Australian Dairy Industry

Represented by

Australian Dairy Industry Council Inc. and

Dairy Australia

Response to

Australian Government, Department of Health, Office of the Gene Technology Regulator – Technical Review of the Gene Technology Regulations 2001.

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

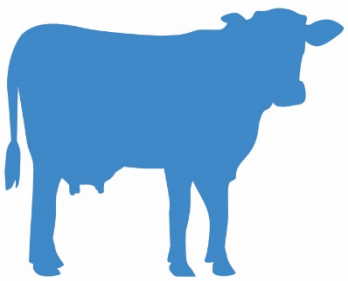
Japan
103,100 tonnes

Malaysia
58,150 tonnes

Dairy industry workforce

Approximately 38,000 people are directly employed in the industry

Other 9%
Cheese 30%
Drinking milk 26%
Skim milk or butter milk powder 29%
Whole milk powder 6%



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 Office of the Gene Technology Regulator's (OGTR) *Technical Review of the Gene Technology Regulations 2001*. 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 Key points

- The dairy industry advises that option 4 set out in the OGTR paper represents a scientific risk-based response and is the preferred approach. Organisms that are indistinguishable from those formed using conventional, or unregulated processes ought to be treated in the same way. Gene technologies with no major hazards, such as SDN1, ought to be exempt from GMO/transgenic regulation.
- The dairy industry needs access to animals, pastures and grains that are reliably productive under increasing cost and environmental pressures to remain internationally competitive. Breeding will continue to play a critical role in meeting these challenges, however the benefits of evolving new technologies will only be realized if regulatory oversight does not impede access, is evidence-based, proportionate to the risk and globally-harmonised.
- Current regulation of GMO's is inappropriate for new breeding techniques.
- The dairy industry sees significant opportunities from the use of new gene editing techniques. However, there is limited application of gene editing techniques overseas that are directed towards forages and crops that are relevant to the Australian dairy industry.
- Australia needs to have a domestic capacity to innovate with new gene editing techniques that are wholly directed at improving its own pasture-based dairy farming system.
- DairyBio is using the 'delete' version of gene editing—a zinc-finger nuclease (categorised as SDN1 in the OGTR paper)—to down-regulate gene functions that cause toxicity in cattle, human allergies from ryegrass pollen and reduced digestibility in ryegrass and tall fescue. While Option 3 would result in this technique being unregulated, this may present an overly simplistic and short-term approach given the rapid development of new genetic techniques and technologies.
- At the present time, there is no legal clarity about whether this new gene editing technique is captured by Australia's regulatory scheme. Regulatory resolution is critical to ensuring innovations in biotechnology have a place in the Australian dairy farming system. Investors and researchers are seeking technical and procedural clarity around the processes to achieve commercialisation of products derived from new breeding techniques. Costs imposed by regulation not commensurate with risk will prove prohibitive.
- The dairy industry has trust in the rigorous scientific assessment of risks undertaken by the OGTR and expert opinions in this review.
- The definitions resulting from this OGTR review should be harmonised across all other relevant Australian Government agencies.
- This review provides an opportunity for the Australian Government to show leadership domestically and internationally in scientific risk-based regulation of modern biotechnology.
- The dairy industry seeks a subsequent review of Australian policy settings for gene technology and the *Gene Technology Act 2000* (Cwlth.) in 2017.

3 New breeding techniques applied in the Australian dairy R&D pipeline

The Technical Review of the Gene Technology Regulations 2001 is timely and important because new breeding techniques that are being considered in the review are in active use in the Australian dairy R&D pipeline. Uncertainty towards the appropriate regulation and legislation for new breeding technology is a material investment risk.

New breeding techniques—for both animals and plants—will be broadly applicable to the dairy industry and are expected to be the foundation of future productivity gains.

3.1 New breeding techniques in stockfeed

Large quantities of wheat and canola are fed to dairy cattle and a current application of new breeding techniques is to make wheat more drought tolerant. This would increase yields in drought years and one of the subsequent benefits of this is that the prices for wheat fed to dairy cattle would not spike as greatly in a drought year. A realistic scenario is that in a one-in-six drought year, the cost of feeding dairy cows would be $170/cow cheaper than under the full effect of drought affected grain prices. This would be a saving to the dairy industry of $221 million.

3.2 New breeding techniques in pasture

Another example of particular relevance is the current investment in the development of breeding platforms (both conventional and using gene technology) for two forage species: ryegrass and tall fescue and their respective fungal endophytes.

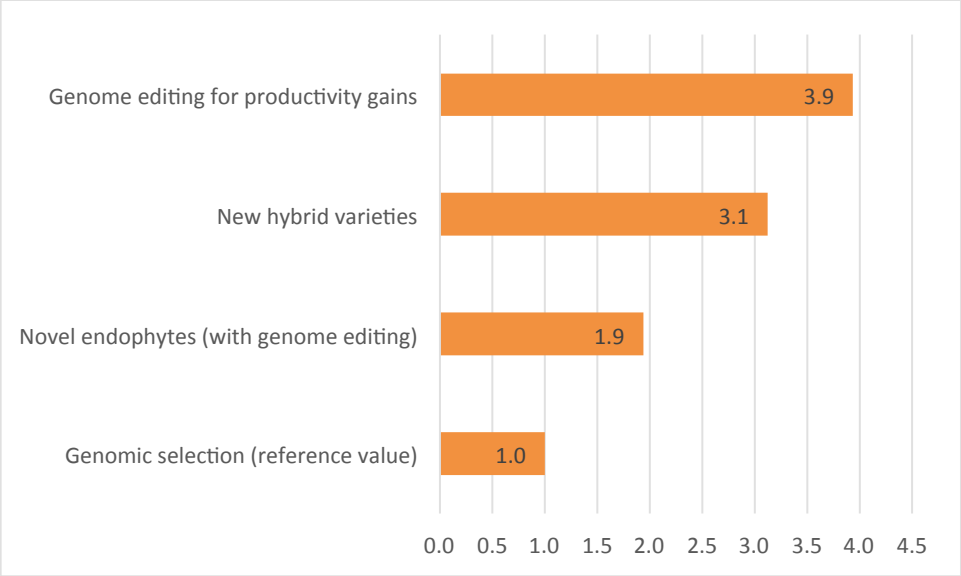
Through DairyBio (jointly funded by Dairy Australia and the Victorian Government at $10.5 million per annum for five years), the forage R&D program for the Australian dairy industry involves, among other techniques, the use of targeted genome editing discussed in the OGTR paper. Indeed, Australia has a preeminent global position in the use of gene technologies for pasture improvement. An important Australian entity, Agriculture Victoria Services (AVS), holds a licence for the use of key new breeding techniques[1]. This is clear evidence of the important role of Australia in global forage innovation, as AVS now holds global rights for one of the most important new breeding technologies.

New breeding techniques hold the capacity to dramatically improve pasture productivity. This unlocks a whole new opportunity for productivity gains, because existing methods of plant breeding deliver only modest improvements, estimated to be less than 1% per year [2,3].

One of the critical success factors for DairyBio is the ability for many innovations to converge into a single commercial breeding program. This way the new pasture cultivars can contain multiple innovations and deliver productivity gains of over 30%.

New breeding techniques are estimated to have the greatest economic impact of all the current innovations under development by DairyBio – see Figure 1. However, their value is not greater than the collective value of all other innovations. Thus, for the practical realisation of value, new breeding techniques need to be able to be integrated into a single breeding program. The options proposed in the issues paper for the Technical Review have far-reaching consequences on the ability to achieve this integration.

Figure 1: Relative economic value of DairyBio innovations



DairyBio is using a Zinc Finger Nuclease to cause a targeted mutagenesis, making a precise change to a DNA sequence—the 'delete' version of genome editing (known as ZFN1). This involves the deletion of a single or several base pairs in endogenous plant gene sequences followed by natural DNA repair with no sequence change elsewhere. In other words, there is no insertion of a foreign DNA sequence. The following list provides a snapshot of the use of this gene editing technology in programs that have commenced this year:

- ZFN1 will be used to deliver perennial ryegrass with increased digestibility and reduced risk of hayfever from pollen allergens.
- ZFN1 will be used to deliver endophytes for pasture/forage applications targeting reduced production of toxic tremorgenic (affecting central nervous system) alkaloids.

Dairy farmers will benefit from a 2MJ increase in metabolisable energy concentration per kilogram in pasture as a result of the ZFN1 technique to reduce the indigestible parts of forage plants. The improved nutritive value of pasture has a modelled benefit of $315/ha/yr, which is presumed to drive an adoption rate of over 90% of farm businesses within 12 years of market entry, delivering an annual productivity gain of $235 million. Productivity gains will be shared across the supply chain, and if this distribution is consistent with recent productivity gains, we can project that consumers will receive $43M, the processing and distribution sector $12M, with farmers retaining $180M (based on the target markets made up of 90% Vic/NSW and 10% Tasmania).

Further economic benefits will be delivered from reducing the risk of animal toxicity from the presence of fungal endophytes and from reducing hayfever by modifying ryegrass pollen.

The examples summarized above demonstrate the dairy industry's immediate interest in new breeding techniques—particularly ZFN1 at this stage (categorised as a 'site-directed nuclease' in the OGTR paper, abbreviated to SDN1). Some of the products resulting from these innovations may be ready for commercialisation in just five years.

However, the commercial viability of varieties incorporating the use of ZFN1 hinges, at least in part, on the regulatory framework governing their use. An alternate investment scenario has been modelled and demonstrates that a premature exit of the proposed genome editing projects would reduce the benefits from the current portfolio of investment in pasture improvement by 27%.

Regulatory resolution is critical to ensuring new innovations have a place in the Australian dairy farming system.

4 Response to consultation questions

To remain internationally competitive, the dairy industry needs access to forages and crop types that are reliably productive under increasingly extreme climatic pressures and pressures from pests and diseases. Plant breeding will continue to play a critical role in meeting these challenges, however it can only do so under appropriate regulatory frameworks that are assessed low risk and evidence-based, proportionate and globally-harmonised. New innovations carrying no more risk than those currently exempted from GMO regulation should also be exempt.

4.1 Option analysis

Following is the dairy industry analysis of the four options outlined in the OGTR paper, in support of option 4:

Option 1: status quo i.e. no amendment to the Gene Technology Regulations 2001.

- This lacks legal clarity. Technology has developed beyond what was imagined in 2001, as has scientific terminology. Stakeholders would therefore continue to have differences of opinion about how to interpret the exclusions from regulation and disputes would arise. Commercialisation of new products would be hampered by unnecessary time and cost constraints and as the path to market is uncertain, new technologies are unlikely to be delivered into dairy farm systems in this country.

Option 2: regulate all new gene editing techniques as GMOs.

- This would provide legal clarity.
- However, the scientific basis for regulating the full span of new gene editing techniques is difficult to establish:
    i. The new techniques result in changes that are identical to, or indistinguishable from, those resulting from conventional breeding or natural mutation.
    ii. These existing processes are already excluded from regulation.
- The new techniques in the regulations (such as conventional breeding or natural mutations) do not pose any new or different risks to humans or the environment. Because the resulting organisms are indistinguishable from naturally occurring mutants or those resulting from techniques that are not considered gene technology, sequencing would not be able to reveal what technique had been used to effect the change, making compliance impossible to enforce. This not only affects the ability of OGTR to perform its role, it may also have a significant impact on international trade.
- None of the methods set out in the OGTR discussion paper pose any differing risk than methods such as electromagnetic radiation, particle radiation, and chemical induction, which cause numerous and random changes to the genetic makeup of plants, but are excluded from the regulations[4].

Option 3: exclude from regulation those specific techniques known as SDN 1.

- This would provide legal clarity for researchers and the dairy industry and adheres to Australia's overarching 'process-based' policy settings.
- Organisms that are indistinguishable should be regulated in the same way. The changes made by use of SDN1 are indistinguishable from mutations that can occur spontaneously or in mutation breeding. Risks posed would not be different to naturally mutated organisms—which are already excluded from the definition of GMO—and the problems associated with enforcement are resolved.

- However, all other new gene editing techniques would be regulated as GMOs. Where the resulting organisms are indistinguishable from those resulting from techniques that are not considered gene technology, the problem of enforcing compliance (as in Option 2) remains in relation to those techniques.
- Furthermore, given the evolution of scientific endeavour in this field, the narrow focus of this option may mean subsequent reviews of other techniques may be required in the short term, making an Option 3 decision inefficient (and costly for both government and industry stakeholders).

Option 4: Exclude organisms from regulation where they are indistinguishable from products of techniques that are not gene technology.

- This would provide legal clarity. Organisms that are indistinguishable should be regulated in the same way since they present the same risks.
- However, the dairy industry understands that, in keeping with the 'process' regulatory trigger, specific techniques or organisms would be excluded rather than providing broad exclusions based on the properties of the final organism.
- The option proposes to exclude SDN 1 and SDN 2 techniques along with oligo-directed mutagenesis techniques from the regulatory scheme, while SDN 3 techniques would be considered gene technology.
- The dairy industry understands that the challenge lies in supporting a clear legal distinction between specific techniques. This could be addressed by amending the definitions in the schedules to the Gene Technology Regulations 2001.
- The concern noted in the discussion paper about successive rounds of use of new breeding techniques is inconsistent with commercial practice – where repeated rounds of breeding with techniques excluded from regulation is a routine approach and does not lead to any justification for querying the exclusion of the technique.

The dairy industry advises that Option 4 represents a scientific risk-based response and is the preferred way forward. Organisms that are indistinguishable should be regulated in the same way. Those gene editing techniques that result in products that are indistinguishable from those derived from techniques that are excluded from the regulatory scheme should also not be regulated.

The dairy industry recognises that trust and transparency are hallmarks of the dairy food supply chain and understands that consumers support adequate regulation where risks are posed. Regulating the full spectrum of gene editing techniques as if they were GMOs gives the message that they carry the same risks. Where they do not pose different risks to conventionally bred organisms, they should be excluded from GMO regulation.

If the OGTR strikes technical legal difficulties with implementation of Option 4, then Option 3 would at least provide legal clarity for the current (but not necessarily future) dairy R&D endeavour and secure a regulatory path to market for the products coming out of the current R&D pipeline, commensurate with scientific risk, in the short term.

Option 1 does not resolve the critical issues of achieving legal clarity for scientists and industry going forward. Moreover, the scientific basis for Option 2 is difficult to establish.

The dairy industry anticipates that the report of the OGTR review would comprehensively canvass and explain the pros and cons of each option.

4.2 Harmonisation

The outcome of this review will be clarification of what constitutes a "genetically modified organism" and what is excluded from that definition. This reform needs to be reflected throughout Australia's national scheme for gene technology—i.e. in the legislation and regulations administered by FSANZ,

APVMA, NICNAS, TGA and DAWR's Quarantine Division as well as in legislation enacted in states and territories—to ensure harmonisation of definitions and exclusions across all regulatory agencies.

4.3 Regional leadership

An Australian decision to exclude new gene editing techniques from regulation on the basis of sound scientific risk assessment provides leadership to neighbours and trading partners to follow suit with their own scientific risk-based approach to regulating the techniques of modern biotechnology.

4.4 Review of policy settings and the *Gene Technology Act 2000*

Though outside the scope of this particular review, its instigation clearly suggests that Australia's national scheme for gene technology is no longer wholly fit-for-purpose and warrants review.

The dairy industry calls for a robust review of Australia's policy settings for gene technology and a review of the *Gene Technology Act 2000* as soon as possible to ensure contemporary fit-for-purpose arrangements are in place that do not impede innovation, but instead facilitate access to new and safe technological innovations so critical to dairy industry competitiveness.

A review of the Act must consider the broader implications of the current gene technology policies, including their impact on creating social perceptions that are inconsistent with the experience gained from 20 years of global use of gene technology.

[1] http://www.dowagro.com/en-us/newsroom/pressreleases/2016/12/milestone-achievement-continues-for-dow-agrosciences-and-agriculture-victoria#.WEi-CeZ96Uk
[2] http://www.adssymposium.com.au/inewsfiles/2014proceedings/40WimsADSS2014.pdf
[3] http://www.grassland.org.nz/publications/nzgrassland_publication_480.pdf
[4] Refer to Schedule 1 of the OGTR Regulations (2001) https://www.legislation.gov.au/Details/F2016C00615