass safety approval processes where this is a potential issue, otherwise they should be exempt from the chain.
- Accurate record keeping at each stage of the chain resulting in a paper or audit trail of chain participants and their actions.
- Application of appropriate standards such as ISO or HACCP to reduce the risks of contamination at all chain stages.
- Identification of all participants in the food or feed collection and processing chain, with legally binding requirements.

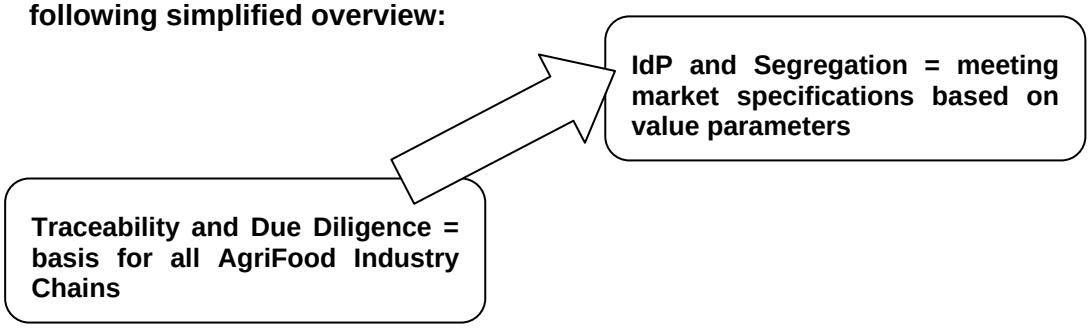
Identity Preservation and Segregation

Identity Preservation is considered to be a more active process however where actions are taken to preserve the identity of a higher value product as it passes through the chain to a specific end market. Such systems are market or demand driven in that customer requirements and specifications related to content, quality, method of production or origin, or some other attribute drives the process. Such systems are not applied for safety reasons, but to preserve certain specifications based on agreement between suppliers and their customers, which usually has a direct or implied value.

Segregation of raw materials or ingredients in the chain is one of the consequences of applying an Identity Preservation system, referring to actions rather than the overall concept. Agricultural commodities are usually grown in response to overall demand and are not handled in an Identity Preservation context unless market requirements and associated value premiums offset the extra costs associated with implementing both information systems and physical segregation.

The cost of such a system is relative to the complexity and number of actions in the chain to meet the information management and physical segregation requirements. A key factor influencing the complexity of the Identity Preservation requirement with GMOs, as for other perceived 'contaminants', is the tolerance level for 'contamination' or 'unintended presence'.

Overall, the distinction between traceability and IP approaches is reflected in the following simplified overview:



It is important to understand that moving from traceability based systems, considered fundamental for food and feed chains; to Identity Preservation systems needs to be based on increased 'value', recovered from the extra costs incurred in price premiums, offsets against price discounts or penalties for non-compliance, or enabling or maintaining market access.

Starlink Corn – a case study.

Attitudes to GM products in agrifood supply chains have been influenced considerably by the Starlink corn issue in the USA over the last year, fuelled by opponent activism against GMOs.

In 1998, the US EPA issued a registration for Starlink corn - an insect resistant corn from Aventis containing a novel B.t. protein (Cry9C). Initial approval, through an exemption provision, was granted for feed and industrial non-food uses, however EPA did not extend this to food uses due to concerns that Cry9C may be a potential food allergen. Evaluation of Starlink corn continued through 1999 and 2000 on the applicability of Starlink for food grade uses. EPA approved plans allowed Aventis to supply Starlink to the market provided that farmers were informed of its non-food status, the need for appropriate buffer strips, and the requirement to segregate for feed and/or industrial uses.

In September 2000, a consortium of seven Washington based consumer organisations (Genetically Modified Food Alert) announced that they had detected evidence of Starlink corn in taco shells produced by Kraft Foods. US FDA subsequently became involved and, after further testing, initiated a product recall. A number of other food manufacturers followed suit and eventually nearly 300 corn based products were recalled, plus testing of corn procurements by large food companies began.

The problem was also detected in corn meal by the Consumers Union in Japan, where Starlink corn was not yet approved for any use. This resulted in US corn exports to Japan initially reducing by two-thirds and a total ban in South Korea. Following this initial action however, the Japanese government has moved to approve feed uses of Starlink corn and to implement a 5% tolerance from April 2001 to enable the crucial supply of corn from the USA to continue, highlighting the importance of key commodity imports into Japan and their pragmatic approach to balancing risk assessment with trade necessities.

Subsequent action in the USA saw:

- Aventis stop Starlink sales and purchase the existing Starlink corn in the food supply system, plus pay growers for corn on-farm that was not intended for feed use.

- Aventis announced the cancelling of registration of Starlink corn meaning that it could not be used for any agricultural purpose.

- Aventis petitioned the EPA to extend the Cry9C tolerance exemption to a four-year exemption for foods made from Starlink corn, supported by new data on the potential allergenicity of the protein.

- Following independent review, a scientific advisory panel found that there was a medium likelihood of potential allergenicity, but given the low level of the protein entering the human diet, there was a low likelihood that Starlink corn would result in sensitisation of some individuals to the Cry9C protein.

- Aventis now faces class action suits relating to the loss of domestic and export corn markets, plus individuals claiming allergic reactions to eating the Starlink derived food products.

- Reform proposals have emerged relating to mandatory food labelling, and FDA has proposed that food developers be required to notify FDA at least 120 days prior to commercial distribution of GM food or animal feed, and to provide suitable safety information.

- Announcement by the Centres for Disease Control in June 2001 that no allergic reactions could be attributed to Starlink corn, potentially clearing the way for the EPA to support granting Aventis' request to set a tolerance level for any minute amount of the Cry9C protein that may be found in the food chain.

- EPA's subsequent decision in July that it could not establish a residue limit food tolerance for Starlink corn citing from a range of studies that the Cry9c protein still has a 'medium likelihood of being a potential human allergen'. This was despite advice from its Scientific Advisory Panel that there is a 'low probability of allergenicity' due to the limited amount of Starlink corn now in the food supply.

Starlink highlighted the current lack of statutory linkage between EPA, FDA and the Department of Agriculture APHIS agencies, and this may result in legislative moves to strengthen this area. (Australia already has stronger links between its GMO, food and agricultural regulatory agencies – OGTR, ANZFA, and NRA.) While there have been calls for tighter controls and mandatory food labelling in the USA, the FDA has reaffirmed its decision not to require special labelling of GM foods where substantial equivalence with non-GM foods is maintained, thus basically preserving the current approach. US EPA has indicated that it is very unlikely that a split registration, i.e. for food and non-food uses requiring a 'two-track' system (essentially Identity Preservation and Segregation), would be approved again.

This incident has been seen as a major 'wake up call' for the US grain industry, with the wheat industry in addition to corn and soybean now developing protocols and systems for Identity Preservation and Segregation. While Identity Preservation and Segregation systems existed in the US grain handling system, they were mainly applied to specialty grades of crops where information flow through the chain was very evident and premiums enabled the costs to be recovered. Overall the US system involves high volume and high speed operations reflecting the traditional bulk commodity supply chain and essentially trade based on 'spot markets'. A recent analysis in ISB New Report (March 2001) concluded that "*farmers will need to plant, harvest, and store grains separately, then have them tested to*

meet certain purity standards. In most complex cases, every step in the process from seed selection to final delivery will need to be documented and monitored. The product will be certified, tested, and have a paper trail that allows traceability back to its origin."

This appears to be a hybrid between traceability and Identity Preservation/Segregation, and suggests that thought still needs to be given to the process as much as the actions. Recently the US grain industry has begun to use the term 'grain channelling' reflecting the development of a new approach. Specification of tolerance levels, and hence the degree of co-mingling, in particular appears to require attention as the basis for protocols through the supply chain. Current tolerance levels vary by country ranging from 1% in the EU (and Australia), to 5% in Japan, 3% in South Korea, and no specific levels yet in the USA or Canada.

Costs of Identity Preservation and Segregation

Most available information on the costs of Identity Preservation and Segregation relate to corn and soybean production in North America and Europe. A comprehensive study by a joint USA – French study in 2000 highlighted the key issues to be covered throughout the production and supply chain to meet requirements, summarised as follows:

- **Seed purity** – this already is the basis of the seed industry, but requires greater scrutiny to ensure GM-free seed as well as GM-true seed.

- **Farm production** – purity is required to be maintained in the planting and harvesting operations through either equipment cleanout or the use of dedicated equipment (or contractors), as well as discouraging cross-pollination between GM and non-GM crops.

- **Transport off-farm** – options involve on-farm storage, clean down of trucks, and scheduling deliveries to silos.

- **Silo/Grain Elevator** – options depend on the simplicity or complexity of operation of the silo complex, with a trade off between operational efficiency and the ability to segregate. Storage capacity and separation options also impact the ability to implement specialty segregation.

- **Transport ex-silo** – rail car availability, decontamination and flexibility of deployment is the major issue, as well as outloading inspection and approval.

USDA surveying in 1999 showed that 8% of the USA soybean and 9% of the USA corn crop was being segregated for non-GM end use. Estimated average total cost of segregation, including testing, is summarised below:

SOYBEAN
Total cost = US$0.54/bushel = US$21.28/t = on average 12% of the sale price
Premium to grower = US$0.15/bushel = US$5.91/t = on average 3% of price

CORN
Total cost = US$0.22/bushel = US$8.48/t = on average 12% of the sale price
Premium to grower = US$0.10/bushel = US$3.67/t = on average 5% of price

Based on the above, testing costs represent approximately 4% (soybean) and 22% (corn) of the overall cost of Identity Preservation and Segregation through the chain to export vessel. Total extra costs overall represent on average 12% of the sale price. The premium to the grower is modest reflecting recovery of cost, rather than added value.

Another analysis of Identity Preservation and Segregation costs by the European Directorate-General for Agriculture across a range of crops (non-GM and speciality soybean, corn, canola, sunflower) in the USA, Canada and Europe shows on average a range of 10-15% of the sale price. Absolute costs were in the A$25-35/t range (at parity rates with USD and Euro). Extending these costs to Australia is difficult, but it would appear that claims of 15% extra costs are generally comparable with USA and European experience. This would equate to approximately A$25-35/t extra cost through the (grain) chain, dependant on the commodity for non-GM Identity Preservation and Segregation. The extra costs for segregation of non-GM cottonseed in Australia have been estimated to be $60 to $80 per tonne, due to the additional cotton gin downtime costs beyond the bulk handling requirements.

Most studies to date conclude that the major costs of non-GM Identity Preservation and Segregation will depend on the tolerance levels set, either by government regulation or the market requirement. Currently, the major cost does not appear to originate from either equipment cleaning or dedication (either on-farm or in the transport system), or from the costs of testing, but rather from 're-shuffling' of the grain handling system. This cost of 're-shuffling' will drive change in the system of grain handling and the provision of capabilities and capacity for Identity Preservation and Segregation.

Beyond North America where adoption of GM crops and export market reaction is driving some segregation, there is evidence of grain handlers in Australia developing their systems and capabilities to handle GM and non-GM crops, especially with the introduction of GM canola expected from 2003. A paper presented to Outlook 2001 described the development by the Grain Pool of WA working in 'insurance mode' to introduce on-farm QA systems, not just for GM crops but also to address overall food safety issues, and to integrate these with the existing IP system already in place with the CBHWA at the bulk handling level.

The analysis of Identity Preservation and Segregation to date has involved that of 'added cost', rather than 'added value'. Such systems are not new, nor unique to GM crops, as they have been previously developed for specialty grades of commodities where market premiums or access are the drivers.

An assessment of the meat and livestock industry's understanding of, and preparation for gene technology was made recently in a study for AFFA on "Segregating Gene Technology Products – Requirements, Costs and Benefits of Identity Preservation, Segregation and Certification", referred to earlier. This included extensive industry consultation with feedback summarised in the following six key areas:

- Gene Technology application within the industry, and associated industry policy position.
- Supply Chain Management ethos, culture, effectiveness and issues.
- Industry consultative process for Gene Technology Policy and Issues Management.

- Clarity of Market Requirements relating to Gene Technology and output products.
- Capability within the Industry for IP and Segregation, and associated issues.
- (Potential) Role of Government in assisting to address IP and Segregation issues.

The issues pertaining to the red meat and livestock industry are outlined below:

- *Gene Technology Position and Policy*
  - R&D focus similar to dairy – both plant and animal focus through MLA and CRC for Cattle and Beef Quality (genomics based).
  - Like dairy, aware of strong international competition in feed base and animal performance driven by genomics.
  - Options based policy developed in 2000 under the SAFEMEAT umbrella, with implementation underway in 2001 including a useful initiative on a customised User Guide for the Red Meat Industry on Standard A18 relating to GM labelling, and associated supply chain and Identity Preservation issues.
- *Supply Chain Management Ethos etc*
  - The industry has developed a sound supply chain ethos and approach due to MLA, processors and SAFEMEAT activities focused around safety, integrity and market access, i.e. freedom to operate. The SAFEMEAT model in particular creates a common purpose and focus for action.
  - The industry has developed good information management processes to underpin QA systems associated with food safety and hormonal growth promotants. This includes the National Vendor Declaration Scheme and the National Livestock Identification Scheme; plus individual systems along the industry chain involving Cattlecare, Feedlot Accreditation, Truckcare, National Saleyard Quality Assurance Program, ARMCANZ Standards for abattoirs and smallgoods, and Retailer Food Safety Codes. These systems use HACCP and QA as the basic framework, and serve as a useful example for other industries.
- *Industry Consultative Process*
  - The industry has achieved a workable consultation process through both MLA and particularly SAFEMEAT, which provides a sound platform for further development.
  - Better links with grain and cotton industries needed on GM-feed issues.
- *Clarity of Market Requirements*

- Like dairy, export markets are requesting certification that Australian meat products are GM-free and produced with GM-free processes, including feed and pasture. The level of enquiry still appears to be sporadic by comparison, reflecting individual trader or distributor positions.

- Domestic market issues, where relevant, have been driven by fast food chains and supermarkets through their procurement policies and relate to the whole chain process, not just product.

- *Industry IP and Segregation Capability*

  - The HGP experience provides a ready on-farm QA base for traceability and segregation, if required.

  - The customised Standard A18 User Guide – see above – is a practical example of simple communication assistance to the industry to understand and deal with traceability, IP and segregation issues.

- *Role of Government (does not imply agreement by AFFA at this stage)*

  - Support MLA funding of R&D for testing technology and potentially better supply chain management, especially information management through the supply chain.

  - Encourage the industry to undertake strategic foresighting on the GM issue.

  - Encourage linkages with other industries on overall approaches to GM management.

As a result of the above study, the Federal Government has recently announced that it will undertake a three-year project to examine the feasibility of segregating genetically modified products across entire production chains. While AFFA considers these issues for all agrifood industries, MLA and SAFEMEAT have the opportunity to progress a number of these from an industry perspective as part of the industry's Gene Technology Strategy. A particular initiative will be to progress cross-industry approaches to the GM feed issue referred to earlier.

2.4 Developments across all Industries

Issues arising across all major agrifood industries are summarised in the table on the following pages. Overall these issues across all agrifood industries are summarised strategically as:

Demand driven

- poor clarity of market signals for non-GM

- mixed availability of QA systems,

- food companies mainly aiming for silent labelling for Standard A18 compliance,

- retailers taking a pragmatic but generally non-GM position, and
- extra IP and Segregation costs most likely impacting margins, and hence Traceability based audit trails, with some testing, being most practical and preferred.

Supply driven

- market access certification needs are unclear,
- costs of infrastructure to segregate and Identity Preserve,
- focus on input R&D more than technology and solutions delivery,
- margin distribution and value sharing by technology providers, and
- the attitudes of producers, handlers and traders, and processors to closed loop systems.

Interpretation of the issues above shows that on-farm QA systems are a useful starting point for through chain information management associated with Traceability, IP and Segregation. Attitudes to closed loop and related approaches are also important in altering processes to meet more specific downstream chain requirements beyond the farm gate. The lack of overall supply chain ethos (mixed across industries) and related innovation in the food processing industry overall also pose potential barriers to development and adoption, with current deregulatory tensions in a number of industries exacerbating this issue, especially grain and dairy.

Through-chain and across-chain issues of note are patchy and generally poor awareness and understanding of GM related issues and their potential impacts, a solid existing base in the food industry of systems that can address IP and Segregation requirements with some modification for GM, industries largely in a reactive mode to the GM issue with little strategic foresighting, and a strategic vulnerability in capturing real future market value when acceptable traits of higher value need to be segregated.

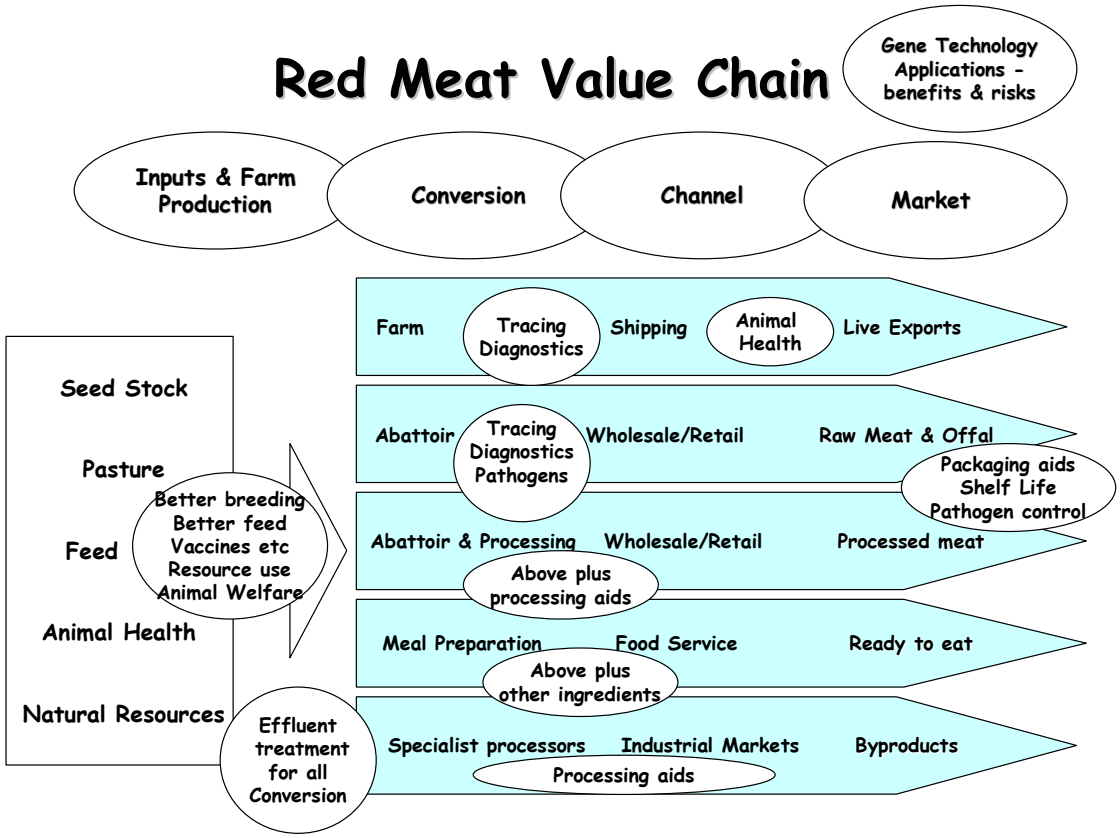
These issues cannot be addressed in isolation, and require the development of **Industry CAPABILITY** through **RECOGNITION** of the issues, **COGNITION** to understand, and **ACTION** to address.
The red meat and livestock industry is already well placed to progress these issues through its investment in 2000-01 in policy development, and strategic elements already under implementation.

Industry Base	Public / consumer Issues	Export market issues	Supply Chain opportunities	Foresight of future issues	Industry Links to implement
Grains	Address with pending GM canola releases, and longer term grain developments.	Clarity of requirements to enable bulk handling developments.	Current industry deregulation and tensions requires leadership.	Need to ensure R&D investment payback and freedom to operate.	Encourage feed grain links with, stockfeed dairy and beef feedlot industries.

Industry Base	Public / consumer Issues	Export market issues	Supply Chain opportunities	Foresight of future issues	Industry Links to implement
Cotton	Not seen as a major issue due to existing GM crop use, and regulatory approvals.	Relatively clear market needs in established GM markets.	Encourage ACIC to build industry supply chain ethos.	Need to ensure R&D investment payback and freedom to operate.	Encourage links with dairy and beef feedlot re cottonseed meal as feed.
Sugar	While sugar (highly refined) will not require GM labelling, overall consumer attitudes affect food industry response.	Clear market needs established through current specifications with Qld Sugar Ltd.	Encourage industry supply chain approach for GM issue management.	Need to ensure R&D investment payback and freedom to operate.	Encourage links with other industries to ensure shared knowledge, especially of best management practice systems.
Dairy	Sensitivity in liquid milk market requires focus on risks/benefits, plus need to address GM feed and pasture use.	Need for clarity on domestic and export market issues. Potential infomediary role by DRDC and Aust. Dairy Corp.	Current industry deregulation and tension requires leadership and consensus.	Need to ensure R&D investment payback and freedom to operate.	Encourage links with feed supply industries – cotton and grain.
Meat	GM food issues not seen as an issue directly, however similar GM feed and pasture use issue.	Need for clarity on domestic and export market issues. Potential infomediary role of MLA.	Expand on current industry supply chain ethos, especially through SAFEMEAT model.	Need to ensure R&D investment payback and freedom to operate.	Encourage links with feed supply industries – cotton and grain.
Horticulture	GM food issues not seen yet due to mainly R&D developments, with opportunity for +ve response based on functional food.	Potential infomediary role in support of Horticulture Australia.	Encourage industry supply chain ethos to build on existing commercial led developments.	Need to ensure R&D investment payback and freedom to operate.	Encourage links with other industries to ensure shared knowledge, especially of best management practice systems.

3. STRATEGIC IMPACT ON THE RED MEAT INDUSTRY

The livestock value chain and potential gene technology applications were presented in the 2000 Policy Paper as outlined below:



Over the last year, the focus from the policy development process has been on establishing the likely risks to the industry from GM feed and pasture as the basis for strategic analysis and planning, and on ensuring that industry supply chain members can comply with the new food labelling requirements from December 2001.

A number of opportunities, risks and associated issues were identified in the 2000 policy development process (see table next page), and these largely remain relevant. What has perhaps altered since the initial policy development process, is an understanding that the industry has developed a sound base through SAFEMEAT upon which to act and launch initiatives related to gene technology. The key areas outlined in this section form the basis of the 2001-02 program.

Industry Sector	Opportunities	Risks	Issues Arising
Grass fed livestock production	• Pasture & crop for feed base • Animal health & husbandry • Animal Production • Environmental management • Carcase & meat quality • Food safety & quality • Market segments • Marker share outcomes • Human health	• Environmental • Accidental GM contamination • Unforseen secondary complications • Regulatory costs • Labelling based on GM feed • Value not captured • Ethical and public backlash • Trade barriers • Loss of discerning markets	• Consumer focus • Gene technology as strategic opportunity • Likely pasture based benefits first • Segmentation of markets and potential benefits • Need to better understand markets and attitudes to GM • Segregated supply chains to avoid contamination

Industry Sector	Opportunities	Risks	Issues Arising
	spinoffs		
Lot Feeders	• Market education on potential benefits • Education of industry and suppliers	• GM feed based concerns – both in feedlot and feeder stock on pasture • Segregated supply chains	• Driven already by buyer specification and/or enquiry
Live Exporters	• Better animal with disease resistance • Better presented animal • Marketing based on improved environment, animal or cost	• Trading country rejection of animal, GM feed system, use of GM based animal health products • Segregation • Costly labelling and trace-back	• Need to better understand markets and attitudes to all aspects of GM
Processors and Channels to Consumers	• Enhanced recovery of higher value biologicals • Global value chain relationships with Life Science Co's for therapeutic and health based product development • Functional food products – either directly from meat and/or co-products, or through further processing • DNA based tracking of product integrity • Minimised food safety risks • Better environmental compliance	• Opportunity lost through inaction • Poor supply chain management skills risk relationships and value capture • Industry dynamics hamper thinking and vision of higher value outcomes • Lack of suitable IT support &/or skills in industry for tracking systems • Allowing market fickleness to drive tactical responses – see "market savvy" under Issues Arising… • Competitors develop higher value outcomes	• Human capital as skills and expertise • Training to support human capital • Globally aware industry, esp. re technology and competition • "Market savvy" related to market positioning, plus customer needs and perceptions • Use of Australia's strong regulatory position – OGTR and ANZFA – to support "market savvy" approach • Industry paradigm focussed on higher industry and customer value, plus differentiation.

The key areas and issues requiring focus by, and within, the industry over the next 12-18 month timeframe are proposed as:

3.1 Feed and pasture base

Earlier, this was highlighted as the major GM related issue currently facing the industry. The review prepared by BRS has highlighted the potential issues arising from the adoption of GM feed as pasture, grain or meal. While there does not appear to be any undue technical risk in relation to animal welfare or product characteristics from the use of GM feed, the potential market response involves a range of perceptions ranging from no market concerns to requirements for completely GM free processes, including feed.

While a number of studies have shown no (deleterious) effects from GM feed on animal performance and resultant meat and milk composition, the feeding of GM based materials to livestock is potentially an issue in EU, Japanese and Korean markets where a complete GM-free production chain process may be desirable to some market segments. Australian exporters of meat (especially lot feeders) and dairy products have been receiving market 'enquiry' over the last year on this matter causing feedlot and diary company reaction to seek

out non-GM sources of current cottonseed meal, and to be wary of impending GM canola developments. Dairy companies are now implementing GM thresholds in their supplier agreements, with most starting at 5% in the feed base as a precautionary measure from 2001-02. The meat industry needs to develop its position through the current SAFEMEAT Gene Technology Sub-committee process.

The Japanese have recently approved the feeding of Starlink GM-corn given their high dependence on cornmeal for livestock feeding sending mixed signals to the market. EU developments are also confusing in that while some supermarkets and fast food chains are seeking livestock products from GM-free processes, producers are experiencing considerable difficulty in meeting such requirements economically. This has been exacerbated by the ban on meat meal use due to BSE and the high reliance on soybean meal, much of which is GM in origin. Spanish and Portuguese stockfeed manufacturers have called for more access to GM corn and soybean imports to enable competitive production and pricing.

Overall the EU position is likely to segregate into both GM and non-GM based livestock feeding coexisting as two separate supply chains based on Identity Preservation and Segregation, with true market premiums influencing the relative shares. The time period for this to shake out is influenced by the current timeline of the CODEX process influencing GM regulations, the speed of the European Commission in addressing the problem (evidence that this is improving), and the supply of GM and non-GM based sources of feed. A potential approval of herbicide tolerant GM-soybeans by Brazil for example to enable competitive production with Argentina would also significantly alter the situation with the EU virtually forced to address the GM feed issue sooner rather than later.

The BRS GM feed review has been condensed into a brochure for distribution throughout the industry. This will be followed up systematically to establish the level of understanding of the issues within each sector of the industry, the nature and level of concern over the issues, and the extent to which short term tactical responses are required compared to longer term strategic developments – see below.

As a result, the industry will also need to assess its requirement for Identity Preservation and Segregation systems and product flows (GM and non-GM based) in the near future, in essentially a non-GM operating environment, to enable it to develop and test appropriate options while not committing to additional costs until market requirements are more clearly established.

3.2 Knowledge gaps and investment in longer term R&D

The GM feed review highlighted some areas of knowledge gaps relating to fully understanding physiological mechanisms of animals dealing with foreign proteins and DNA in their diets, and establishing the risk potential for transfer up the food chain (albeit considered extremely low based on current knowledge). There are research groups internationally working in this area, identified in the BRS report, that it would seem prudent for MLA to develop linkages with in terms of either technology transfer or co-funded research. These issues are also applicable to the dairy industry as Australia's other major livestock based industry, and a joint approach would be most suitable in terms of resource use and shared risk.

Beyond the animal nutrition and physiology areas of research; more applied R&D of appropriate Identity Preservation and Segregation, and associated information management

systems is required to determine practical and cost effective options available to the industry should it wish to segment chains into GM and non-GM based segments in the future.

These areas need to be factored into MLA's portfolio planning process. MLA also needs to review the BRS report with other livestock based R&D Corporations (AWI, Australian Pork and DRDC) for a unified approach to the issue of feeling GM feedstuffs to livestock, and associated industry policy developments and responses.

3.3 Supply chain education regarding gene technology developments, regulations and compliance

The implications of the new GM food labelling regulations to be effective from December 2001 are that some manufactured meat products, primarily including soy isolates, may require labelling. The details of ANZFA Standard A18 and their applicability to the meat industry have been incorporated into a user guide based on ANZFA's generic compliance guide.

The user guide has been produced and distributed to meat supply chain members, especially to small goods manufacturers, retail butchers and supermarkets. Followup is required in 2002 to ensure compliance with labelling and issues arising.

3.4 Stakeholder and key influencer engagement

It is clear that the debate on biotechnology and gene technology applications in agrifood industries requires a consideration of not only the scientific and technical aspects of risk, but also the perceptual and emotive aspects, plus a consideration of ethics and the rights to be informed and have choice. This process is beginning to progress worldwide from the initial adversarial approaches of proponents and opponents of the technology to one of more reasoned exchange based on recognition of each party's values and concerns. A summary of recent developments in this area is provided in the next section on global issues.

It is clear that stakeholders, including customers and consumers, and key influencers outside the direct industry supply chain need to be included in a progressive and reasoned coverage of the issues, risks and benefits to enable appropriate positions to be developed by the industry in how it applies gene technologies. It is proposed that this is addressed by a series of workshop and similar inclusive activities over the 2001-02 period.

3.5 Customer engagement regarding gene technology and process issues

As an extension of the issue above, specific export customer engagement on an informed basis is required to convey information on Australia's livestock and meat industry chain related to the current and potential use of gene technologies in terms of both risk and benefit. This will enable the potential market response to be better predicted and factored into industry planning. It will also enable Traceability, Identity Preservation and Segregation options to be concept tested with markets to guide likely developments before significant investments are made, especially if done cognizant of the CODEX developments.

MLA is well placed to conduct such customer and market engagement activities providing its officers are well briefed on the issues and comfortable with progressing such discussions at a technical level.

3.6 Policy Review and Strategic Direction

The policy direction prepared in 2000 is still considered to be applicable to the industry overall. Activities proposed through 2001-02 will address current issues facing the industry (GM feed and food labelling issues), while also beginning to address a number of the longer term strategic issues such as supply chain management capabilities, gene technology based investments in knowledge gaps and opportunity areas, and developing industry capabilities further to both use the technology and also segregate product flows where required.

4. BIO 2001 – GLOBAL BIOTECHNOLOGY DEVELOPMENTS AND DIRECTIONS

The BIO 2001 conference held in San Diego (mid-year) provided an opportunity to assess the current status of the industry globally, developments and attitudes from various regions, technology and commercial developments. BIO (the Washington based Biotechnology Industry Organisation) represents the North American biotechnology industry with an overall market capitalisation of A$600B covering 300 companies, compared to the EU with a market cap of A$120B and 105 companies, and Australia with a market cap of A$6.5B from 35 companies. The BIO conference has grown to become the major global gathering of the industry (medical, pharmaceutical, agrifood and environmental) and associated service sectors, with over 15,000 attendees this year including ~350 from Australia.

The theme of this year's BIO was "Partnering for Life" emphasizing the linkages and alliances that have become apparent as essential elements in the development of sustainable biotech based companies and industries. Conference sessions addressed diverse subjects covering markets (drug development, agrifood, industrial processing, environmental management, therapeutic devices), regulatory and policy issues, business management (financing, Intellectual Property and legal, business development, product development, management strategies), communications and ethics, and of course science breakthroughs.

Some key issues emerged overall as challenges that the growing biotech industry must address better:

- **Financing** based on deliverable business plans that are market value focussed, especially in the light of the stock market experience in 2000 with technology based companies.

- **Identity Preservation and regulatory compliance management** as technologies and products progress towards commercialisation and competition, combined with an understanding that **'freedom to operate'** involves a broad competitive focus more than just IP portfolio management.

- **Doing business globally** based on an ability to move and adapt quickly, and to form alliances for both freedom to operate and market access capabilities.

- **Integration with downstream supply chain and market or technology positions** that enable companies to define their pathways forward to outcomes, rather than being solely 'technology boutiques'.

- **Ethical and communication challenges** that must be addressed in an inclusive manner with the broader community.

Whereas the focus at BIO2000 was on the technology platforms and tools, especially genomics and bioinformatics, with the human genome project nearing its first major milestone, the industry is now moving on to the applications of these tools and the associated ramifications.

Key areas relevant to the Australian agrifood industries, and hence the red meat and livestock industry, are summarised below to help shape thinking on the further development of the industry's policy and strategy elements on gene technology and its applications.

4.1 Tools to Applications

As referred to above, the focus of the last few years on discovery using the rapid screening techniques of genomics and bioinformatics is shifting to one of understanding the activity and function of the downstream protein and carbohydrate chemistry regulated by genes. This is where the end products or results of gene regulation and modification are evident, especially in terms of potential outcomes. Areas such as proteomics, protein and carbohydrate chemistry and phenotypic expression in plants and animals are now recognised as equally as important as the genetic discoveries; and this is an area where Australian science is competitive and can add value to basic genetic discoveries.

Given the dominance of the 'discovery' area by large players in North America and Europe (notwithstanding some discovery capabilities in Australia and NZ in various bio-medical and agrifood niches), Australian organisations need to focus on alliances with such players where we can add value and be part of the global team. The Proteome Systems commercial development at Macquarie University in an alliance with key international companies is a good example of such an approach. Currently, MLA is considering its investment and positioning in the sheep and cattle genomics areas, with the need to identify how it can best leverage its investment for outcomes in the supply chain rather than solely at the technology level.

4.2 Identity Preservation and Segregation

There is no doubt that the Starlink corn experience has been a major 'wake-up call' for the USA agrifood industries, and that it has 'spooked' the investment community and the regulatory system. The lack of effective integration between the USA EPA, FDA and USDA APHIS regulatory systems has been exposed by Starlink, and it will hasten the overhaul of the system that was already underway. It has also highlighted the need for the commodity based grain industries to address Identity Preservation and Segregation systems in the context of supply chain management capabilities, which again has been an underlying issue waiting to surface as market segmentation and product differentiation opportunities become more apparent in modern agrifood markets. The next generations of output and related traits will require such systems for regulatory, QA and market value capture issues to be addressed. Perhaps the Starlink incident will be seen as a useful catalyst in the longer term. It has not deterred North American producers who have planted GM corn, soybean, cotton and canola crops in 2001 at record levels again.

In Australia, our agrifood industries are beginning to deal with the Identity Preservation and Segregation issues in relation to domestic food labelling from 2001, and uncertainty on export market acceptance of GM based products. This issue has been covered earlier in this report, and it will become an increasing area of focus for Australia's agrifood industries, including the red meat and livestock industry.

4.3 Supply Chain Management

Following on from the above, the role of QA systems and traceability in supporting not only Identity Preservation and Segregation (where required), but also meeting regulatory and related requirements, is becoming recognised. This will necessitate a supply chain approach where industry participants develop better ways of working together. Input and output linkages, especially in the agrifood industries, are critical especially if the current consumer unease about the technology is to be addressed through better definition and demonstration of benefits. The US Grocery Manufacturers for example currently feel disconnected with the 'benefits' of the current GM crops, since they cannot articulate these into benefits for their consumers, and they also feel that the science has got ahead of the applications if the food industry – either real or perceived.

Associated with this, there is also a growing realisation within the biotech industry itself of the 'connectivity' required for companies and organisations to operate. The large life sciences and pharmaceutical companies are acutely aware that they do not have all the technology bases covered, and that they need the supply chain of R&D organisations and smaller specialised companies to develop the components of the 'technology jigsaw' to take to market. Alliances, joint ventures, and mergers and acquisitions are increasingly underpinning product and market developments, e.g. Cargill-Dow JV to produce bio-plastics through corn bioprocessing. Again, Australian organisations have the opportunity to position themselves into global alliances and teams based on their piece of the jigsaw in terms of either development capabilities or specific technologies.

4.4 Agrifood Technology Developments

Beyond the range of developments identified earlier in Section 2.1; specific plant based developments presented at BIO focussed on the application of GM crops for the developing world, e.g. insect and disease resistant crops in Africa and 'golden rice' with increased beta-carotene levels (vitamin A pre-cursor) in Asia, and the use of plants as 'factories' and feedstock into bioprocessing.

While the life sciences companies commercially will focus on the major crop markets of cereals and oilseeds in western agricultural markets, they also recognise the humanitarian and social value in making their technologies available to the developing world on very beneficial terms. It has also brought international development agencies and leading research centres such as the International Rice Research Institute into the mainstream biotechnology process, which will inevitably influence world opinion and acceptance of the technology. The 'golden rice' development has seen companies such as Syngenta, Monsanto, Bayer, Novartis and Zeneca combine their Intellectual Property into a concerted approach to addressing humanitarian needs in the developing world, with strong endorsement from governments of key countries such as Kenya and India.

Beyond the obvious output traits such as quality and composition related to nutrition and food processing, astounding plant based developments are occurring with the production of vaccines and other therapeutic proteins in plants such as corn, rice, bananas, tomatoes and

lucerne; and in plants being developed as factories and raw materials for bioprocessing. Plants are seen as providing lower cost of production compared to industrial plants, a capacity for scale-up to volume and the opportunity to produce multiple products from the one system. Dow and DuPont are aggressively developing future business positions in these areas, while companies such as Monsanto have moved on to producing specialist high-value proteins in plants. The value of plants as animal feeds has also been recognised with the development of nutritional attributes and animal disease therapeutics and prophylactics in the feed grain system. Beyond the life sciences companies, food companies such as Unilever are also progressing transgenic based developments towards the market.

In the animal area, the use of transgenic animals to produce vaccines and therapeutic proteins in milk has now become an established business with Genzyme, PPL (Roslin Institute) and Pharming all now producing products for sale or for use in clinical trials. PPL is already working close to Australia with experimental production of a therapeutic agent for Multiple Sclerosis in sheep milk in New Zealand, while Pharming are considering establishing a dairy herd in Australia in association with the newly established CRC for Innovative Dairy Products. The New Zealand livestock industries were represented at BIO by Meat NZ, Genesis R&D and various consultants. An environmental based development of interest for the intensive animal industries is the transfer of genes for increased phytase (phytic acid digestive enzyme) production in the salivary glands of pigs to significantly increase phosphorus absorption from feed, and to reduce phosphorus loss in excrement and associated environmental problems. The model system for this has now been demonstrated in mice.

4.5 Regulatory Developments

In the USA, the hitherto separate regulatory processes under EPA (environmental), FDA (food safety) and USDA (plant and animal health) are converging more into greater interagency coordination, especially in the wake of the Starlink corn issue. The individual agencies are overhauling their processes based on the experiences from regulatory oversight of the initial biotechnology crops and a realisation that issues such as allergenicity, pollen and gene flow, GM thresholds as adventitious presence, split food and feed/industrial approvals (the cause of the Starlink problem), and seed purity need to better addressed. In addition, international issues such as the precautionary principle and the growing need to maintain public trust in regulatory systems are influencing developments. Developments are oriented around a regulatory system that will be seen to be predictable; based on sound science; open, transparent and participatory; and responsive to change.

Food labelling is not contemplated in the short term in the USA, although there are proposals for pre-market notification of GM foods before their release, again in the wake of the Starlink issue. Australia's developments with the new OGTR and Gene Technology Act and food labelling regulations position it ahead of the USA in terms of regulatory coverage and focus on international trade issues.

In the EU, the revised EC Directive 90/220 in early 2001 has been seen as providing a new 'horizontal' framework for their 'second generation' of regulations beyond the initial product approvals of the late 1990s and mandatory food labelling. Most importantly, these new measures are seen as setting the framework for currently exempt categories such as animal feeds to be regulated, traceability requirements to be strengthened but also to differentiate between viable GMOs (grains) and derived GM products (foods), thresholds and tolerances to be codified for adventitious GM presence, and labelling to be more extensive in terms of process and not just product basis.

The EC is attempting to present these changes as providing greater certainty for applicants and greater confidence for the public, to support the notion of allowing informed consumer choice. They are currently encouraging the EU member states to review product approvals that have been delayed by the defacto moratorium in an attempt to break the current impasse and demonstrate a more open, but still precautionary approach to approval of GM agrifood products. Real change will take time, but the EU appears to have decided to also overhaul their regulatory system and processes to ensure the potential benefits of agrifood biotechnology can be realised, while still addressing both scientific risk and the distinctly different view on agrifood technologies held by the European general public compared to North America.

Since these pronouncements at the BIO 2001 Conference, the EC has announced further proposed developments in the regulatory area, which were covered earlier in this review. This highlights the need to constantly monitor developments in this area across world markets for export oriented industries to ensure that their tactical responses and strategic planning are both appropriate to short term and longer term developments, respectively.

4.6 Attitudes

Clearly the difference in fundamental attitudes between North America and Europe will continue to impact the overall approval and trade process. Nevertheless, the EU appears to be sending some clear signals to the USA in particular regarding regulatory and trade harmonisation. These are summarised as:

- strict regulation that favours consumer information and choice,
- the need for business to adapt especially through industry supply chains,
- a realisation that there is no legal quick fix, e.g. using WTO sanctions,
- a commitment to putting in the time and effort, and
- a preparedness to work together.

An observation of the agrifood sector is that the balance of commercial control of biotechnology developments is also swinging back to favour both sides of the Atlantic with Monsanto, Dow and DuPont being the dominant USA players balanced by Syngenta, BASF and now Bayer following their acquisition of Aventis being the dominant European players. Beyond the next 3-5 years of the EU accommodating agrifood biotechnology and North America altering their regulatory and trade systems to accommodate more both the EU and Asia, the second half of this decade continues to loom as one of significant growth and opportunity based on the convergence of technologies that are very output and benefit focussed with policies that are more open to trade in agrifood biotechnology products. It is critical that Australian agrifood industries monitor these changes and be positioned to be part of this main game.

A final issue relating to communications and attitudes is that the biotechnology industry does need to shift from its current focus on ‘educating the consumer’ (with associated ‘dumbing down’ connotations) to ‘informing the community’ (and allowing a more inclusive and informed choice based on assessment of risk and benefit). Again, Australian agrifood industries will need to be astute and nimble in world markets to ensure that we position ourselves as the market attitudes develop on this new technology.