National Competition Policy Review

Agricultural and Veterinary Chemicals Legislation

Inter-Governmental Response

January 2000

Contents

1. Executive Summary

This document contains the inter-governmental response to the recommendations of the independent National Competition Policy (NCP) of agricultural and veterinary (agvet) chemicals legislation.

The review Report presents a thorough and clear analysis of legislation governing the National Registration Scheme for agvet chemicals and the control of use arrangements in Victoria, Queensland, Western Australia and Tasmania.

The review was originally scheduled to commence in 1999. However, on the 24 March 1997 the Prime Minister, with the agreement of all jurisdictions, brought forward the review as part of the Commonwealth Government's response to the report by the Small Business Deregulation TaskForce. The aim of the TaskForce, Chaired by Mr Charlie Bell, was to produce a report recommending ways of reducing the compliance costs and paper work burden on Australian businesses, in particular small business. The recommendations contained within the Report offer substantial potential benefits to small business in Australia.

The review is the first truly national NCP review to be undertaken in Australia. As a national review, several of the restrictions on competition identified in the Report are directly related to inconsistencies between the operation of similar legislation in different jurisdictions. Some key issues present throughout the report, reflected in the recommendations, and considered in this inter-government response are:

- the extent to which monopoly provision of registration services is cost effective and maintains Australia's credibility on world markets in respect of chemical matters;
- the opportunities for increased levels of contestability in the purchasing of assessment services either by the NRA or by potential registrants;
- the potential efficiency effects of the current cost-recovery arrangements for the National Registration Authority for Agricultural and Veterinary Chemicals (NRA);
- the opportunities to reduce costs to registrants in areas such as low risk chemicals;
- the need for data protection to protect the commercial investment of chemical registrants in data required for registration purposes; and
- the need for national harmonisation of regulation governing the use of agvet chemicals.

1.1 The Review

The review was commissioned by the Victorian Department of Natural Resources and Environment on behalf of all State and Territory Governments and funded by all Governments according to a SCARM approved funding formula. Overseeing the project was a multi-jurisdictional Project Team comprising Victorian, Western Australian and Commonwealth Government representatives.

A Steering Committee comprising the Chief Executives of the Victorian Department of Natural Resources and Environment, the Department of Agriculture, Fisheries and Forestry-Australia and Agriculture Western Australia considered the final draft report and determined that it adequately addressed the review's terms of reference.

The review was conducted by independent consulting firm PriceWaterhouseCoopers, and was completed in January 1999. It covers the Commonwealth, State and Territory legislation that establishes the National Registration Scheme (the scheme) for agvet chemicals as well as the control of use legislation in Victoria, Queensland, Western Australia and Tasmania. The review does not cover control of use legislation in New South Wales, South Australia or the Northern Territory — these legislations are subject to separate NCP reviews by the respective jurisdictions. A full list of the legislation subject to this review is contained in the Report.

The Terms of Reference for this review were approved by SCARM/ARMCANZ and the review was conducted in accordance with the Victorian Government's *Guidelines for Review of Legislative restrictions on Competition.* These guidelines provide administrative and methodological guidance for conducting reviews of legislative restrictions on competition in accordance with the *National Competition Principles Agreement.*

The guiding principle underlying legislation review is that legislation should not restrict competition unless it can be shown that the benefits of the restriction to the community as a whole outweigh the costs and that the objectives of the legislation can only be achieved by restricting competition.

In order to determine the extent to which the legislation under review is consistent with this guiding principle, the review team were required to undertake eight key analytical steps as follows:

- clarify the objectives of the legislation;
- identify the nature of the restriction on competition;
- identify and consult with the groups likely to be affected by the legislation;
- analyse the likely effect of the restriction on competition and on the economy in general;
- examine the need to promote greater integration of the different regulatory restrictions;
- assess the net public benefit of each restriction;
- identify relevant alternatives to the legislation, including non-legislative approaches; and
- assess the net public benefit of the alternatives.

Public consultation was a central element of this review. Public submission were called for via advertisements placed in the major daily newspaper in all capital cities, and an Issues Paper was mailed to all key stakeholders. The review team had discussions with several stakeholders and 39 written submissions were received.

The review identified several restrictions on competition in the legislation under review and made 20 specific recommendations. These recommendations can be broadly divided between those relating to the registration scheme (recommendations 1-11) and to the control of use legislation of Queensland, Western Australia, Tasmania and Victoria. See Summary Table (pages 5-8).

1.2 The Response

The report was considered by SCARM/ARMCANZ in February 1999. ARMCANZ agreed to the establishment of a Signatories Working Group (SWG) with responsibility for drafting a response to the NCP review of Agricultural and Veterinary Chemicals legislation. It was also agreed at ARMCANZ that the National Registration Authority would provide technical and policy advice directly to the SWG.

The SWG considered the recommendations individually and the inter-governmental response to each recommendation is presented in the following pages in the order in which they are presented in the report. A table summarising the restrictions identified by the review team, their recommendations and the inter-governmental response to those recommendations follows.

1.3 Summary Table

Restriction on competition	Recommendations	Response
The registration monopoly: The adoption by all States and Territories of the Agvet Code as law in their jurisdiction and the adoption of the NRA to administer the Agvet Code creates a monopoly by establishing a single provider of registration decisions in the NRA (the single provider). A legislative monopoly is a restriction on competition.	1. *The Review Team recommends retention of a single provider of registration decisions in Australia.*	Recommendation 1 is supported
Low risk chemicals: The ambit of the Scheme and the registration process does not significantly differentiate between categories of risk, leading to producers of low risk chemicals incurring largely the same cost as high risk chemicals. There may also be chemicals inappropriately included in the Scheme. The imposition of any unnecessary compliance costs (and fees) on manufacturers of low risk chemicals restricts competition by discouraging them from entering or remaining in the market. This issue is of particular concern for small businesses.	2. *The Review Team recommends that the Agvet Code be altered to specifically provide for the identification of low risk chemicals, hence enabling potentially faster registration. This would enable unnecessary registration cost burdens on the manufacturers of these chemicals to be removed. The Review Team expects that for reasons of practicality the preferred outcome is likely to entail a form of pre-categorisation of chemicals.* 3. *The Review Team recommends that sections 4 and 5 of the Agvet Code be amended to provide guiding principles for the inclusion or exclusion of chemicals by regulation. These principles should emphasise the relevant risks that the Scheme was developed to manage, such as the risks arising from chemical use in agricultural and related activities.*	The intent of recommendations 2 and 3 is supported. An inter-jurisdictional Low Regulatory Activity Task Force has been established by SCARM to examine how best to regulate low risk chemicals.
Assessment services: The NRA purchases its environmental, health and OH&S assessments solely from the relevant Commonwealth bodies: Environment Australia, the TGA and NOHSC. There is no legislative requirement that restricts the NRA to purchase assessment services from these bodies. However, there is a practice of doing so which creates a restriction on competition by denying others entry into the market for the provision of these assessment services.	4. *The Review Team recommends that the NRA establish service agreements with its current suppliers and purchase assessment services on a fee for service basis.* 5. *The Review Team recommends that the NRA both accept alternative suppliers of assessment services and actively alert likely providers of this fact.*	Recommendation 4 is supported Commonwealth will establish a Working Group to examine all issues raised by Recommendation 5 associated with the provision of assessment services by alternative providers in accordance with the Competition Principles Agreement.
Efficacy review: Section 14(3)(f) of the Agvet Code is interpreted to require the NRA to satisfy itself that a chemical product's claimed efficacy is both true and appropriate. This involves regulation of product standards and is therefore a restriction on competition.	6. *The Review Team recommends that Section 14(3)(f) of the Agvet Code be amended to specify that efficacy review extends only to ensuring that the chemical product meets the claimed level of efficacy on the label.*	Recommendation 6 is not supported.

Full cost recovery: The operations of the NRA are essentially funded through application (or registration) fees, levies and annual renewal fees. While application fees are intended to be cost reflective (user pays), the levy and renewal fee burden varies depending upon the level of sales of each agvet chemical. This two pronged approach to funding the NRA creates two potential restrictions on competition: • the structure of the levy and the annual renewal fee results in discrimination between firms in respect of their contribution; and • application fees, being upfront fees, can pose a significant hurdle to smaller businesses and may discourage their involvement in the industry.	7 *The Review Team recommends that the levy be changed to a simple flat rate levy (on sales as at present) with no exemptions or caps. The annual renewal fee should be abolished and a nominal minimum levy liability (per registered product) set instead.* 8 *The Review Team recommends that application and other registration service fees be cost reflective.*	The Commonwealth will establish a Working Group to consider the appropriateness of current levies and renewal fees charged by the NRA and prepare final response to Recommendation 7. Recommendation 8 is supported.
Manufacturer licensing: Part 8 of the Agvet Code contains provisions that requires manufacturers of agricultural or veterinary chemicals to be licensed, unless the manufacture is of exempt products only. At present, manufacturers of agricultural chemical products are included among the exemptions. Licensing is a restriction on competition because it limits entry to the industry only to those holding a licence. Licensing may also restrict competition to the extent that it prescribes how manufacturers are to conduct their operations.	9 *The Review Team recommends the retention of licensing of veterinary chemical manufacturers. However, GMP should be optional for manufacturers of low risk veterinary chemicals, in line with the introduction of a low risk category of registration.* 10 *The Review Team recommends that the Agvet Code be amended to remove the present (albeit exempted) requirement for licensing of agricultural chemical manufacturers until the case for such an extension is made.*	The licensing of veterinary chemical manufacturers is supported, but the second part of Recommendation 9 is not supported Recommendation 10 is not supported at present. The provision should be retained in its exempted state until the Commonwealth completes a review of the need for the provision. Any activation would be conditional on satisfaction of requirements of a thorough Regulatory Impact Assessment.
Data protection: When a chemical is reviewed, the NRA may call upon a person, for example the manufacturer, to provide certain information regarding that chemical to support the continuation of registration. In certain circumstances the data is protected, requiring third parties to compensate the originator should they wish to benefit from the data (for example, to continue to register their image product). Data protection imposes a cost on persons wishing to utilise the data, in that they must pay compensation, and therefore is a *prima facie* restriction on competition. However, the absence of data protection may also restrict competition because the ability to free ride on information will reduce the incentive to generate it in the first place.	11 *The Review Team recommends that the compensation process provisions of the Agvet Code be modified to adopt the procedures and principles for determining third party access pricing under the various Codes in operation under Part IIIA of the Trade Practices Act.*	Recommendation 11 is considered to be adequately covered as part of the current Commonwealth review of data protection which will be presented to SCARM/ARMCANZ for consideration.

Control of Use

Off-label use: A combination of provisions in the Agvet Code and the various state control of use legislation authorise off-label use of agvet chemicals. The manner in which off-label use can occur varies markedly between the four states under review. The inconsistency restricts competition between growers with different degrees of access to off-label use and may undermine the Scheme.	12 *The Review Team recommends that ARMCANZ establish a control of use task force to develop a nationally consistent approach to off-label use. (Whilst off-label use would be the highest priority for this task force there are a number of other control of use matters to address eg: on-label use).*	Recommendation 12 is supported. The terms of reference of the Task Force should be expanded to apply to all other recommendations relating to Control of Use, that is Recommendations 13-20 below.
Veterinary surgeons exemption: Veterinary surgeons hold various exemptions from provisions relating to both the supply and use of agvet chemicals. The exemption varies between the four states under review. The exemption for veterinary surgeons constitutes a restriction on competition because of the discriminatory nature of the exemption between veterinary surgeons and all other persons. This requires agvet chemical users to incur the cost of a veterinary surgeon to make use of certain agvet chemicals. The variation in the operation of certain exemptions between states also imposes a restriction on competition in that it may afford users in some jurisdictions advantages over users in other jurisdictions.	13 *The Review Team recommends the retention of the veterinary surgeon exemption in the Agvet Code.* *14 The Review Team recommends that Tasmania's control of use legislation be amended to limit the exemption afforded to pharmaceutical chemists to those circumstances where they are acting under the instructions of a veterinary surgeon.* 15 *The Review Team recommends that Victoria and Queensland's control of use legislation be amended to remove the exemption afforded to veterinary surgeons in respect of agricultural chemicals.* *16 The Review Team recommends that the ARMCANZ control of use task force address the veterinary exemption.*	
Control of use licensing: Each state requires agvet chemical spray contractors to hold various forms of business and/or occupational licences or accreditations. Licensing may pose a barrier to entry through training costs and licence fees, and is therefore a restriction on competition. The variation between competency and other requirements in each State also creates a restriction on competition in that it can constrain the ability of persons to operate across state borders.	17 *The Review Team recommends that an appropriate business licensing system for agvet chemical spraying businesses (ground or aerial) would entail no more than:* • *the relevant State agvet authority issuing a licence; subject to* • *maintenance of detailed records of chemical use;* • *using only appropriately licensed persons to perform application activities (as below); and* • *the provision of infrastructure to enable persons to operate at the appropriate competency level.* *18 The Review Team recommends that an appropriate occupational licensing system for persons undertaking agvet chemical spraying (ground or aerial) for fee or reward would entail no more than:*	

	• the relevant State agvet authority issuing a licence; subject to • holding an accreditation of appropriate competencies (including scope for provisional accreditation of new employees); • operating at that competency level; and • working only for a licensed business (as above). 19 *The Review Team recommends that the States and Territories examine the scope to co-ordinate their business and occupational licensing requirements, specifically the scope to standardise accreditations and the scope to recognise interstate licences. This would be an appropriate matter for the ARMCANZ control of use task force.* *20* *The Review Team recommends the retention of the exemption from business and occupational licences (but not generic controls) for persons spraying agvet chemicals on their own land (this exemption is mainly aimed at primary producers).*	

2.1 Registration Monopoly

Recommendation 1 of the Review

1. *The review team recommends the retention of a single provider of registration decisions in Australia.*

Response

The review identified as a restriction on competition the legislated monopoly given to the NRA for the making of decisions in regard to the registration of agvet chemicals. A legislated monopoly restricts the entry of any other organisation into the market, in this case the domestic market for the provision of registration decisions.

This legislated monopoly arises through the working of the Commonwealth Acts establishing the Agvet Code and the NRA, and the various State and Territory Agricultural and Veterinary Chemicals Acts that apply the Code in their jurisdictions and empower the NRA to administer the Code in their jurisdictions.

The review examined both the benefits and costs associated with the existing registration scheme and concluded that there were net public benefits in retaining the monopoly arrangements.

The recommendation of the Report is supported. There are significant benefits to Australia from having a single provider of registration decisions. It has reduced the costs of administration to Australian governments, compliance to industry and increased the standing of our registration processes, especially with respect to trade and market access.

2.2 Low Risk Chemicals

Recommendations 2 and 3 of the Review

2 *The review team recommends that the Agvet Code be altered to specifically provide for the identification of low risk chemicals, hence enabling potentially faster registration. This would enable unnecessary registration cost burdens on the manufacturers of these chemicals to be removed.*

3 *The Review Team recommends that sections 4 and 5 of the Agvet Code be amended to provide guiding principles for the inclusion or exclusion of chemicals by regulation. These principles should emphasise the relevant risks that the Scheme was developed to manage, such as the risks arising from chemical use in agriculture and related activities.*

Response

The Signatories Working Group supports the intent of recommendations 2 and 3, namely to reduce any unnecessary regulatory burden on the chemical industry and thus reduce the cost of such chemicals to consumers. The recommendations will be addressed in detail by a low regulatory activity Signatories Working Group established by SCARM independent of, but consistent with, the NCP response process. Membership of this Group will be drawn from all signatories to the scheme.

The work of this Group will involve further consideration of the recent Commonwealth proposal on "Amendments to the National Registration Scheme for Agricultural and Veterinary Chemicals to establish new regulatory mechanisms for chemicals requiring low regulatory activity". This proposal was in the context of ensuring that chemicals, which currently fall under the Agvet Code, are regulated in the most appropriate way consistent with the legislative objectives of the Code. On completion of its work the Working Group will present its report to SCARM/ARMCANZ for consideration.

Recommendation 3 implicitly raises the question as to which chemicals should be managed under the scheme. In this regard, the Agvet Code clearly defines the chemicals that fall within its scope. As a result of explicit decisions made at the time the Code was enacted, this scope extends beyond "chemical use in agriculture and related activities."

In this context, an important role of the Group will be to consider the implications of the existing and any new regulatory arrangements on the control of use responsibilities of the State/Territories.

Chemicals that do not fall within the scope of the Agvet Code are regulated under NICNAS. Therefore, if the definition of chemicals covered by the Code were to be changed, this could have significant implications for other chemical regulatory arrangements/scheme. These implications were not evaluated in the above review but would require evaluation before decisions are made, particularly in respect of the overall regulatory burden. Depending on its deliberations, an aspect of the work of the above Working Group may involve making recommendations on how best to address such implications if the Group considers that some chemicals, which currently fall within the scope of the Code, would be more appropriately regulated through other regulatory arrangements/schemes.

2.3 Assessment Services

Recommendations 4 and 5 of the Review

4 *The Review Team recommends that the NRA establish service agreements with its current suppliers and purchase assessment services on a fee for service basis*; and

5 *The Review Team recommends that the NRA both accept alternative suppliers of assessment services and actively alert likely providers of this fact.*

Response

Recommendation 4 is supported. The NRA has already initiated fee for service negotiations with its current suppliers of external assessment services.

With respect to Recommendation 5, the review identifies as a restriction on competition the practice of the NRA (there is no legislative basis for doing so) of purchasing assessment services mainly from three government agencies. This practice effectively creates three monopoly providers. The NOHSC is effectively the monopoly provider of OH&S assessments to the NRA, the TGA of health assessments and Environment Australia the only provider of environmental assessments to the NRA.

The review considered the benefits and potential costs of this practice and concludes that there would be benefits if a more contestable market for assessment services were developed. However, the review is silent on a number of key policy considerations such as which organisations could operate as a supplier of such services to the NRA and how would the required quality and standard of assessments be determined, monitored and enforced. Such matters need to be considered before making a decision to allow the NRA to accept alternative suppliers of assessment services.

To enable all the matters relevant to assessment service provision to be considered in further detail, the Commonwealth will establish a Working Group. The review will consider the matters raised in accordance with the Competition Principles Agreement. State and Territory Governments will be invited to participate in the review process. The Working Group will prepare a report for consideration by SCARM and approval by COAG.

2.4 Efficacy Review

Recommendation 6 of the Review

6 *The review team recommends that Section 14(3)(f) of the AgVet Code be amended to specify that efficacy review extends only to ensuring that the chemical product meets the claimed level of efficacy on the label.*

Response

The report expresses concern that efficacy is required, pursuant to the AgVet Code, to be evaluated in respect of "truth" and "appropriateness". The Report recommends that only the "truth" of the chemical registrant's claim be verified by the NRA.

The "appropriateness" requirement is regulation of product standard. It constrains the role of the market in determining consumer preferences and is therefore a restriction on competition. Nevertheless, the recommendation is not supported.

If this recommendation was implemented, a chemical registrant could submit to the NRA that a chemical be marketed with, for example, a 45 per cent efficacy. The registrant's claim would then be assessed by the NRA and the product registered if the claimed level of efficacy was found to be true.

Limiting the NRA's consideration to "truth" would mean that there was no direct assessment by the NRA of any flow-on or induced effects resulting from the use of a chemical with an efficacy level as determined only by the registrant.

Such an approach would negate the wider community considerations regarding a product's efficacy through induced risks to public health, risks to occupational health and safety, and the adverse impact on the environment as explained below. In assessing these risks, the NRA does so against standards it has established, many of which are recognised internationally and practiced by several other nations, including member countries of the OECD.

It is the view of the SWG that the "appropriateness" requirement is necessary if the objectives of the legislation, and Australia's international obligations, in relation to the protection of public health, protection of occupational health and safety and protection of the environment, international risk reduction and disease prevention efforts are to be met and maintained. These concerns are expanded upon below:

- Minimising the chemical residue risk to public health through providing scientific data as the basis for establishing Australian maximum residue limits (MRL). In essence, the required level of efficacy of a product (as determined to be necessary by the NRA) is integral to reliably establishing Good Agricultural Practice, setting of MRLs, and establishing With-Holding Periods for agricultural produce. In respect of international MRLs, as set by the Codex Alimentarius Commission, the consideration of efficacy by the NRA in the establishment of MRLs significantly enhances Australia's ability to credibly argue that Australian MRLs are justifiable, and based upon use-rates that are the minimum necessary to achieve effective control of pests and diseases. The setting of Codex MRLs has associated trade implications for Australia.

- One objective of the agvet scheme is to protect occupational health and safety. A chemical with adequate efficacy (ie. as determined by the NRA) has the effect of minimising the quantity of chemical required to be used in a particular situation and thus minimises worker exposure to that chemical. In contrast, a chemical with inadequate efficacy (ie. as could be determined by the registrant) could lead to excessive use of that chemical, relative to the use pattern of a chemical with adequate efficacy, to achieve an equivalent control over pests and diseases. In brief, inadequate efficacy of a chemical is likely to equate to an increased occupational health and safety risk to workers.

- The use of agricultural and veterinary chemicals with inadequate efficacy may also give rise to unnecessary risk to the environment. The use of inadequate efficacy products is likely to entice more frequent application and higher rates of application of a chemical in order to achieve effective control of pests and diseases. There is little, if any, justification for the taking of such risks with the environment through the use of chemicals with inadequate efficacy which, by definition, have a low level of efficiency to control pests and diseases.

- The assessment of a chemical for its risks to human health and the environment is necessarily incomplete. This is especially the case for the environmental assessment, where risks must be extrapolated from a limited number of species to entire ecosystems. The use of chemicals with inadequate efficacy implies higher application rates, or the unnecessary use of chemicals (because of the chemical's failure to control the pest or disease). Hence, there could be greater impacts on non-target organisms and ecosystems, and unnecessary contamination of the environment. This is a strong argument in favour of assessing efficacy in terms of appropriateness.

- Australia's commitment to international risk reduction efforts is inconsistent with the registration of agricultural and veterinary chemical products which, in respect of inadequate efficacy, are not compatible with the objective of achieving the efficient control of pests and diseases.

- The effective management of chemical resistance in pests and diseases exposed to agricultural and veterinary chemicals is a matter requiring increasing regulatory attention. There is a substantial argument based on populations of pests and diseases surviving exposure to chemicals with adequate efficacy, to support the view that the use of chemicals with inadequate efficacy could accelerate the development of resistance in pests and diseases.

- Truth in labelling of a chemical product, under the *Trade Practice Act 1974* (Cth), is intended to provide an assurance to the community that a chemical will be effective (ie. efficacious) for the intended use of the chemical.

To help reduce the potential costs of the "appropriateness" requirement, the SWG considers that the NRA should make as much information available up front to chemical manufacturers regarding the levels of efficacy likely to be required for a particular product or product type. This would allow chemical manufacturers to establish in advance the level of efficacy they will need to demonstrate.

2.5 Full Cost Recovery

Recommendations 7 and 8 of the Review

7 *The Review Team recommends that the levy be changed to a simple flat rate levy (on sales as at present) with no exemptions or caps. The annual renewal fee should be abolished and a national minimum levy liability (per registered product) set instead.*

8 *The Review Team recommends that application and other registration fees be cost reflective.*

Response

Recommendation 8 is supported as is the intent of Recommendation 7. The SWG has interpreted this intent as the pursuit of an efficient and equitable cost recovery mechanism. However, Recommendations 7 and 8 are silent on the question of balance between revenue sources. To address this aspect and other implications of Recommendation 7, the Commonwealth will establish a Working Group. The considerations of this Working Group will be consistent with the Competition Principles Agreement.

In considering these recommendations, issues relating to funding the overall cost of regulating agricultural and veterinary chemicals were raised. In particular the relationship between funding the control of use activities of the States/Territories and the assessment and registration activities of the National Registration Authority were discussed. This issue will be addressed by the Control of Use Task Force (see Attachment 1), which will specifically evaluate the resources required to ensure the effectiveness of control of use arrangements and identify the most appropriate source of funds to provide those resources.

2.6 Manufacturer Licensing

Recommendations 9 and 10 of the Review

9 *The Review Team recommends that the retention of licensing of veterinary chemical manufacturers. However, GMP should be optional for manufacturers of low risk veterinary chemicals, in line with the introduction of a low risk category of registration.*

10 *The Review Team recommends that the Agvet Code be amended to remove the present (albeit exempted) requirement for licensing of agricultural chemical manufacturers until the case for such an extension is made.*

Response

The retention of licensing of veterinary chemical manufacturers is supported. Such licensing serves two purposes. It ensures that veterinary products sold in Australia meet quality standards and it facilitates trade in foreign markets by allowing for an accreditation scheme to be developed. It does however impose a significant compliance cost on business.

The licensing of veterinary manufacturers is a restriction on competition but the public benefits it creates as an adjunct to the general compliance program outweigh the costs to business. The Review Team considers that manufacturer licensing should be concentrated in higher risk areas, with a targeted compliance program directing less effort to low risk chemicals. The review notes that, at present, no distinction between high and lo risk chemicals is made, so that manufacturers of low risk chemicals incur the same standards and hence the same compliance costs as manufacturers of high risk chemicals.

In considering the notion of different "risk" categories attracting different licensing standards, it is important to note that substandard products, regardless of their prima facie risk status, may result in damage to people, crops or animals. GMP is designed to address risks associated with the chemical manufacturing process as distinct from the risks associated with the use of a chemical and addresses matters such as contamination of chemicals during manufacture. Disinfectant teat spray for example is a relatively innocuous product that could be classified low risk, however the effect of the use of a substandard product in dairy production could have serious implication for public health. Accordingly, this aspect of Recommendation 9 is not supported.

With respect to recommendation 10, the SWG supports the view that licensing and other restrictive practices should only be retained where it can be demonstrated that the restriction produces a net public benefit and is essential to the achievement of the objectives of the legislation.

The provisions providing for the licensing of agricultural manufacturers are presently exempt, and therefore are not imposing any cost (or producing any benefit) on the community. It is understood by the SWG that the quality of such technical grade active constituents is coming under increased attention from a public health, occupational health and safety, and environmental impact perspective.

Rather than removing the provisions, the SWG is of the view that the appropriate and pragmatic course of action is to retain them in their exempt state, and only activate them when (if) the requirements of a Commonwealth Regulatory Impact Assessment (including a public benefit test) have been satisfied. To resolve this issue, the Commonwealth will establish a Working Group to determine if the exempt provisions need to be activated. The Working Group will complete its work by June 30, 2000.

2.7 Data Protection

Recommendation 11 of the Review

11 *The Review Team recommends that the compensation process provisions of the Agvet Code be modified to adopt the procedures and principles for determining third party access pricing under the various Codes in operation under Part IIIA of the Trade Practices Act.*

Response

When a chemical is initially assessed or reviewed, the NRA may call upon a person, for example the manufacturer, to provide certain information regarding that chemical to support the continuation of registration. Data protection imposes a cost on persons wishing to utilise the data, in that they must pay compensation, and therefore is a *prima facie* restriction on competition. However, the absence of data protection may also restrict competition because the ability to free ride on information will reduce the incentive to generate it in the first place.

There is then a need then to establish a system which offers suitable incentives for innovation whilst at the same time ensuring that the system does not give the first party undue market power. The Review Team suggest that in order to achieve this balance in the most efficient manner, the key principles which underly third party access regimes in Part IIIA of the Trade Practices Act (TPA) could provide useful guidance.

The Signatories Working Group recognises that Part IIIA of the TPA provides for third party access to spare capacity in nationally significant infrastructure, which is a very different situation to data protection for agvet chemical registrants, which is more about second party behaviour than third party access. Currently, the primary registrant (first party) provides information to the NRA (second party) which then makes a regulatory decision. An image applicant (third party) lodges a registration request but does not *access* information from the first party. The NRA, having made certain conclusions about a chemical product and its use, generalises that conclusion to another similar product. In other words the NRA accesses its own decision, which was based (to varying degrees) on information provided by the first party.

Data protection is therefore different from third party access as intended in Part IIIA of the TPA. It is about referencing rather than accessing information. However, the principles underlying Part IIIA of the TPA and the related Hilmer reforms remain relevant to the discussion. This is because the purpose of both Part IIIA and data protection is essentially the same. Both are seeking to overcome market power whilst recognising the right of the first party to earn a fair return on investment. The relevant third part access principles, which should be considered in discussions regarding ways in which the current data protection system could be improved, are outlined in the Report.

Considerable work has already been undertaken by the Commonwealth in assessing the need for, and costs and benefits of, data protection, including the preparation of a Regulatory Impact Statement. This followed a joint proposal from the National Farmers' Federation, Avcare and the Veterinary Manufacturers and Distributors Association for increased data protection.

The Commonwealth Government has decided to increase the data protection for three categories of chemicals by way of data exclusivity and compensated cross referencing.

Negotiations have commenced on the arbitration mechanism that will apply with respect to compensated cross referencing and involve key stakeholders such as the National Farmers Federation, Avcare, VMDA and the NRA. In developing the arbitration process, AFFA will consider opportunities to adopt the principles for determining third party access pricing under the various Codes in operation under Part IIIA of the Trade Practices Act.

The SWG considers that the response to this recommendation should be absorbed into the current AFFA review of data protection. The outcome of this review will be provided to SCARM and ARMCANZ for consideration as required under the Ministerial Agreement establishing the Agvet Code.

2.8 Matter relating to Control of Use

Off-label Use / Veterinary Surgeons Exemptions / Control of Use Licensing

Recommendations 12 to 20 of the Review

12 *The Review Team recommends that ARMCANZ establish a control of use task force to develop a nationally consistent approach to off-label use. (Whilst off-label use would be the highest priority for this task force there are a number of other control of use matters to be addressed).*

The review also recommended that this task force consider recommendations 16 and 19, relating to the development of a nationally consistent approach to the following control of use matters:

- exemptions from provisions relating to the supply and use of unregistered chemical products by veterinary surgeons; and
- control of use licensing requirements.

Response

The SWG considers that the Task Force should not confine itself to considering recommendations 12, 16 and 19, but consider all the recommendations relating to control of use (ie:12- 20).

Each State and Territory maintains its own legislation covering the control of use of Agvet chemicals. The structure of control of use legislation varies between each jurisdiction. Each of Victoria, Queensland, Western Australia and Tasmania maintain some specific control of chemical use Acts. In addition, Western Australia derives many of its control of use powers from its Health Act.

Control of use in all jurisdictions covers matters such as licensing of Agvet contractors, aerial spraying, permits controlling use for purposes other than those deriving from the Code and scope for exemptions. These Acts may also control the use of stock feeds and fertilisers, which are not covered by the Agvet Code, and restrict the handling and sale of contaminated land, livestock and other produce.

Progress toward reducing inconsistency between States, in terms of the requirements for controls over the use of Agvet chemicals, needs to have as a basis general agreement as to the outcomes sought through a consistent approach to Control of Use.

To that end ARMCANZ will assemble a task force comprising of a representative from each State, Territory and the Commonwealth to formulate principles relating to government involvement in controlling the use of Agvet chemicals. The Task Force should specifically address opportunities for national harmonisation of control of use outcomes.

Attachment 1 includes details of the proposed Control of Use Task Force including, terms of reference and proposed membership.

3. Other Issues

The Review Team was asked by the Project Team to note in the Report issues relevant to the management of AgVet chemicals raised during consultations with stakeholders which are not directly related to the terms of reference. A number of such issues were raised throughout the review.

The review team reported that stakeholders raised issues relating to their dealings with the NRA. These matters are outside of the scope of the review and are best addressed by the NRA rather than in this inter-governmental response to the NCP review recommendations. Through its extensive involvement in the review, the NRA is fully aware of the matters raised.

The remaining "other issues", listed below, are important to the cost-effective management of agricultural and veterinary chemicals. As appropriate, the issues will be addressed by one of the Task Forces/Working Groups that the SWG recommends be established, or referred to the AVCPC for consideration and reporting to SCARM..

1. The role of pharmaceutical chemists in dispensing agvet chemicals.
2. The variation in state controls on veterinary surgeons.
3. Legislative mechanisms to control Genetically Modified Organisms.
4. The potential overlap in the role of Material Safety Data Sheets (MSDS) and agvet chemical labels.
5. Concerns that labels contain domestic withholding periods only, not export requirements.
6. The inability of importers of certain active constituents for agricultural chemicals to utilise the services of brokers to have their importation sources certified.
7. The possibility that the emphasis on agricultural use might exclude or ignore other uses, such as forestry.
8. The direct importation for use of agvet chemicals, bypassing registration.
9. The way in which chemicals are listed for review in the Existing Chemical Review Program (ECRP).
10. The adequacy and appropriateness of the definitions of agricultural and veterinary chemicals in the Agvet Code.
11. The requirement to include a contaminating blue dye in intra-mammary preparations.
12. The benefits (or otherwise) of undertaking an agvet chemical system-wide review.

ARMCANZ Control of Use Task Force

Background

The national NCP review of agricultural and veterinary (agvet) chemicals legislation recommended that ARMCANZ agree to the establishment of a Control of Use Task Force to consider specific recommendations of the review relating to control of use issues.

In response, the Signatories Working Group recommends that:

- ARMCANZ establish a Control of Use Task Force to address recommendations 12 to 20 relating to control of use and the overarching recommendation that ARMCANZ sponsor the development of a control of use framework that is nationally consistent and consistent with the National Registration Scheme; and
- the following terms of reference apply to the establishment and operation of the Task Force.

Terms of Reference

The ARMCANZ Control of Use Task Force shall:

(a) specify principles that should be applied, and outcomes sought from, a consistent approach to Control of Use;

(b) evaluate the control of use arrangements operative in each jurisdiction with respect to consistency of outcomes achieved and consistency of the arrangements, individually and collectively, with the objectives and operation of the National Registration Scheme;

(c) evaluate and prepare detailed responses to each of recommendations 12 to 20 of the NCP review report;

(d) with respect to (c), and without limiting the scope of its work, consider :
- the effectiveness of the current arrangements of each jurisdiction governing off label use of agvet chemicals;
- the effect of the exemptions from the provisions of the Agvet Code applying to veterinary surgeons and the recent decision of the jurisdictions to harmonise their exemption arrangements; and
- the need for, and effectiveness of, business and occupational control of use licensing;

(e) specify what needs to be done to increase the effectiveness of, and consistency of outcomes from, the control of use arrangements for all jurisdictions, both individually and collectively;

(f) evaluate the resources required to ensure the effectiveness of control of use arrangements in all jurisdictions in terms of compliance;

(g) identify the most appropriate source of funds to provide the required resources as determined in (f);

(h) prepare a final report for ARMCANZ by December 2000 incorporating its recommendation with respect to (a), (b), (c), (d), (e), (f) and (g); and,

(i) in the interim, prepare progress reports to each meeting of SCARM.

Membership

The Task Force will:

- be chaired by a Chairperson independent of any one jurisdiction (to be advised);
- draw one member from each of the jurisdictional signatories of the National Registration Scheme and from the National Registration Authority; and
- consult with interested organisations and professional associations, including but not limited to, Avcare (National Association for Crop Protection and Animal Health), Veterinary Manufacturers and Distributors Association, Aerial Agricultural Association of Australia, and the National Farmers Federation.

Secretariat

Secretariat support for the Task Force will be provided by Agriculture, Fisheries and Forestry - Australia.