Australian Dairy Industry

Represented by the Australian Dairy Industry Council Inc. and Dairy Australia

Response to

Third Review of the National Gene Technology Scheme

Contacts

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Australian dairy industry at a glance

$13.7b
The value of the farm, manufacturing and export industry

Dairy
is Australia's 3rd largest rural industry

Dairy export

34% of Australian milk production was exported in 2015–16

$3b of export revenue was generated in 2015–16

6% of the world dairy trade is contributed by Australia

3,043,000 tonnes
(inc. drinking milk)
is produced for the domestic market

Major markets for Australian dairy products

Indonesia
61,000 tonnes

Greater China
178,000 tonnes

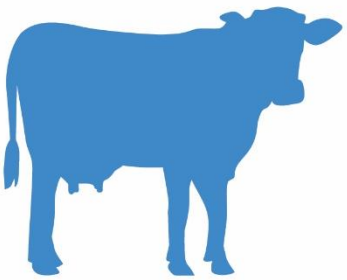
Singapore
82,800 tonnes

Japan
103,100 tonnes

Malaysia
58,150 tonnes

Dairy industry workforce

Approximately 38,000 people are directly employed in the industry



Milk production
9,539 m litres

Average annual milk production per cow
5,669 litres

Average herd size
273 cows

National dairy herd
1.66 m cows

Annual per capita consumption
Drinking milk 105 litres
Cheese 13.9 kg

Annual production of main commodities
Milk powders 321,900 tonnes
Cheese 344,300 tonnes
Butter 118,600 tonnes

1 The Australian Dairy Industry[1]

Dairy is a leading Australian rural industry. It is a $13.7 billion farm, manufacturing and export industry, comprising 6100 farms, around 120 factories and providing employment for 38,000 people.

The dairy industry's farm gate value totalled $4.3 billion in 2015/16, ranking third behind beef and wheat for Australia's top performing rural industries.

Australia is a significant exporter of dairy products with 34% of milk production exported in 2015/16. Australia ranks fourth in world dairy trade. Total export value was just under $3 billion in 2015/16.

However, recent significant challenges both domestically and internationally have resulted in a 2% fall in milk production during 2015/16 and substantial pressure on farm cost structures more generally. Australia's share of international trade has trended lower as local milk production has contracted over the past 15 years.

The dairy industry recognises that innovation drives productivity and is critical to long term profitability and competitiveness. Dairy Australia invested $66.4 million in the industry in 2015/16, of which 64% of this investment was directed at R&D and extension activities across the supply chain. For this reason, and particularly at this time, the dairy industry welcomes ongoing review of regulation affecting investment in and adoption of R&D.

The dairy industry is pleased therefore to provide a submission to the review of the Australia's Gene Technology Scheme initiated in 2017 by all Australian Governments through the Legislative and Governance Forum on Gene Technology.

The outcome of this review will impact on research with the highest potential value of all current R&D targets for the dairy industry. Modern biotechnology is expected to be a foundation of future productivity gains in the dairy industry, and a regulatory environment that is commensurate with risk is of critical importance to the dairy industry.

This is a joint submission from the Australian Dairy Industry Council (ADIC) and Dairy Australia.

The ADIC is the national peak policy body for the Australian dairy industry and represents all sectors of the industry on issues of national and international importance. Its constituent organisations - Australian Dairy Farmers Limited (ADF) and the Australian Dairy Products Federation (ADPF) - represent the interests of dairy farmers, manufacturers, processors and traders across Australia.

Dairy Australia is the dairy industry-owned service company, limited by guarantee, whose members are farmers and the industry bodies, ADF and the ADPF.

[1] Dairy Australia 2016. *Australian Dairy Industry in Focus 2016*. Melbourne, 52pp.

2 Dairy industry position

- The dairy industry welcomes and supports a review of the Gene Technology Scheme, including the Gene Technology Agreement, to ensure it is:
  - Forward-looking and fit-for-purpose,
  - Designed to facilitate the commercialisation of safe gene technology innovations important to dairying,
  - Responsive to changing risk profiles of gene technology and that it utilises a rigorous application of science and economics,
  - Consistently applied across all Australian states and territories, and
  - Supportive of global trade. In particular, the scheme should recognise the need for transparency with customers and consumers and traceability where it is required for compliance with differing regulatory regimes in export jurisdictions.
- This submission **should be read in conjunction with the dairy industry submission** to the current Technical Review of the *Gene Technology Regulations 2001* made in December 2016.
  - That submission pointed out that existing legislation is out of date and not keeping up with new gene technologies such that a predictable approvals process can be undertaken to bring new safe innovations to market.
  - A modern scheme should categorise regulatory response commensurate with risk.
  - The dairy industry argued that new gene editing technologies that carry the same risks as unregulated techniques should be regulated in the same way—and consistently across jurisdictions.
  - Australia should demonstrate leadership in the region for scientific risk-based regulation of new gene technologies.
- The dairy industry supports the federal regulatory scheme for gene technology including the role of the Office of the Gene Technology Regulator in assessing environmental and human safety risks associated with 'dealings with' GMOs, Food Standards Australia New Zealand, the Therapeutic Goods Administration, the Australian Pesticides and Veterinary Medicines Authority, the National Industrial Chemicals Notification and Assessment Scheme and the Department of Agriculture and Water Resources.
- A key strength of this regulatory architecture is that it results in a predictable approval system separate from the political process and subject to rigorous scientific risk assessment for products whose development has involved 'dealings with' GMOs. It is essential that this approach continues and that it evolves, with the capacity to consider the risk of all gene technologies with the potential to advance the Australian dairy industry.
- Advancements in gene technology are fast moving, but it is possible to compare and contrast most of the new methods with existing methods, especially when considering safety and risk. It is only in situations where there are no existing methods as benchmarks that there is difficulty in describing safety and risk. Twenty years of commercial agricultural use of gene technology, preceded by many decades of plant and animal improvement techniques, provides a strong basis for these assessments. For example, a targeted approach of genome editing to delete small sections of DNA sequence creates fewer mutations and is more tightly controlled than methods using chemical or radiation agents that are considered to be safe and are excluded from the definition of a gene technology in the *Gene Technology Act 2001* (Cwlth.).
- These risk assessments need to be made in the context of agricultural applications and are fundamentally different to risk assessments for the use of gene technology in human medical and disease applications. The current scheme does not differentiate and does not give direction in either the relevant Acts or the Regulations to consider the history of use or the application-specific risks.

This is an impediment to setting appropriate risk-based regulatory strategies for new gene technologies.

- Australian dairying is world competitive from a cost of production point of view, but to retain its role as a major exporter of agricultural produce it needs access to technology that improves animals, pasture and grains in order to withstand increasing cost and environmental pressures. Breeding - for both animals and plants - will continue to play a critical role in the industry's profitability and competitiveness. See section 3 of this submission for a description of the role of gene technology in plant and animal improvement for the Australian dairy industry.
- In particular, Australia is in a preeminent global position in the use of gene technologies for pasture improvement and must innovate for improving its own pasture-based system since there are few prospects of accessing gene technologies for Australian pastures from overseas.
- However **the ability for Australian states and territories to designate GM-free areas on market grounds undermines this national regulatory scheme**. Industry will deliver products that markets and customers demand, without the need for Australian jurisdictions to intervene on trade. The ability for jurisdictions to enact a policy principle allowing for state-based moratoria on market grounds warrants review.
- The lack of consistency across jurisdictions has a material impact on plant and animal improvement in Australia. An important example of this point is the market size for new pasture cultivars of ryegrass. Australia is a relatively small market and any reduction of market size to manage an inconsistent approach to regulation across Australian jurisdictions will significantly reduce the economic case for commercialisation and adoption of new technology.
- A consistently applied national regulatory scheme for gene technologies should **continue** to support **four** further well-established principles:
  - **Markets should determine whether segregation is required** and pricing will normally determine this.
  - **Acceptable thresholds and tolerance levels** for adventitious presence of GMOs in agricultural landscapes and supply chains provide a sound basis for co-existence of GM and non-GM products in the supply chain. Co-existence (such as the concurrent cultivation of conventional, organic and GM pastures) is essential for farmers to be able to maximise their own opportunities according to their own business imperatives. This includes the ability to choose production method and the ability to take advantage of the wide variety of technologies available to them, while at the same time operating in a community where working with their neighbours is integral.
  - **Detectability should underpin labelling requirements**. Meat, milk and eggs from GM-fed fish, poultry and livestock should not be subject to mandatory labelling requirements.[2] Product stewardship and/or traceability systems may evolve from both ends of the supply chain to meet different market needs—governed by contracts and independent from a role for government.
  - **Australia's gene technology scheme must not impede trade**. Where overseas jurisdictions regulate gene technologies in a different way, industry must be able to provide the transparency and traceability necessary to meet those requirements.

[2] See the systematic literature reviews of livestock feeding studies undertaken by Van Eenennaam & Young 2014 & 2017: No study has ever revealed any differences between the nutritional profile of animal products derived from GM-fed animals. There have been no detectable or reliably quantifiable traces of GM components in meat, milk and eggs following poultry or livestock consumption of GM feed. Furthermore, "*collectively, studies have failed to identify full-length endogenous or rDNA transcripts or recombinant proteins in meat, milk, or eggs*." (Abstract, Van Eenennaam and Young 2017). Sourced 14 Aug 17: https://www.animalsciencepublications.org/publications/jas/abstracts/92/10/4255 https://www.animalsciencepublications.org/publications/jas/abstracts/95/7/3247

- In summary, the dairy industry supports the existing national scheme for gene technology as long as:
  - Regulatory oversight is right-sized and based on assessment of risks. Two important examples are that:
    - Newer gene editing techniques are regulated the same way as other technologies of equal risk; and
    - Gene technology in agricultural applications and gene technology in human medical and disease applications are subject to risk assessments that are relevant for each application.
  - The policy principle allowing jurisdictions to designate GM-free areas on market grounds is subject to review, and
  - The system continues to facilitate trade through appropriate tolerance levels, labelling requirements and traceability as required.

3 Gene technologies applied in the Australian dairy R&D pipeline

Gene technologies have an important role in current and future improvement programs for the Australian dairy industry. They fit within a range of tools for genetic improvement and are applied in both a research and a commercial setting.

The key focus areas for dairy are:

- quality traits for **pasture** and their fungal **endophytes**,
- welfare and disease resistance traits for **animals**, and
- improvement to other **feed** inputs such as cereal grains, oil seeds, hay and food by-products.

Gene technologies are typically expensive options for plant and animal improvement and so are focussed on high impact targets that cannot be achieved through other forms of improvement. For example, gene technology in pasture improvement has been focussed on quality traits rather than yield traits, as yield traits can be addressed through genomic selection and new breeding schemes, while quality traits do not have an alternate method with comparable potential.

3.1 Genetic improvement is critical for dairy industry prosperity

Genetic improvement is a major contributor to dairy industry profitability and competitiveness, in both advancing the performance of plants and animals and also generating positive adaptation to changes in the environment. For example, genetic improvement of cattle has been reported to be one of the three most important drivers of productivity gain over the past 30 years.[3]

Plant breeding has the broadest range of tools for genetic improvement, with activities that include intensive measurement of plants (phenomics), DNA-based selection (genomic selection), management of heterosis (hybrid breeding), targeted editing of the genome (down regulation of genes that is the subject of the current technical review of regulations by the OGTR) and conventional genetic modification (enhanced gene function that is a 'genetically modified organism' and regulated by the OGTR). Further, it is also important to consider the genetic selection and improvement of secondary genomes, such as fungal endophytes and beneficial microbiomes, as important but less well understood aspects of genetic improvement for pasture plants.

Animal breeding is largely focussed on traditional genetic selection, aided by genomic selection. However, there is rapid progress overseas in the use of gene technology (e.g. genome editing for polled cattle) that also needs to be considered. Overseas innovations are highly relevant in Australia as 75% of the genetics used on farm is imported as frozen semen or embryos.

Gene technology is regularly used as a research tool to validate new methods of genetic improvement. For example, the management of heterosis (hybrid breeding) requires detailed understanding of gene function in order to reliably predict the compatibility of different lines of pasture plants. Gene technology has significantly reduced the technical risks involved with developing this new breeding method, without having a role in the commercial application of the method.

[3] Centre for International Economics 2011, The impact of innovation on the dairy industry over the last 30 years. http://www.thecie.com.au/wp-content/uploads/2014/06/Dairy-report.pdf

3.2 Current areas of focus with gene technology – plant improvement

Gene technologies in plant breeding needs to be considered in three different time periods:

1) traditional genetic modification in use for over twenty years
2) the initial phase of genome editing (new techniques such as CRISPR, TALENS, or zinc finger nucleases), and
3) future use of gene technology.

The dairy industry has a long-term investment in traditional genetic modification of pastures. The targets were perennial ryegrass and white clover, and to a lesser extent, tall fescue. The main successes of this period were the creation of a high energy ryegrass and virus resistant white clover. Both technologies have been successfully introduced into commercial germplasm and could be made available for use by Australian dairy farmers with appropriate regulatory and market approval, following field trials currently underway in Argentina. Further work in white clover has also delayed leaf senescence and expanded the range of soils suitable for growing white clover. All three gene technology traits for white clover have been bred in a stacked manner into commercial germplasm.

Genetic modification has also been used (in containment) in New Zealand to create perennial ryegrass with increased lipid content and white clover with a lower incidence of bloating in ruminants. These traits are also relevant for Australian dairy farmers.

The current focus of dairy industry investment is now on the use of genome editing for traits that are already well defined and with established gene targets. These methods of genome editing closely resemble other established methods of mutagenesis (e.g. chemical or radiation methods) that delete a small amount of DNA and down-regulate targeted genes. (The Australian dairy industry position on the regulation of new gene editing techniques was submitted to the current technical review being undertaken by the Office of Gene Technology Regulator in Dec 2016.[4])

The targets for perennial ryegrass are both the plant itself and its fungal endophyte. Plant traits are increased nutritional quality (more digestible grass) and reduced hay fever risk (from pollen). Endophyte traits are increased pasture persistence while increasing animal safety (reduced toxin levels). Success will be transferable to tall fescue, a pasture species of increasing importance in Australia.

In the future, the dairy industry will look to utilise a broader range of gene technologies, such as the capacity to edit and add to DNA sequences of plants and their microbial populations. This is likely to include multiple and simultaneous iterations of breeding with gene technology to accelerate progress in a mixed model of farmer and community benefits.

3.3 Current areas of focus with gene technology – animal improvement

The initial use of gene technology in animal improvement has been to create induced pluripotent stem cells as a strategy for the preservation of elite genetics as cultured stem cells and their distribution as embryos. Australia is a world leader in the creation and preservation of bovine stem cells, but there is no active distribution of elite genetics using stem cell technology.

Genome editing of cattle is rapidly developing in North America, Europe and Asia. There is now a concerted scientific effort to use genome editing to improve health and welfare traits that is complementary with the existing activities in genetic improvement. It is likely that some international sources of elite genetics will adopt gene technologies for health and welfare traits, and this would likely then be available in Australia through the routine importation of frozen semen. Initial targets include the polled trait and resistance to catastrophic diseases such as foot and mouth disease.

[4] The Australian dairy industry position on the regulation of gene editing techniques can be found at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewsubmissions-htm

3.4 Gene technology in dairy stockfeed

Along with their use in pasture improvement and animal genetics, gene technologies also play a significant role in improving dairy feedstuffs. Existing or planned use of gene technologies include:

- Wheat
- Barley
- Canola
- Maize
- Soybean
- Cottonseed
- Ryegrass
- Tall Fescue
- White Clover
- Tropical grasses
- By-products and co-products from the horticultural industry

Where these innovations enable, for example, reduced chemical use, or confer drought and salt tolerance or provide an improved nutritional profile, the dairy industry will benefit from access.

Key points:

The Australian dairy industry wants the ability to access new safe gene technologies for pasture, stockfeed and animal improvement to maintain profitability and competitiveness.

The dairy industry needs contemporary fit-for-purpose regulatory arrangements for gene technology that do not impede innovation, but provide a predictable approval system subject to rigorous scientific risk assessment.