

**Pastoralists and Graziers
Association of W.A. (Inc)**

And

Generic Agricultural Chemical Association

**Submission to the Senate Select
Committee on the Free Trade
Agreement between Australia and the
United States of America**

May 2004

Introduction

The Pastoralists and Graziers Association (PGA) of WA has a large and growing grain producer membership in Western Australia, represented by the PGA Western Graingrowers Committee (WGG). Currently the PGA have about 1900 individual members in the Western Australian wheatbelt area producing 2 million tonnes of wheat. The PGA is a full member of the National Farmers Federation (NFF) and have been at the forefront of policy development nationally as well as locally.

Aims of the PGA Western Graingrowers Committee:

- To achieve an open and competitive environment for all sectors of the Australian grains industry.
- Encourage State and Federal Government to formulate policy and initiatives which enhances competition and growth in the Australian grains industry.
- Support all areas of research & development which fosters new technology and improves farming systems for the Australian grains industry.

The Generic Agricultural Chemical Assn (GACA) was formally established in March 2004 with 15 inaugural members made up of businesses involved in the generic agricultural chemical industry. Members include manufacturers, resellers, importers, distributors and drum recyclers. Another 70 potential members have indicated their interest in joining the GACA in the coming year. Please see a list of GACA members in appendix 1.

This submission addresses only the Intellectual Property Rights Chapter (17) of the US-Australia Free Trade Agreement (AUSFTA). Both the PGA and the GACA seek to bring to the Committee's attention certain concerns about this chapter relating to agricultural chemicals. We do not see to address the broad balance of costs and benefits in the entire agreement.

US-Australia FTA Agreement: Chapter 17 - Intellectual Property Rights Article 17.10

The area we will be focussing on in this submission is Chapter 17 - Intellectual Property Rights Article 17.10 (b)). In particular the changes to 'off-patent' Agricultural and Veterinarian Chemicals (Ag Vet Chemicals) which now will protected for an additional 10 years over and above their patented rights.

These change will have a devastating effect on the independent generic chemical companies which provide competitively priced chemicals to farmers. The changes proposed in the FTA agreement will delay the entry of generic chemical companies into the market hence allowing the large multinational companies to enjoy a competitive free environment for an additional 10 years, which will result in lack of competition, reduced innovation and higher costs of chemicals for farmers, who are the end users. We also want to dispute claims that this proposed time frame for data protection is consistent with the reforms already being developed by the government. The data protection proposal prior to the FTA was strongly opposed by both PGA and GACA, who are two key stakholders in the legilsation.

In the context of this submission we ask that the Senate Committee to consider taking the important issue of data protection out of the FTA agreement or set aside Chapter 17 of the FTA from the broader agreement. This will allow Australia to set our own laws which best serve our market and stakeholders.

Data Protection and Effect on Australian Farmers

This submission focuses on the key issues surrounding the data protection time lines negotiated in the AUSFTA and the implications for Australian farmers and the internationally competitiveness of our agricultural products.

1. Extending the data protection for off patent chemical will drive up the price of Ag vet chemicals by decreasing competition and innovation in the Australian market.

1.1 Competition in market

The National Farmers Federation have been working on the area of data protection for some time and the NFF Farm Chemicals Sub-Committee wrote "Data Protection Position Paper" prepared in response to AFFA's Paper "Data Protection: Consultation on Issues and Refinements" 6 September 2002. Which stated:

NFF believes that the findings of AFFA's Study Tour (AFFA (2002) Data Protection - Overseas Study Tour Report) provide clear justification why the length of the exclusive data protection provided to 'new chemistry' within Australia should be significantly less than comparable protection periods within countries such as the UK and US. The principal reason relates to the need to continually promote competition and to drive innovation within Australia's limited market for agricultural and veterinary chemicals (1.8% of global agricultural chemical market). NFF believes that the presence of generic manufacturers within all market sectors is imperative in maintaining competition and in driving product development, within what represents a limited market. AFFA's Study Tour clearly highlights the detrimental effect that excessive exclusive protection periods can have on the presence of generic manufacturers within markets (eg: US and EU markets). On this basis, NFF contends that the Australian market could not sustain such levels of protection without leading to unacceptable fundamental structural changes.

Over the last 8 years, there has been a significant rationalisation in the number of farm input companies manufacturing and supplying chemical and fertilizer products to Australian farmers. Market restructuring have resulted in significant concentration of market power with a number of major farm input companies¹.

According to a paper prepared by the Summers and Jocusen (2002)² of the University of Queensland, 90% of all existing sales in the Ag Vet chemical area are currently attributed to the large multinational companies while the remaining 10% is made by smaller local firms. Of these small generic companies (more than 700 individual companies) nearly half have only one registered product and the remainder have five or less registered. Summers and Jocusen (2002) conclude with a handful of large multinational companies controlling 90% of the market, increasing data protection (as proposed by the AUSFTA) will only result in more control and power in the Ag vet chemical market. This will more than likely result in marginalising the small local generic companies, many of whom serve niche markets and majority of which have sales less than \$10,000 per year.

The new data protection agreement will increase the compliance costs to the generic companies. Previously generic companies had a process where they had to prove that a generic chemical they manufactured was similar to the patented product (e.g. that generic Glyphosate was similar in make-up to Roundup®). The new data protection regime will require them to produce the exact 'recipe' for this product which will involve the generic companies to go through the same procedure that the multinational company did when they introduced the product to the new market. This includes the many health and safety tests and trials, which is 'reinventing the wheel' as all these tests were carried out before the patented product was released into the Australian market. This aspect of the data protection was never proposed at any time by DAFF or any of the major stakeholders when investigating changes to data protection legislation.

The AUSFTA is imposing the United States data protection periods upon Australia – the very thing that will be detrimental to our competitive agricultural chemical market.

1.2 Price effect

There are significant differences between the price Australian farmers and American farmers pay for well known chemicals.

Example 1. Average Retail Price of Glyphosate (commonly known as Roundup®) April 2004 (all prices in \$A dollars)³

United States of America	= \$16 per litre
Australia	= \$5 per litre

Example 2. Difference in price of off patent chemicals

Bifenthrin, came off patent this earlier year, the price went from A\$170/kg (when on patent) to only A\$70/kg as an off patent product⁴.

There are several reasons for the extraordinary difference between the two markets in Example 1. The first that the US Data Protection laws are much stricter than the current Australian laws and allows multinational companies to keep extending their protection on chemicals once their patent protection runs out. After the 20 year patent runs out major chemical companies can extend their patent for up to 16 years

¹ Source: NFF Farm Costs and Farm Competitiveness Discussion Paper 2004

² Response to a report on the impact of proposed data protection for Agvet chemicals proposed by the Department of Agriculture, Fisheries and Forestry – Australia by Dr Jane Summers and Dr Graham Jocusen, May 2002

³ Source: John Firth, 4Farmers Pty Ltd

⁴ Source: Gharda Chemicals Ltd

– meaning 36 years of protection for that product. This is why the PGA, GACA and the NFF were pushing for a shorter data protection time periods than the USA currently have.

Another significant reason these two prices are different is the US market place is distorted by government subsidies to farmers. Companies will price according to what their customers will pay. Australian farmers have no subsidies to aid payment for input costs like chemicals, they survive in a distorted world market by keeping their input costs minimal. The competitive generic chemical market has evolved to meet the Australian farmers requirements and needs to remain for Australian farmers to stay internationally competitive.

Example 2. demonstrates how protective the patent system is on the price of products and the dramatic effect that generic competition can on reducing the price when chemicals come 'off patent'.

Summers and Jocumsen (2002) suggested that in the current Australian market with 90% of the market controlled by big players, *“increasing data protection time frames...(may mean) there is most likely to be an upward pressure on prices to reflect market power and not a price neutral impact as speculated in the DAFF report (2002).”*

Significant Cost of Chemicals as an input cost WA Farmers

According to the 2002/03 Bankwest Benchmarks⁵ the average chemical costs (over the last five years) for broad acre farmer makes up 14% of total input costs. The average cost per hectare (over all crops grown) was \$148 with pesticides and herbicides costing an average \$37/ha. The NFF (Farm Costs and Farm Competitiveness Discussion Paper 2004) estimated farm chemicals, including agricultural and veterinary products and fertilisers, at around 10% of farm input costs on an average Australian farm (across all sectors). Both of these figures indicate that Ag Vet Chemicals are a key input cost and any significant increase in price of this input will have major impact on gross margins and viability of a crop.

1.3 Innovation in market

Increasing the data protection time frames will also have an impact on innovation in the Ag vet chemical market. The PGA and GACA are not trying to limit patented rights, but we take objection to large multinational companies trying to gain additional protection over old products. These 'off-patent' products have no new technology or modifications and protecting them for long periods of time is simply a delaying tactic by large chemical companies and stifles innovation in the market by generic and other companies.

The effect of the extended data protection periods in the AUSFTA will be not be felt for at least 4-5 years when the Australian ag vet chemical market will see no new products from generic manufacturers, who will be restricted by the 10 year protection period.

If Australia loses its generic companies, due to 10 years data protection, it will end new use patterns which have been essential to maintenance of Australian farmers to compete without subsidies. 'New Use Patterns' are simply new ways of doing certain things for example in Australia the use of minimum tillage when putting in a crop is a new use pattern in broad acre farming. Generic companies have a good record of coming up with new ways to improve the way farmers use 'old' products. Each patented chemical has a label which gives recommended applications but what

⁵ Bankwest Benchmarks are a survey of the financial and production performance of West Australian farm businesses which involves the collation of over 55,000 individual pieces of data and includes farm businesses with a combined land holding of almost 1.3 million hectares.

generic companies have done is to adapt the application, or the time of application to suit the Australian market. Australian total sales of agricultural chemicals only make up 1.8% of the world market which is not a big incentive for large multinational companies to apply the same type of innovation. The generic companies drive the innovation in Ag vet chemicals in the Australian market and this innovation would suffer under the proposed data protection timelines.

2. The FTA overrides much of the work done by various stakeholder groups on Australian legislation in this area.

Significant work has been done since 1998 on drafting new legislation dealing with data protection of Ag vet chemicals. Many stakeholders (including the PGA and NFF) have been involved in providing feedback for this process.

2.1 Two major stakeholders were opposed the proposed legislation which will be required to be passed in order for this AUSFTA agreement to be implemented in Australia.

In the 'Guide to Australia-United States Free Trade Agreement' (DFAT 2004) it states:

*"The Parties have agreed to provide a period of 10 years protection to...a new agricultural product.... **This is consistent with the reforms already being developed by the Department of Agriculture, Fisheries and Forestry in consultation with State and Territory partners involved in the National Registration Scheme for Agricultural and Veterinary Chemicals, and with industry and other stakeholders.**"*

In the Centre for International Economics Analysis of the AUSFTA agreement (CIE, 2004) it states:

*"legislative changes will be required to extend the data protection period for agricultural chemicals, **these changes are consistent with the proposed system already under consideration.**"*

Both highlighted statement are not correct as Department of Agriculture, Fisheries and Forestry (DAFF) did not have approval from major stakeholders in the farming sector and industry to their proposed legislative changes.

According to DAFF "the agreement between the Commonwealth and the States and Territories establishing the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) requires the Department (DAFF) to consult with all parties to the agreement on changes to agricultural and veterinary chemicals legislation. The Department also consults with the States and Territories on any policy issues relating to the NRS."⁶

In June 2003 members from the PGA and the John Firth, of 4Farmer Chemicals (now a member of the GACA), met with DAFF and WA Department of Agriculture staff to discuss the proposed changes to the legislation. **The PGA's and the National Farmers Federations originally opposed the proposed changes in timelines for data protection.** The legislative proposal was also not in line with the GACA's timeline proposal, which was agreed by the PGA and NFF, of 4 years protection for agricultural chemicals and 2 year protection for veterinarian products. The WA Farmers Federation (WAFF) are also categorically opposed to the AUSFTA timelines and did not agree with DAFF proposals. The PGA and GACA have not seen a draft

⁶ Department of Agriculture Forestry and Fisheries Website 2004, Regulation of agricultural and veterinary chemicals <http://www.daff.gov.au/content/output.cfm?ObjectID=6EDD7B1F-6B85-4582-B5D3DE4A8AC19849#relationship>

of this legislation since and can only assume it has remained unchanged and at odds with what Western Australian farmers and the generic chemical companies require.

The NFF were also been heavily involved in providing feedback to the proposed changes but made a final decision on the data protection time frames in the context of deciding to support or reject the AUSFTA. The representative to the NFF from the PGA disagreed with the decision which is noted in the NFF Farm Chemical Sub Committee Minutes in February 2004.

2.2 The AUSFTA make no distinction between the three classes of chemicals DAFF have written legislation for. The AUSFTA takes a 'broad brush' approach to data protection and ignores the careful work that gone on between major stake holders and DAFF.

In the draft proposal by DAFF they defined three classes of chemicals, please see Appendix 2 for the more detailed description of these classes. The AUSFTA does not acknowledge these the unique differences between the three classes and the different legislative requirements proposed for each. DAFF have spent significant time investigating the best arrangement for the Australian market and industry, all of which will be thrown out if the AUSFTA data protections time lines are implemented.

3. The AUSFTA will restrict the ability of Australia's parliament to legislate on certain areas (including data protection) of Intellectual Property.

Below is an extract from the Office of the United States Trade Representative as a Summary of the AUSFTA to the American public⁷.

*(AUSFTA) Provides for the extension of patent terms to compensate for delays in granting the original patent, **consistent with U.S. practice.***

- *Limits the grounds for revoking a patent, thus protecting against arbitrary revocation.*
- *Clarifies that test data and trade secrets submitted to a government for the purpose of product approval will be protected against unfair commercial use for a period of 5 years for pharmaceuticals and 10 years for agricultural chemicals. Closes potential loopholes to these provisions.*
- *Requires measures to prevent the marketing of pharmaceutical products that infringe patents, and to provide notice when the validity of a pharmaceutical patent is to be challenged.*
- *Assures protection for newly developed plant varieties and animals.*

This extract shows that the AUSFTA was negotiated to be consistent with existing US laws. As pointed out earlier in this paper, these laws if implemented in Australia, they have the potential destroy the generic companies that exist in Australia and the beneficial competition that goes along with their presence in the market.

The Senate Committee should recognise that 6 years of work has gone into the drafting of the new legislation (which goes into much more detail of data protection than discussed in this document). The PGA and GACA want the drafting of the legislation to proceed without outside interference and restrictions from the US. These laws should be formed, debated and legislated by Australian parliament to meet the needs of the Australian community and industry.

⁷ Extracted from <http://www.ustr.gov/releases/2004/02/2004-02-08-factsheet-australia.pdf> Patents & Trade Secrets: Stronger Protections Pages 6

4. Pharmaceutical products (including animal veterinarian products) receive 5 years data protection while Agricultural Chemicals have 10 years protection which is unfair discrimination against Ag Chemical users versus those that use animal veterinarian products.

Conclusion

As stated at the beginning of this report the PGA and GACA have not set out to provide a full analysis of the AUSFTA. We have focussed on Chapter 17, Intellectual Property and the alarming implications the new data protection timelines proposed in the AUSFTA will have on Australian broad acre farmers. We understand that this forms a small part of the entire AUSFTA but we stress that significant work had gone into formulating new legislation in this area which allowed Australia to retain an innovative and competitive Ag Vet Chemical market. We would like to continue with the formulation of this legislation without the interference of the United States through the AUSFTA and we ask that data protection be taken out of the Intellectual Property Chapter or the entire Chapter be set aside for re-negotiation. We thank the Committee for the opportunity to make this submission, and if you require more information regarding the arguments outlined above please contact either of the people below who have worked on this submission and both have extensive knowledge in this area.

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Appendix 1: List of Generic Agricultural Chemical Association

ChemAg
Drum Services
Opal Manufacturing
Quadrant Manufacturing
Imtrade AgroSciences
Conquest AgroChemicals
Binary Industries
Gulmohar
Kenso
4 Farmers
United Farmers
Loral Ipsum
Western Stock Distributors
Summit AgroChemicals

Appendix 2. Extract from Department of Agriculture, Fisheries and Forestry ‘Data Protection Policy Paper’ (pg 11-18)

PROPOSED DATA PROTECTION SCHEME

For the purposes of the Agvet Code, information protection will be divided into three separate streams - referred to as ‘classes’:

Class A: generally relating to protected information provided by an applicant for the purpose of a determination to:

- grant an approval of an active constituent; and
- register certain chemical products (**associated chemical products**); and
- approve labels for containers of chemical products that are associated chemical products;
- provided that none of the active constituents, chemical products or labels had been approved or registered previously in Australia.

Class B: generally relating to protected information provided by an applicant for the purpose of a determination to:

- register a chemical product, other than an associated chemical product;
- approve a label, other than the first label, or vary a label or vary the conditions of a label of a container for a chemical product that is an associated chemical product;
- vary an approval, or vary the conditions of an approval for an active constituent;
- vary a registration, or vary the conditions of a registration for a chemical product;
- other than a determination relating to an approval or registration relating to use on non food-producing animal species.

Class C: generally relating to protected information provided by a registrant for the purposes of a determination, as set out in the relevant provisions in Part 2, Division 4 (Reconsideration) of the Agvet Code, to:

- affirm an existing approval, or vary an existing approval, or vary the conditions of an existing approval of an active constituent; and
- affirm an existing registration, or vary an existing registration, or vary the conditions of an existing registration of a chemical product, and
- affirm an existing approval, or vary an existing approval, or vary the conditions of an existing approval of a label for a container of a chemical product.

An **associated chemical product** is a chemical product that meets the following criteria:

- an application has been made for registration of the chemical product, containing an active constituent (*the relevant active constituent*), for which an application has been made for Class A protection (both applications per section 11 of the Agvet Code); and
- the APVMA has accepted the application for registration of the chemical product containing the relevant active constituent (per new section 11A of the Agvet Act

2003); and

- each application for registration of an associated chemical product is made by the same applicant who applied for the approval of the relevant active constituent; and
- the application has been made, and accepted by the APVMA, before its determination relating to the first approval of the relevant active constituent.

Any application which has not been made, or accepted, by the time of the determination relating to the first approval of the relevant active constituent will not be considered as an associated chemical product.

CLASS A

Class A – Information that will gain protection

Class A protection will apply to protected information provided by a primary applicant⁸ for the purpose of a determination within Class A as indicated above.

Class A protection will also apply to any protected information submitted by a subsequent applicant⁹ for the purpose of the same active constituents, and/or any chemical product that would be an associated chemical product.

Class A - The basic period of protection

Except as specifically otherwise provided, the APVMA will not be permitted to reference Class A protected information for the purposes of any other determination in favour of another applicant for a period of eight years (the base period of protection for Class A) commencing upon the date of the APVMA's first determination to either grant approval for the relevant active constituent or to registration of the associated chemical products (as the case may be).

Class A – Extending the basic period of protection

An extension to the base period of protection for Class A protected information may be granted under the following framework¹⁰:

- upon a determination, following an application by a registrant to approve a label, or to vary a label, to include a non-major use in a label, which would be a successful determination relating to each fifth non-major use, the basic data protection period for all Class A protected information relating to the approval of the relevant active constituent, the registration of the associated chemical product and approval of the first label for a container of a chemical product that is an associated chemical product, will be extended by one year;
- the base protection period for Class A information may be extended by no more than 3 consecutive periods of one additional year;
- all protected information used for the purpose of an approval of the first label, or the variation of the label, to include a non-major use in a label of an associated

⁸ Subsequently the approval holder and the registrant.

⁹ This is most likely to occur in cases where parties seek to gain approval/registration for active constituents and associated chemical products that are well established overseas but which are yet to be approved by the APVMA for use in Australia.

¹⁰ Refer to Class B for additional conditions for eligibility of determinations that may extend the base period of protection for Class A protected information.

chemical product, will receive Class A protection;

- only those applications for an approval of a label, or a variation of the label that are submitted and accepted by the APVMA prior to the first determination of the approval of the active constituent will receive the benefit of the extension to the Class A protection period.
- **NOTE:** all protected information used for the purpose of approval of a label, or the variation of a label, that includes a non-major use in a label for a chemical product, other than an associated chemical product, will receive Class B protection;
- the definition of ‘non major use’ will be defined taking into account the relevancy and viability of the non-major use to Australian agricultural practice.

CLASS B

Class B – Information that will gain protection

Class B protection will apply to protected information provided by an applicant for the purpose of a determination as indicated above.

Class B - The basic period of protection

Veterinary chemicals

Except as specifically otherwise provided, the APVMA will not be permitted to reference Class B protected information for the purposes of any other determination associated with **veterinary** chemical products for a period of three years commencing upon the date of the relevant determination falling within the scope of Class B for which the required information was submitted.

- Note: Veterinary chemicals that are for use on non food-producing and fibre species are excluded from Class B protection.

Agricultural chemicals

Except as specifically otherwise provided, the APVMA, will not be permitted to reference Class B protected information for the purposes of any other determination associated with **agricultural** chemical products for a period of five years commencing upon the date of the relevant determination falling within the scope of Class B for which the required information was submitted.

Class B – Extending the basic data protection period

There will be no capacity to extend the basic protection period for Class B information.

Class B – Capacity of a Class B determination to extend Class A protection

A key element of the new data protection regime is the introduction of an incentive scheme whereby certain determinations falling within the scope of Class B will be able to be used to extend Class A protection for relevant protected information.

The benefit from the incentive scheme will be derived under the following mechanism:

- any determination relating to an application to approve a label, or to vary a label, to include a non-major use in a label will be eligible for the purpose of deriving an

extension to Class A protection;

- an eligible application, can only be an relevant eligible application, if a determination to approve a label, or to vary a label, to include a non-major use¹¹ in a label is lodged with the APVMA within six years from the date of the determination to approve the relevant active constituent;
- each eligible application will be assessed on its own merits in accordance with the provisions of section 11A of the Agvet Act 2003;
- upon a determination, following a relevant eligible application by a registrant, which would be a determination that would cause the inclusion of each fifth non-major use in a label, the base period of protection for all Class A protected information relating to the previous approval of the relevant active constituent, the previous registration of the associated chemical product and the approval of the first label of a container for a chemical product that is an associated chemical product, will be extended by one year.
- Any determinations that cause the inclusion of any first four of any sequence of five ‘non-major’ uses will not provide any additional benefit to any Class A protected information.
- No additional benefit will be derived for Class B protected information associated with a determination to approve a label, or to vary a label to include a non-major use from the incentive mechanism.

CLASS C

Class C - information that will gain protection

Class C protection will apply to protected information provided by an applicant for the purpose of a determination as indicated above.

Class C – The basic protection period

Except as specifically otherwise provided, the APVMA, will not be permitted to reference Class C protected information for the purpose of any other determination for a period of 10 years from the date of the APVMA’s first determination for which the protected information was used.

Class C - Information Ownership

With regard to Class C, the identification of the party (the authorising party) who has the authority to grant authority to the APVMA to use Class C protected information (and associated determinations) is critical to the efficient delivery of the cross-referencing element of the data protection regime.

Any authorising party responsible for protected information that has been granted Class C protection must grant authorisation for the APVMA to use that protected information, should a request be made by another party under this scheme for the APVMA to do so. Each party seeking authorisation for the APVMA to use the protected information for the purpose of a determination by the APVMA must compensate the authorising party per terms that they mutually agree or are otherwise determined via arbitration under this scheme.

¹¹ i.e. those not identified in the list of major uses

Consequently:

- each party who submits required information to the APVMA for the purposes of a reconsideration will be required to declare details of the authorising party responsible for each piece of information, regardless of whether that information is ultimately granted protection under Class C as a result of a determination following a reconsideration (as an extension of the provisions that require a person to provide information falling within the scope of Class C);
- each party, that submitted required information for the purposes of a reconsideration, must ensure that the information concerning the identity of each authorising party remains current:
 - changes to the details must be notified within 30 days to the APVMA;
 - there will be a potential for protection to be voided if the owner can not be identified by the APVMA (procedural elements to be established, including appeal provisions);
 - penalty provisions may apply for non-provision of the necessary information on ownership of information to ensure that the Protected Information Register is kept up to date;
 - the requirement to keep current the details of each authorising party, who is responsible for information that is required information but is not included in the Protected Information Register as a result of a relevant determination made by the APVMA, is voided once the APVMA makes that determination;
- the identity of each authorising party for each piece of required information, submitted for the purposes of the reconsideration, may be disclosed by the APVMA upon request;
- the details of each authorising party for each piece of information granted Class C protection will be included in the Protected Information Register at the time that the determination is made.